
GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 226 OF 2006

MEDICINES CONTROL COUNCIL

CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT No. 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by Council.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965).
5. The registration of this medicine shall be subject to regular review regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The registration dossier is subject to review at intervals as determined by Council.
8. A post-registration inspection must be conducted in the first production batch of the locally manufactured product.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

MRF 15 (MBR 15)

Registration number: 01/2.1/14

Name of medicine: ALFAXAN-CD RTU Anaesthetic Injection

Dosage form: INJECTION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
ALFAXOLONE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KYRON LABORATORIES (PTY) LTD

Manufacturer: JUROX, RUTHERFORD, NEW SOUTH WALES,
AUSTRALIA

Packer: JUROX, RUTHERFORD, NEW SOUTH WALES,
AUSTRALIA

Laboratory: FPRC: JUROX, RUTHERFORD, NEW SOUTH WALES,
AUSTRALIA
FPRC/FPRR: KYRON LABORATORIES, BENROSE, **RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A04/21.9102

Name of medicine: RILEXINE 75

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEPHALEXIN MONOHYDRATEEQUVALENT TO
CEPHALEXIN 75,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: VIRBAC RSA (PTY) LTD

Manufacturer: VIRBAC SA, CARROS-CEDEX, FRANCE

Packer: VIRBAC SA, CARROS-CEDEX, FRANCE
VIRBAC RSA, CENTURION, RSA

Laboratory: FPRC: VIRBAC SA, CARROS-CEDEX, FRANCE
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: VIRBAC RSA, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR,15)

Registration number: A04/21.9/03

Name of medicine: RILEXINE 300

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 300,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: VIRBAC RSA (PTY) LTD

Manufacturer: VIRBAC SA, CARROS-CEDEX, FRANCE

Packer: **VIRBAC SA, CARROS-CEDEX, FRANCE**
VIRBAC RSA, CENTURION, RSA

Laboratory: FPRC: VIRBAC SA, CARROS-CEDEX, FRANCE
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, **RSA**
FPRC/FPRR: VIRBAC RSA, CENTURION, **RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR15)

Registration number: A04/21.9/04

Name of medicine: RILEXINE 600

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS :
CEPHALEXIN MONOHYDRATE EQUIVALENT TO
CEPHALEXIN 600,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: VIRBAC RSA (PTY) LTD

Manufacturer: VIRBAC SA, CARROS-CEDEX, FRANCE

Packer: VIRBAC SA, CARROS-CEDEX, FRANCE
VIRBAC RSA, CENTURION, RSA

Laboratory: FPRC: VIRBAC SA, CARROS-CEDEX, FRANCE
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: VIRBAC RSA, CENTURION, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 93/16.1/3

Name of medicine: SYNULOC PRED LC

Dosage form: INFUSION

Active ingredients: EACH SYRINGE CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 200,0 MG
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 50,0 MG
PREDNISOLONE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PFIZER LABORATORIES (PTY) LTD

Manufacture: PFIZER ITALIANA S.p.A, LATINA, ITALY

Packer: PFIZER ITALIANA S.p.A, LATINA, ITALY

Laboratory: FPRC: PFIZER ITALIANA S.p.A, LATINA, ITALY
FPRR: PFIZER LABORATORIES, PIETERMARITZBURG,
RSA

Shelf-life: 18 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **35/7.1/0179**

Name of medicine: **DINATRIX**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
INDAPAMIDE 2,5 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **LENNON LTD, KORSTEN PORT ELIZABETH**

Packer: **LENNON LTD, KORSTEN PORT ELIZABETH**

Laboratory: **FPRC/FPRR: LENNON LTD, KORSTEN PORT ELIZABETH
PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **48 months packed in Securitainers
36 months packed in Blisters**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 36/21.5.1/0105

Name of medicine: METICORTEN 20 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PREDNISONONE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SCHERING-PLOUGH (PTY) LTD

Manufacturer: SCHERING-PLOUGH, ISANDO, RSA

Packer: SCHERING-PLOUGH, ISANDO, RSA

Laboratory: FPRC/FPRR: SCHERING-PLOUGH, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/24/0176

Name of medicine: POTIDE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
POTASSIUM CHLORIDE 600,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months packed in Blisters
60 months packed in HDPE securitainers

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/20.1.1/0221

Name of medicine: BETAMYCIN 250 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ERYTHROMYCIN STEARATE EQUIVALENT TO
ERYTHROMYCIN 250,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory: FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: **24 months**

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: 36/20.1.1/0241

Name of medicine: PHARMACARE AMIKACIN 100MG/2 ML

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
AMIKACIN SULPHATE EQUIVALENT TO
AMIKACIN 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Packer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Laboratory: FPRC: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 48 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/20.1.1/0242

Name of medicine: **PHARMACARE AMIKACIN 500 MG/2 ML**

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:
AMIKACIN SULPHATE EQUIVALENT TO
AMIKACIN 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Packer: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG

Laboratory: FPRC: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 48 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0291

Name of medicine: P & U ENALAPRIL MALEATE 2,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACIA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL.

Packer: DEXCEL LTD, OR AKIVA, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR AKIVA, ISRAEL
PERIO PRODUCTS JERUSALEM, ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0292

Name of medicine: P & U ENALAPRIL MALEATE 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACLA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL

Packer: DEXCEL LTD, OR **AKIVA**, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR **AKIVA**, ISRAEL
PERIO PRODUCTS, JERUSALEM, **ISRAEL**
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0293

Name of medicine: P & U ENALAPRIL MALEATE 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACIA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL

Packer: DEXCEL LTD, OR AKIVA, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR AKIVA, ISRAEL
PERIO PRODUCTS, JERUSALEM ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0294

Name of medicine: P & U ENALAPRIL MALEATE **20 MG**

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENALAPRIL MALEATE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACIA S.A. (PTY) LTD

Manufacturer: DEXCEL LTD, OR AKIVA, ISRAEL

Packer: DEXCEL LTD, OR AKIVA, ISRAEL

Laboratory: FPRC: DEXCEL LTD, OR **AKIVA**, ISRAEL
PERIO PRODUCTS, JERUSALEM, ISRAEL
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, **RSA**
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
FPRR: PHARMACIA, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 3612.810379**Name of medicine:** MYBUCOD**Dosage form:** TABLET**Active ingredients:** EACH TABLET CONTAINS:
IBUPROFEN 200,0 MG
PARACETAMOL 350,0 MG
CODEINE PHOSPHATE 10,0 MG**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7**Applicant:** PHARMACARE LIMITED**Manufacturer:** LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON**Packer:** LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION WILSONIA,
EAST LONDON**Laboratory:** **FPRC:** LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON
FPRR: PHARMACARE, KORSTEN, PORT ELIZABETH**Shelf-life:** 24 months**Date of registration:** 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/7.1.3/0382

Name of medicine: DIOVAN 40

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
VALSARTAN 40,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND

Packer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 36/2.2/0524

Name of medicine: SANDOZ-ZOPICLONE 3,75

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ZOPICLONE 3,75 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/13.4.2/0040

Name of medicine: TRETODERM 10

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ISOTRETINOIN 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SWISS CAPS, KIRCHBERG, **SWITZERLAND**

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, **INDUSTRIA WEST**, GAUTENG, RSA

Laboratory: **FPRC:** SWISS CAPS, KIRCHBERG, **SWITZERLAND**
PHARMA-Q, **INDUSTRIA WEST**, GAUTENG, **RSA**
CONSULTING CHEMICAL, LABORATORIES, STAR
STREET, **BOKSBURG**, RSA
FPRR: ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, **WESTMEAD**, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/13.4.2/0041

Name of medicine: TRETODERM 20

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ISOTRETINOIN 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SWISS CAPS, KIRCHBERG, SWITZERLAND

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory:FPRC: SWISS CAPS, KIRCHBERG, SWITZERLAND
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: ANALYTICON, KEMPTON PARK, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 3715.410106

Name of medicine: DAS-OXYBUTYNIN HCL 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
OXYBUTYNIN HYDROCHLORIDE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES SA (PTY) LTD

Manufacturer: ROTTENDORF PHARMA GmbH,
ENNIGERLOH, GERMANY

Packer: ROTTENDORF PHARMA GmbH,
ENNIGERLOH, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA NATURA, WYNBERG, SANDTON, RSA

Laboratory: FPRC: ROTTENDORF PHARMA GmbH,
ENNIGERLOH, GERMANY
COLUMBIA PHARMACEUTICALS, BARDENE,
BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BOKSBURG, RSA
SYNTHON, NIJMEGEN, THE NETHERLANDS
FPRR: STRIDES, ARCADIA, PRETORIA, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0145

Name of medicine: DILUENT FOR RISPERDAL CONSTA

Dosage form: INJECTION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS :
SODIUM CARBOXYMETHYLCELLULOSE 22,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: JANSSEN PHARMACEUTICA(PTY) LTD

Manufacturer: VETTER PHARMA FERTIGUNG GmbH,
RAVENBERG, GERMANY

Packer: CILAG AG, SCHAFFHAUSEN, SWITZERLAND

Laboratory: FPRC: JANSSEN PHARMACEUTICANV, BEERSE,
BELGIUM
FPRR: JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Shelf-life: 36 months

Rate of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0157

Name of medicine: CIPLA-FLUOXETINE ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 5,0 ml SOLUTION CONTAINS:
FLUOXETINE HYDROCHLORIDE EQUIVALENT TO
FLUOXETINE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, SATARA, INDIA
CPLA LTD, VIKHROLI, BOMBAY, INDIA

Packer: CIPLA LTD, SATARA, INDIA
CIPLA LTD, VIKHROLI, BOMBAY, INDIA

Laboratory: FPRC: CIPLA LTD, SATARA, INDIA
CIPLA LTD, VIKHROLI, BOMBAY, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **37/34/0158**

Name of medicine: **MYFORTIC 180**

Dosage **form**: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
MYCOPHENOLATE SODIUM EQVALENT TO
MYCOPHENOLATE 180,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **NOVARTIS SOUTH AFRICA (PTY) LTD**

Manufacturer: **NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND**

Packer: **NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, **KEMPTON** PARK, RSA**

Laboratory: FPRC: **NOVARTIS PHARMA **STEIN**,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA**
FPRC/FPRR: **NOVARTIS, SPARTAN, KEMPTON PARK, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/34/0159

Name of medicine: MYFORTIC 360

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MYCOPHENOLATE SODIUM EQUIVALENT TO
MYCOPHENOLATE 360,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND

Packer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0188

Name of medicine: CLOZAPINE-HEXAL 25

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**
CLOZAPINE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **HEXAL PHARMA (S.A.) (PTY) LTD****Manufacturer:** HEXAL AG, HOLZKIRCHEN, GERMANY**Packer:** HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA**Laboratory:** FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, **RSA**
ANALYTICON, KEMPTON PARK, **RSA**
FPRR: **HEXAL PHARMA, WESTMEAD, RSA**

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0189

Name of medicine: CLOZAPINE-HEXAL 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: **FPRC:** HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0190

Name of medicine: CLOZAPINE-HEXAL 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSALaboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0191

Name of medicine: HEXAL-CLOZAPINE 25 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.)(PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: 37/2.6.5/0 192

Name of medicine: HEXAL-CLOZAPINE 50 MG TABLETS

Dosage form: TABLETActive ingredients: EACH TABLET CONTAINS:
CLOZAPINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: **HEXAL AG, HOLZKIRCHEN, GERMANY**Packer: **HEXAL AG, HOLZKIRCHEN, GERMANY**
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSALaboratory: FPRC: **H E W AG, HOLZKIRCHEN, GERMANY**
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: **HEXAL PHARMA, WESTMEAD, RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.6.5/0193

Name of medicine: HEXAL-CLOZAPINE 100MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CLOZAPINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer: HEXAL AG, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA WEST, RSA

Laboratory: FPRC: HEXAL AG, HOLZKIRCHEN, GERMANY
PHARMA Q, INDUSTRIA WEST, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MER 15)

Registration number: 37/2.2/0211

Name of medicine: DAS-MIDAZOLAM 5 MG/5 ML

Dosage form: INJECTION

Active ingredients: EACH 5,0 ml AMPOULE **CONTAINS :**
MIDAZOLAM 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES S.A. (PTY) LTD

Manufacturer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, **AUSTRIA**

Packer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
DNPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA NATURA, WYNBERG, SANDTON, **RSA**

Laboratory: FPRC: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
INSTITUTE FOR PHARMACEUTICALS SERVICES,
BARDENE, BOKSBURG, RSA
SYNTHON BV, NIJMEGEN, THE NETHERLANDS
FPRR: STRIDES, ARCADIA, **PRETORIA, RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/2.2/02 12

Name of medicine: DAS-MIDAZOLAM 15 MG/3 ML

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml AMPOULE CONTAINS:
MIDAZOLAM 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES S.A. (PTY) LTD

Manufacturer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA

Packer: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA NATURA, WYNBERG, SANDTON, RSA

Laboratory: FPRC: PHARMA HAMELN GmbH, HAMELN, GERMANY
NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
INSTITUTE FOR PHARMACEUTICALS SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: SYNTHON BV, NIJMEGEN, THE NETHERLANDS
STRIDES, ARCADIA, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number:	37/2.2/0213
Name of medicine:	DAS-MIDAZOLAM 50 MG/10 ML
Dosage form:	INJECTION
Active ingredients:	EACH 10,0 ml AMPOULE CONTAINS: MIDAZOLAM 50,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	STRIDES S.A.(PTY) LTD
Manufacturer:	PHARMA HAMELN GmbH, HAMELN, GERMANY NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA
Packer:	PHARMA HAMELN GmbH, HAMELN, GERMANY NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA PHARMA NATURA , WYNBERG, SANDTON, RSA
Laboratory: FPRC:	PHARMA HAMELN GmbH, HAMELN, GERMANY NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA INSTITUTE FOR PHARMACEUTICALS SERVICES, BARDENE, BOKSBURG, RSA SYNTHON BV, NIJMEGEN, THE NETHERLANDS
FPRR:	STRIDES, ARCADIA, PRETORIA , RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0225

Name of medicine: CO-DIOVAN **160 PLUS**

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
VALSARTAN 160,0 MG
HYDROCHLOROTHIAZIDE 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND

Packer: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN,
SCHAFFHAUSERSTRASSE, STEIN, SWITZERLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: **37/34/0254**

Name of medicine: **NEUMEGA STERILE WATER FOR INJECTION**

Dosage form: **INJECTION**

Active ingredients: **EACH VIAL CONTAINS:
WATER FOR INJECTIONS 1,0 ml**

Conditions of registration: **1,2, 3, 4, 5, 6, 7**

Applicant: **WYETH S.A. (PTY) LTD**

Manufacturer: **GENSIASICOR PHARMACEUTICALS, IRVINE, USA**

Packer: **GENSIASICOR PHARMACEUTICALS, IRVINE, USA**

Laboratory: FPRC: **GENSIASICOR PHARMACEUTICALS, IRVINE, USA
PHARMA-Q, INDUSTRIA, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA**
FPRR: **WYETH, MIDRAND, RSA**

Shelf-life: **36 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/10.2.1/0273

Name of medicine: ATROVENT 20 HFA

Dosage form: METERED DOSE INHALER

Active ingredients: EACH METERED DOSE CONTAINS:
IPRATROPIUM BROMIDE EQUIVALENT TO
IPRATROPIUM BROMIDE ANHYDROUS 0,02 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer: BOEHRINGER INGELHEIM PHARMA, INGELHEIM
AM RHEIN, GERMANY

Packer: BOEHRINGER INGELHEIM PHARMA, INGELHEIM
AM RHEIN, GERMANY

Laboratory: FPRC: BOEHRINGER INGELHEIM PHARMA, INGELHEIM
AM RHEIN, GERMANY
AVENTIS PHARMA, WALTLOO, PRETORIA
ANALYTICON, KEMPTON **PARK**, RSA
FPRR: INGELHEIM PHARMACEUTICALS, RANDBURG

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 37/15.2/0275

Name of medicine: DEXAGEL

Dosage form: GEL

Active ingredients: EACH 1,0 g GEL CONTAINS :
DEXAMETHASONE SODIUM
PHOSPHATE 0,985 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SOFLENS (PTY) LTD

Manufacturer: DR MANN PHARMA, BERLIN, GERMANY

Packer: DR MANN PHARMA, BERLIN, GERMANY
COLUMBIA PHARMACEUTICALS, BARDENE,
BOKSBURG, RSA

Laboratory: FPRC: DR MANN PHARMA, BERLIN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: SOFLENS, RIVONIA, SANDTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: 37/13.4.2/0292

Name of medicine: ISOTRETINOIN-HEXAL 10

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ISOTRETINOIN 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SWISS CAPS, KIRCHBERG, SWITZERLAND

Packer: DNPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA

Laboratory: FPRC: SWISS CAPS, KIRCHBERG, SWITZERLAND
PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WSTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/13.4.2/0293
Name of medicine:	ISOTRETINOIN-HEXAL 20
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: ISOTRETINOIN 20,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	SWISS CAPS, KIRCHBERG, SWITZERLAND
Packer:	DNPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA
Laboratory:	FPRC: SWISS CAPS, KIRCHBERG, SWITZERLAND PHARMA-Q, INDUSTRIA WEST, GAUTENG, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/26/0359

Name of medicine: VINELBA 10

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
VINORELBINE TARTRATE EQUIVALENT TO
VINORELBINE 10,0 MG

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: TEMA MEDICAL (PTY) LTD

Manufacturer: PIERRE FABRE MEDICAMENT PRODUCTION,
IDRON, FRANCE

Packer: PIERRE FABRE MEDICAMENT PRODUCTION,
IDRON, FRANCE
TECHNIKON LABORATORIES, FLORIDA, RSA

Laboratory: **PIERRE** FABRE MEDICAMENT PRODUCTION,
IDRON, FRANCE
TECHNIKON LABORATORIES, FLORIDA, **RSA**
KQATSA, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
TEMA MEDICAL, SANDTON, RSA

Shelf-life: 36 months

Date of registration: 7 MAY 2004

MRF 15 (MBR 15)

Registration number: **37/26/0360**

Name of medicine: **VINELBA 50**

Dosage form: **INJECTION**

Active ingredients: **EACH 5,0 ml SOLUTION CONTAINS:
VINORELBINE TARTRATE EQUIVALENT TO
VINORELBINE 50,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **TEMA MEDICAL (PTY) LTD**

Manufacturer: **PIERRE FABRE MEDICAMENT PRODUCTION,
IDRON, FRANCE**

Packer: **PIERRE FABRE MEDICAMENT PRODUCTION,
IDRON, FRANCE
TECHNIKON LABORATORIES, FLORIDA, RSA**

Laboratory: **PIERRE FABRE MEDICAMENT PRODUCTION,
IDRON, FRANCE
TECHNIKON LABORATORIES, FLORIDA, RSA
KQATSA, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
TEMA **MEDICAL**, SANDTON, RSA**

Shelf-life: **36 months**

Date of registration: **7 MAY 2004**

MRF 15 (MBR 15)

Registration number: 37/2.2/0375

Name of medicine: DAS-ZOPICLONE 7,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ZOPICLONE 7,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: STRIDES S.A. (PTY) LTD

Manufacturer: DRAGENOPHARM, TITTMONING, GERMANY

Packer: DRAGENOPHARM, TITTMONING, GERMANY
MPF BV, HEERENVEEN, THE NETHERLANDS
PHARMA NATURA, WYNBERG, SANDTON,
GAUTENG, RSA
DNPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA

Laboratory: FPRC: DRAGENOPHARM, TITTMONING, GERMANY
SYNTHON BV, NIJMEGEN, THE NETHERLANDS
COLUMBIA PHARMACEUTICALS, BARDENE,
BOKSBURG, GAUTENG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: STRIDES, ARCADIA, PRETORIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/10.2.1/462

Name of medicine: IPVENT RESPULES

Dosage form: INHALATION

Active ingredients: EACH 2,0 ml SOLUTION CONTAINS :
IPRATROPIUM BROMIDE 0,50 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/3410469

Name of medicine: IMUSPORIN-25

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA,INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA,INDIA

Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA,INDIA
FPRR: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **37/34/0470**

Name of medicine: **IMUSPORIN-50**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:**
CYCLOSPORINE 50,0 mg

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **CIPLA-MEDPRO (PTY) LTD**

Manufacturer: **CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA**

Packer: **CPLA LTD, KURKUMBH, MAHARASHTRA, INDIA**

Laboratory: **FPRR: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA**
FPRC: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/34/0471

Name of medicine: IMUSPORIN- 100

Dosage form: CAPSULE

Active ingredients: EACH **CAPSULE** CONTAINS:
CYCLOSPORINE 100,0 mg

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO(PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, **KURKUMBH**, MAHARASHTRA, INDIA
FPRR: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, **RSA**

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0472

Name of medicine: CIPLA-CYCLOSPORINE-25

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 25,0 mg

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/34/0473

Name of medicine: CIPLA-CYCLOSPORINE-50

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC CPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number : 37/34/0474

Name of medicine: CIPLA-CYCLOSPORINE-100

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
CYCLOSPORINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0479

Name of medicine: IBUSOR 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MEDICINE DEVELOPERS INTERNATIONAL C.C.

Manufacturer: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA

Packer: EMCURE PHARMACEUTICALS LTD, **PUNE**, INDIA

Laboratory: FPRC: EMCURE PHARMACEUTICALS **LTD**, PUNE, INDIA
CONSULTING CHEMICAL **LABORATORIES**,
STAR STREET, BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: **24** months

Date of registration: **25** NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/3.1/0480

Name of medicine: IBUSOR 400

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IBUPROFEN 400,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MEDICINE DEVELOPERS INTERNATIONAL C.C.

Manufacturer: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA

Packer: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA

Laboratory: FPRC: EMCURE PHARMACEUTICALS LTD, PUNE, INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MDI CC, MENLO PARK, PRETORIA, RSA

Shelf-life: 24 ~~months~~

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **37/26/0484**

Name of medicine: IFOLEM 1 G

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
IFOSFAMIDE 1,0G

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY,S.A. de C.V., HUICHAPAN, XOCH, MEXICO

Packer: LEMERY,S.A. de C.V., HUICHAPAN, XOCH, MEXICO

Laboratory: FPRC: LEMERY,S.A. de C.V., HUICHAPAN, XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, **RSA**
FPRR: KEY ONCOLOGICS, SANDTON, **RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/1.2/0491

Name of medicine: ASPEN TRAZODONE 50 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
TRAZODONE HYDROCHLORIDE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN, PORT ELIZABETH
ALPHAPHARM, BRISBANE, QUEENSLAND,
AUSTRALIA

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS LTD, POTTERS BAR, HERTFORDSHIRE,
UK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0492

Name of medicine: ASPEN TRAZODONE 100 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
TRAZODONE HYDROCHLORIDE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: LENNON LTD, KORSTEN, PORT ELIZABETH
ALPHAPHARM, BRISBANE, QUEENSLAND,
AUSTRALIA

Packer: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND

Laboratory: FPRC: LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERIC LTD, POTTERS BAR, HERTFORDSHIRE,
UK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0494

Name of medicine: CARVEDILOL – HEXAL 6,25

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS**:
CARVEDILOL 6,25mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA

Laboratory: FPRC: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, GAUTENG, RSA
FPRR: HEXALPHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	3717.1.310495
Name of medicine:	CARVEDILOL – HEXAL 12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 12,5mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (SA) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, FREDERIKSBERG, DENMARK
Packer:	DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, GAUTENG, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK, FREDERIKSBERG, DENMARK CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, GAUTENG, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 3717.1.310496

Name of medicine: CARVEDILOL – HEXAL 25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARVEDILOL 25mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK

Packer: DNPHEM MANUFACTURING & PACKAGING,
LONGDALE, GAUTENG, RSA

Laboratory: FPRC: GEA FARMACEUTISK FABRIK, FREDERIKSBERG,
DENMARK
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, GAUTENG, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/25/0523

Name of medicine: CISPLATIN-HEXAL 10 MG/20 ML

Dosage form: SOLUTION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
Cisplatin 0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.)(PTY) LTD

Manufacturer: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA

Packer: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: **FPRC:** EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA Q, INDUSTRIA WEST, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/25/0524

Name of medicine: CISPLATIN-HEXAL 50 MG/100 ML

Dosage form: SOLUTION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
Cisplatin 0,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.)(PTY) LTD

Manufacturer: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA

Packer: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: FPRC: EBEWE ARZNEIMITTEL GESELLSCHAFT,
UNTERACH, AUSTRIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
PHARMA Q, INDUSTRIA WEST, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

- Registration number: 37/34/0584
- Name of medicine: PHYSIONEAL 40 GLUCOSE 1,36 % w/v /13,6 MG/ML
- Dosage form: DIALYSIS SOLUTION
- Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
ANHYDROUS GLUCOSE 37,5 G
CALCIUM CHLORIDE DIHYDRATE 0,507 G
MAGNESIUM CHLORIDE HEXAHYDRATE 0,140 G
- Conditions of registration: 1, 2, 3, 4, 5, 6, 7
- Applicant: ADCOCK INGRAM CRITICAL **CARE** (PTY) LTD
- Manufacturer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
- Packer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**
- Laboratory: FPRC: **BAXTER** HEALTHCARE, CASTLEBAR,
COUNTY MAYO, **IRELAND**
BAXTER HEALTHCARE S.p.A, SESTO **FIORENTINO**,
ITALY
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**
- Shelf-life: 24 months
- Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **37/34/0585**

Name of medicine: **PHYSIONEAL 40 GLUCOSE 2,27 % w/v /22,7 MG/ML**

Dosage form: **DIALYSIS SOLUTION**

Active ingredients: **EACH 1000,0 ml SOLUTION CONTAINS:**
ANHYDROUS GLUCOSE 62,6 G
CALCIUM CHLORIDE DIHYDRATE 0,507 G
MAGNESIUM CHLORIDE HEXAHYDRATE 0,140 G

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **ADCOCK INGRAM CRITICAL CARE (PTY) LTD**

Manufacturer: **BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY**

Packer: **BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA**

Laboratory: FPRC: **BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY**
FPRC/FPRR: **ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/34/086

Name of medicine: **PHYSIONEAL 40 GLUCOSE 3,86 % w/v /38,6 MG/ML**

Dosage form: DIALYSIS SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
ANHYDROUS GLUCOSE 106,5 G
CALCIUM CHLORIDE DIHYDRATE 0,507 G
MAGNESIUM CHLORIDE HEXAHYDRATE 0,140 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY

Packer: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
ADCOCK INGRAM CRITICAL CARE, **AEROTON**,
JOHANNESBURG, **RSA**

Laboratory: FPRC: BAXTER HEALTHCARE, CASTLEBAR,
COUNTY MAYO, IRELAND
BAXTER HEALTHCARE S.p.A, SESTO FIORENTINO,
ITALY
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **37/26/0592**

Name of medicine: **ETOPOSIDE *LEMERY* 100MG**

Dosage fom: **INJECTION**

Active ingredients: **EACH 1,0 ml SOLUTION CONTAINS:
ETOPOSIDE 20,0 MG**

Conditions of registration: **1,2, 3, 4, 5, 6, 7**

Applicant: **KEY ONCOLOGICS (PTY) LTD**

Manufacturer: **LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO**

Packer: **LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO**

Laboratory: FPRC: **LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA**
FPRR: **KEY ONCOLOGICS, SANDTON, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/26/0593

Name of medicine: ETOPOSIDE **LEMERY** 500 MG

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ETOPOSIDE 20,0 MG

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Packer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Laboratory: FPRC: LEMERY, **S.A.** de C.V., HUICHAPAN XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, SANDTON, **RSA**

Shelf-life: 24 **months**

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/26/0594

Name of medicine: ETOPOSIDE LEMERY 1000MG

Dosage form: INJECTION

Active ingredients: **EACH 1,0ml SOLUTION CONTAINS:**
ETOPOSIDE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Packer: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO

Laboratory: FPRC: LEMERY, S.A. de C.V., HUICHAPAN XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, SANDTON, RSA

Shelf-life: 24 ~~months~~

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0599

Name of medicine: QUINASPEN 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0600

Name of medicine: QUINASPEN 10MG

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS:**
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETHPacker: MERCK **FARMA y QUIMICA**, BARCELONA, **SPAIN**
LENNON LTD, KORSTEN, PORT ELIZABETHLaboratory: FPRC: MERCK **FARMA y QUIMICA**, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETHShelf-life: **24 months**Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0601

Name of medicine: QUINASPEN 20 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: MERCK **FARMA** y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: **PHARMACARE** LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0602

Name of medicine: QUINASPEN 40 MG

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS :**
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 40,0 MG

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: MERCK **FARMA** y **QUIMICA**, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: **FPRC:** MERCK FARMA y QUIMICA, BARCELONA, SPAIN
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 **months**

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	37/22.1.4/0605	
Name of medicine:	SUPRADYN PRONATAL	
Dosage form:	TABLET	
Active ingredients:	EACH TABLET CONTAINS:	
	VITAMIN A	4000,0 iu
	THIAMINE HYDROCHLORIDE	1,6 mg
	RIBOFLAVINE	1,8 mg
	NICOTINAMIDE	19,0 mg
	CALCIUM PANTOTHENATE	10,0 mg
	PYRIDOXINE HYDROCHLORIDE	2,6 mg
	BIOTIN	200,0 ug
	FOLIC ACID	0,8 mg
	CYANOCOBALAMIN	4,0 ug
	ASCORBIC ACID	100,0 mg
	CHOLECALCIFEROL	100,0 iu
	α-TOCOPHEROL ACETATE	15,0 mg
	CALCIUM	125,0 mg
	COPPER	1,0 mg
	IRON	60,0 mg
	MAGNESIUM	100,0 mg
	MANGANESE	1,0 mg
	PHOSPHORUS	125,0 mg
	ZINC	7,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7	
Applicant:	BAYER (PTY) LTD	
Manufacturer:	ROCHE PRODUCTS, WELWYN, HERTFORDSHIRE, UK	
Packer:	ROCHE PRODUCTS, WELWYN, HERTFORDSHIRE, UK	
Laboratory:	FPRC:	ROCHE PRODUCTS, WELWYN, HERTFORDSHIRE, UK
	FPRC/FPRR:	BAYER, ISANDO, GAUTENG, RSA
Shelf-life:	24 months	
Date of registration:	25 NOVEMBER 2005	

MRF 15 (MBR 15)

Registration number: 37/7.1.3/0613

Name of medicine: CARLOC 6,25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARVEDILOL 6,25 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **37/21.12/0616**

Name of medicine: **SPEC-FLUTAMIDE**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
FLUTAMIDE **250,0 MG****

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **SPECPHARM (PTY) LTD**

Manufacturer: **MIPHARM S.p.A., MILAN, ITALY**

Packer: **MIPHARM S.p.A., MILAN, ITALY**

Laboratory: FPRC: **MIPHARM S.p.A., MILAN, ITALY**
ANALYTICON, KEMPTON PARK, **RSA**
FPRR: **SPECPHARM, RANDBURG, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/34/0649

Name of medicine: IMUSPORIN ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
CYCLOSPORINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/34/0650

Name of medicine: CIPLA-CYCLOSPORINE ORAL SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
CYCLOSPORINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: **FPRC:** CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/1.2/0665

Name of medicine: SEDARIN

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PAROXETINE HYDROCHLORIDE EQUIVALENT TO
PAROXETINE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXI PHARMACEUTICALS (PTY) LTD

Manufacturer: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Packer: GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: XIXI PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **3712610668**

Name of medicine: **BUSULFEX**

Dosage form: **INJECTION**

Active ingredients: **EACH AMPOULE CONTAINS:
BUSULFAN 60,0 MG**

Conditions of registration: **1,2,3,4,5,6,7**

Applicant: **TEMA MEDICAL (PTY) LTD**

Manufacturer: **BEN VENUE LABORATORIES, BEDFORD, OHIO,
USA**

Packer: **BEN VENUE LABORATORIES, BEDFORD, OHIO,
USA
PIERRE FABRE MEDICAMENT, IDRON, FRANCE
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA, RSA**

Laboratory: FPRC: **BEN VENUE LABORATORIES, BEDFORD, OHIO,
USA
PIERRE FABRE MEDICAMENT, IDRON, FRANCE
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA, RSA
KQATSA, PRETORIA, RSA**
FPRR: **TEMA MEDICAL, SANDTON, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/21.1/0670

Name of medicine: BIOSULIN R

Dosage form; **INJECTION**

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
HUMAN INSULIN100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: M.J. BIOPHARM PRIVATE LTD, **RAIGAD**,
MAHARASHTRA, INDIA

Packer: M.J. BIOPHARM PRIVATE LTD, **RAIGAD**,
MAHARASHTRA, INDIA

Laboratory: FPRC: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA
FPRR: RESMED **HEALTHCARE**, **SPRINGFIELD**
PARK, DURBAN, RSA

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 37/21.1/0671

Name of medicine: BIOSULINN

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:
HUMAN INSULIN 100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Packer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Laboratory: FPRC: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD
PARK, DURBAN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/21.1/0672

Name of medicine: BIOSULIN L

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml **SUSPENSION CONTAINS:**
HUMAN INSULIN100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Packer: M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA

Laboratory: **FPRC:** M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD
PARK, DURBAN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 37/21.1/0673

Name of medicine: BIOSULIN 30-70

Dosage form: INJECTION

Active ingredients: **EACH** 1,0 ml SUSPENSION CONTAINS:
HUMAN INSULIN 100,0 IU

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **RESMED HEALTHCARE**

Manufacturer: **M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA**

Packer: **M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA**

Laboratory: **FPRC:** **M.J. BIOPHARM PRIVATE LTD, RAIGAD,
MAHARASHTRA, INDIA**
FPRR: **RESMED HEALTHCARE, SPRINGFIELD
PARK, DURBAN, RSA**

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15

Registration number: 38/1.2/0020

Name of medicine: SERDEP-50

Dosage form: TABLET

Active ingredients: EACH TABLET *CONTAINS* :
SERTRALINE HYDROCHLORIDE EQUIVALENT
TO SERTRALINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Packer: CIPLA LTD, VIKHROLI, MUMBAI, INDIA

Laboratory: FPRC: CIPLA LTD, VIKHROLI, MUMBAI, INDIA
FPRR: CIPLA MEDPRO, ROSENPAK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/5.6/0040

Name of medicine: SERC 24

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
BETAHISTINE DIHYDROCHLORIDE 24,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SOLVAY PHARMA (PTY) LTD

Manufacturer: SOLVAY PHARMACEUTICALS B.V., OLST,
THE NETHERLANDS

Packer: SOLVAY PHARMACEUTICALS B.V., OLST,
THE NETHERLANDS

Laboratory: FPRC: SOLVAY PHARMACEUTICALS B.V., OLST,
THE NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
SCHERING, MIDRAND, RSA
FPRR: SOLVAY PHARMA, MIDRAND, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 3812.510049

Name of medicine: ROLAB-CARBAMAZEPINE CR 200

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CARBAMAZEPINE 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: TARO PHARMACEUTICAL, INDUSTRIES LTD,
HAIFA BAY, ISRAEL

Packer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory: FPRC: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARIS

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/26/0059

Name of medicine: BLASTOCARB 150 MG

Dosage form: INJECTION

Active ingredients: EACH 15,0 ml VIAL CONTAINS:
CARBOPLATIN 150,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY ,S.A. de C.V., XOCH, MEXICO

Packer: LEMERY ,S.A. de C.V., XOCH, MEXICO

Laboratory: FPRC: LEMERY ,S.A. de C.V., XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, HOUGHTON, RSA

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/2.5/0062

Name of medicine: ROLAB-CARBAMAZEPINE CR 400

Dosage form: TABLETActive **ingredients:** EACH TABLET CONTAINS:
CARBAMAZEPINE 400,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **SANDOZ (PTY) LTD**Manufacturer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAELPacker: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARKLaboratory: FPRC: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
FPRC/FPRR: **NOVARTIS, SPARTAN, KEMPTON PARK**
FPRR: **SANDOZ, SPARTAN, KEMPTON PARK**Shelf-life: **24 months**Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 38/5.4.1/0067

Name of medicine: STALEVO 50/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENTACAPONE 200,0 MG
LEVODOPA 50,0 MG
CARBIDOPA MONOHYDRATE EQUIVALENT TO
CARBIDOPA 12,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTHAFRICA (PTY) LTD

Manufacturer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND

Packer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: **FPRC:** ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **38/5.8/0111**

Name of medicine: **FLUSIN SINUS TABLETS**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
PSEUDOEPHEDRINE HYDROCHLORIDE 30,0 MG
PARACETAMOL 500,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON**

Packer: **LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON**

Laboratory: **FPRC:** **LENNON LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, WILSONIA,
EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM**
FPRR: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 38/21.5.1/0126

Name of medicine: PANAFCORTELONE SYRUP

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml **SYRUP** CONTAINS:
PREDNISOLONE 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA

Packer: ADCOCK **INGRAM** HEALTHCARE, WADEVILLE
GERMISTON, RSA

Laboratory: FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE
GERMISTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/26/0134

Name of medicine: BLASTOCARB 450 MG

Dosage form: INJECTION

Active ingredients: EACH 15,0 ml VIAL CONTAINS:
CARBOPLATIN 450,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: KEY ONCOLOGICS (PTY) LTD

Manufacturer: LEMERY, S.A. de C.V., XOCH, MEXICO

Packer: LEMERY, S.A. de C.V., XOCH, MEXICO

Laboratory: FPRC: LEMERY, S.A. de C.V., XOCH, MEXICO
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: KEY ONCOLOGICS, HOUGHTON, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/2.5/0 135

Name of medicine: ROCARB 200 CR

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**
CARBAMAZEPINE 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL

Packer: TARO PHARMACEUTICAL INDUSTRIES LTD,
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory: FPRC: TARO PHARMACEUTICAL **INDUSTRIES** LTD,
HAIFA BAY, ISRAEL
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK
FPRR: SANDOZ, SPARTAN, KEMPTON PARK

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **38/2.5/0136**

Name of medicine: **ROCARB 400 CR**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:**
CARBAMAZEPINE 400,0 MG

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **SANDOZ (PTY) LTD**

Manufacturer: **TARO PHARMACEUTICAL INDUSTRIES LTD,**
HAIFA BAY, ISRAEL

Packer: **TARO PHARMACEUTICAL INDUSTRIES LTD,**
HAIFA BAY, ISRAEL
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory: **FPRC:** **TARO PHARMACEUTICAL INDUSTRIES LTD,**
HAIFA BAY, ISRAEL
FPRC/FPRR: **NOVARTIS, SPARTAN, KEMPTON PARK**
FPRR: **SANDOZ, SPARTAN, KEMPTON PARK**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **38/5.4.1/0137**

Name of medicine: **STALEVO 150/37,5**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:**
ENTACAPONE 200,0 MG
LEVODOPA 150,0 MG
CARBIDOPA MONOHYDRATE EQUIVALENT TO
CARBIDOPA 37,5 MG

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **NOVARTIS SOUTH AFRICA (PTY) LTD**

Manufacturer: **ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND**

Packer: **OFUON CORPORATION ORION PHARMA,
ESPOO, FINLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA**

Laboratory: **FPRC: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA**
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: **36 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: 38/5.4.1/0138

Name of medicine: STALEVO 100/25

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ENTACAPONE 200,0 MG
LEVODOPA 100,0 MG
CARBIDOPA MONOHYDRATE EQUIVALENT TO
CARBIDOPA 25,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: ORION CORPORATION ORION PHARMA,
ESPOO, **FINLAND**

Packer: ORION CORPORATION ORION PHARMA,
ESPOO, FINLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: ORION CORPORATION ORION PHARMA,
ESPOO, **FINLAND**
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON **PARK**, RSA

Shelf-life: **36** monthsDate of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 38/34/0143

Name of medicine: GLEEVEC

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IMATINIB MESILATE EQVALENT TO
IMATINIB 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND

Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: 3813410144

Name of medicine: GLEEVEC 400

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
IMATINIB MESILATE EQUIVALENT TO
IMATINIB 400,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: NOVARTIS **SOUTH AFRICA** (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, **STEIN**,
SWITZERLAND

Packer: NOVARTIS PHARMA **STEIN** AG, **STEIN**,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, **RSA**

Laboratory: **FPRC:** NOVARTIS PHARMA **STEIN** AG, **STEIN**,
SWITZERLAND
NOVARTIS, SPARTAN, KEMPTON PARK, **RSA**
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, **RSA**
FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, **RSA**

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15

Registration number: **38/2.6.5/0167**

Name of medicine: **CLONEX 25 MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
CLOZAPINE 25,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Packer: **ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND**

Laboratory: FPRC: **ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM**
FPRR: **PHARMACARE LTD, KORSTEN,
PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15

Registration number: **3812.6.510168**

Name of medicine: **CLONEX 100 MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
CLOZAPINE 100,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Packer: **ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND**

Laboratory: FPRC: **ALPHAPHARM, CAROLE PARK, QUEENSLAND,
AUSTRALIA
LENNON LTD, KORSTEN, PORT ELIZABETH
GERARD LABORATORIES, DUBLIN, IRELAND
GENERIC LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM**
FPRR: **PHARMACARE LTD, KORSTEN,
PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number:	38/21.5.1/0187
Name of medicine:	SYMBICORD TURBUHALER 320:9 UG/DOSE
Dosage form:	INHALER
Active ingredients:	EACH DELIVERED DOSE CONTAINS: FORMOTEROL FUMARATE DIHYDRATE 9,0 UG BUDESONIDE 320,0 UG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ASTRAZENECA PHARMACEUTICALS (PTY) LTD
Manufacturer:	ASTRAZENECA AB, SODERTAWA , SWEDEN
Packer:	ASTWENEC A AB, SODERTAWA, SWEDEN ASTRAZENECA U.K., MACCLESFIELD, CHESHIRE , UK ASTRAZENECA, ALRODE, ALBERTON, RSA JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA
Laboratory: FPRC:	ASTRAZENECA AB, SODERTAWA, SWEDEN JANSSEN PHARMACEUTICA, HALFWAY HOUSE, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET , BOKSBURG, RSA ANALYTICON, KEMPTON PARK , RSA
FPRC/FPRR:	ASTRAZENECA, ALRODE, ALBERTON, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/7.1.3/02 10

Name of medicine: ADCO-QUINARETIC 10/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 10,0 MG
HYDROCHLOROTHIAZIDE 12,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND

Laboratory: FPRC: DELTA LTD, HAFNMJORDUR, ICELAND
FPRC/FPRR: ADCOCK **INGRAM** HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/7.1.3/0211

Name of medicine: ADCO-QUINARETIC 20/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS :
QUINAPRIL HYDROCHLORIDE EQVALENT TO
QUINAPRIL 20,0 MG
HYDROCHLOROTHIAZIDE 12,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: 38/34/0226

Name of medicine: EBIXA 10MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MEMANTINE HYDROCHLORIDE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: H. LUNDBECK (PTY) LTD

Manufacturer: ROTTENDOW PHARMA GmbH, ENNIGERLOH,
GERMANY

Packer: MERZ + CO. GmbH & CO., REINHEIM, GERMANY

Laboratory: **FPRC:** MERZ + CO. GmbH & CO., REINHEIM, GERMANY
H. LUNDBECK A/S, COPENHAGEN, DENMARK
FPRR: H. LUNDBECK, NORTH **RIDING**, RSA

Shelf-life: **24** months

Date of registration: **25** NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/3.1/0390

Name of medicine: **DISFLAM** (DISPERSIBLE TABLET)

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DICLOFENAC 46,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT **ELIZABETH**
SAD SELF MEDICATION, WILSONIA,
EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, **WILSONIA**,
EAST LONDON

Laboratory: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
SAD SELF MEDICATION, **WILSONIA**,
EAST LONDON
SOUTH AFRICAN **BUREAU OF STANDARDS**,
GROENKLOOF, PRETORIA, **RSA**
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
PHARMACARE LTD, WOODMEAD, RSA

Shelf-life: **24** months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0395
Name of medicine:	TERBINISIL 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory: FPRC:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.2.2/0396

Name of medicine: TERBINISIL 125

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLOFUDE EQUIVALENT TO
TERBINAFINE 125,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: HEXAL PHARMA (S.A.) (PTY) LTD

Manufacturer: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
ILSAN ILAC VE HAMMADDELERI SANAYI,
ISTANBUL, **TURKEY**

Packer: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
ILSAN ILAC VE HAMMADDELERI SANAYI,
ISTANBUL, **TURKEY**
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
ILSAN ILAC VE HAMMADDELERI SANAYI,
ISTANBUL, TURKEY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0397
Name of medicine:	TERBANE 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY // SANILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK , HVIDOVRE, DENMARK SALWTAS PHARMA GmbH, BARLEBEN, GERMANY // SANILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK , HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA , WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0399
Name of medicine:	TERBANE 125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 125,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN LAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN LAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.2/0462

Name of medicine: MYMOX 250

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
AMOXYCLLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: UNICHEM S.A. (PTY) LTD

Manufacturer: UNICHEM LABORATORIES LTD, BADDI, SOLAN,
INDIA

Packer: UNICHEM LABORATORIES LTD, BADDI, **SOLAN**,
INDIA

Laboratory: FPRC: UMICHEM LABORATORIES LTD, BADDI, SOLAN,
INDIA
RESEARCH INSTITUTE FOR **INDUSTRIAL**
PHARMACY, **UNIVERSITY**, POTCHEFSTROOM
CONSULTING **CHEMICAL** LABORATORIES,
STAR **STREET**, BOKSBURG, RSA
INSTITUTE **FOR** PHARMACEUTICAL & CHEMICAL
SERVICES, BARDENE, BOKSBURG, RSA
ALLIANCE **PHARMA**, VILLAGE MAIN,
JOHANNESBURG, RSA
FPRR: UNICHEM, VAN DER HOFF **PARK**,
POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number:	A38/20.1.2/0463
Name of medicine:	MYMOX 500
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UMCHEM S.A. (PTY) LTD
Manufacturer:	UMCHEM LABORATORIES LTD, BADDI, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA
Laboratory: FPRC:	UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, BARDENE, BOKSBURG, RSA ALLIANCE PHARMA , VILLAGE MAIN, JOHANNESBURG, RSA
FPRR:	UNICHEM, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0484
Name of medicine:	TERBICIL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH GENERIC [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: GENPHARM PHARMACEUTICALS, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH GENERIC [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM FPRR: PHARMACARE, KORSTEN , PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0509

Name of medicine: RILACE 1,25 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 1,25 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK **INGRAM** HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/05 10

Name of medicine: RILACE 2,5 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: I, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK **INGRAM** LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, **RSA**
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK **INGRAM** HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A38/7.1.3/0514**

Name of medicine: **XIXIPRIL 1,25**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 MG**

Conditions of registration: **1,2,3,4,5,6,7**

Applicant: **XIXIA PHARMACEUTICALS (PTY) LTD**

Manufacturer: **GENPHARM INC., ETOBICOKE, CANADA**

Packer: **GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA**

Laboratory: FPRC: **GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA**
FPRR: **XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/7.1.3/0515

Name of medicine: XIXIPRIL 2,5

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS(PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/05 16

Name of medicine: XIXIPRIL 5

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: **FPRC:** GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/05 17

Name of medicine: **XIXIPRIL** 10

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 10,0 MG**Conditions** of registration: 1, 2, 3, 4, 5, 6, 7**Applicant:** XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOICE, CANADA

Packer: GENPHARM INC., ETOBICOICE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSALaboratory: **FPRC:** GENPHARM INC., ETOBICOICE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE **FOR** INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/1.2/0520

Name of medicine: STRATTERA 10MG

Dosage *form*: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:**
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO RICO

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO RICO
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA, RSA**
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: **36 months**

Date of registration: **3 JUNE 2005**

MRF 15 (MBR 15)

Registration number: A38/1.2/0521

Name of medicine: **STRATTERA 18 MG**

Dosage form: **CAPSULE**

Active ingredients: EACH CAPSULE **CONTAINS:**
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 18,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.)(PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL **CARIBE**, CAROLINA, PUERTO RICO
BRECON **PHARMACEUTICALS** ,HAY-ON-WYE,
HEREFORD, UK.

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL CARIBE, **CAROLINA** ,PUERTO RICO
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 3 JUNE2005

MRF 15(MBR 15)

Registration number: A38/1.2/0522

Name of medicine: STRATTERA 25 MG

Dosage form: **CAPSULE**

Active ingredients: EACH CAPSULE **CONTAINS:**
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 25,0 mg

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO RICO
SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROENKLOOF, **PRETORIA**, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 Months

Date of registration: 3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/1.2/0523

Name of medicine: **STRATTERA 40 MG**

Dosage form: **CAPSULE**

Active ingredients: EACH CAPSULE CONTAINS:
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO **ATOMOXETINE** 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **ELI LILLY (S.A.) (PTY) LTD**

Manufacturer: **ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK**

Packer: **ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO**

Laboratory: **ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA**

Shelf-life: 36 months

Date of registration: **3 JUNE 2005**

MRF 15 (MBR 15)

Registration number: A38/1.2/0524

Name of medicine: STRATTERA 60 MG

Dosage form: CAPSULE

Active ingredients: EACH **CAPSULE** CONTAINS:
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 60,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL **CARIBE**, CAROLINA, PUERTO RICO
SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROENKLOOF, **PRETORIA**, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/26/0528

Name of medicine: METVIX CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
METHYL AMINOLEVULINATE HYDROCHLORIDE
EQUIVALENT TO METHYL AMINOLEVULINATE
160,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GALDERMA LABORATORIES S.A.(PTY) LTD

Manufacturer: PENN PHARMACEUTICAL SERVICES LTD,
TREDEGAR, GWENT, U.K.

Packer: PENN PHARMACEUTICAL SERVICES LTD,
TREDEGAR, GWENT, U.R.

Laboratory: FPRC: COSI PHARMACEUTICALS, INDUSTRIA,
JOHANNESBURG, RSA
FPRR: GALDERMA LABORATORIES, BRYANSTON,
JOHANNESBURG, RSA

Shelf-life: 12 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/2.5/0567**

Name of **medicine**: **CIPLA – LAMOTRIGINE 25**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LAMOTRIGINE **25,0 M G****

Conditions of **registration**: **1, 2, 3, 4, 5, 6, 7**

Applicant: **CPLA LEE SCIENCES (PTY) LTD**

Manufacturer: **CPLA LTD, RAIGAD, MAHARASHTRA, INDIA**

Packer: **CPLA LTD, RAIGAD, MAHARASHTRA, INDIA**

Laboratory: **FPRC:** **CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA**
FPRR: **CIPLA LIFE SCIENCES, ROSENPARK, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/2.5/0568

Name of medicine: CIPLA - LAMOTRIGINE 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSEN PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0569

Name of medicine: CIPLA - LAMOTRIGINE 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: **FPRC:** CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/2.5/0570**

Name of medicine: **CPLA – LAMOTRIGINE 200**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **CPLA LIFE SCIENCES (PTY) LTD**

Manufacturer: **CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA**

Packer: **CIFLA LTD, RAIGAD, MAHARASHTRA, INDIA**

Laboratory: **FPRC: CPLA LTD, RAIGAD, MAHARASHTRA, INDIA**
FPRR: CPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/21.1/0578

Name of medicine: APEX-METFORMIN 500 MG **TABLETS**

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS:**
METFORMIN HYDROCHLORIDE 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, **RSA**
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, **BOKSBURG, RSA**
INSPECTORATE M&L, ORMONDE, **JOHANNESBURG**
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A3812 1.110579

Name of **medicine**: APEX-METFORMINFORTE 850 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS**:
METFORMIN HYDROCHLORIDE 850,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, **INDIA**

Laboratory: FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, **RSA**
INSPECTORATE M&L, **ORMONDE, JOHANNESBURG**
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA**

Shelf-life: ~~24 months~~

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/10.2.2/0584

Name of medicine: SINGULAIR SPRINKLES

Dosage form: GRANULES

Active ingredients: **EACH PACKET CONTAINS:
MONTELUKAST SODIUM EQUIVALENT TO
MONTELUKAST 4,0 MG**

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MSD (PTY) LTD

Manufacturer: **MERCK MANUFACTURING DIVISION, WEST POINT,
PA, USA**

Packer: **ANDERSON PACKAGING, ROCKFORD, IL, USA
MMD-HAARLEM, HAARLEM, THE NETHERLANDS
MSD, HALFWAY HOUSE, RSA**

Laboratory: FPRC: **MERCK MANUFACTURING DIVISION, WEST POINT,
PA, USA**
FPRC/FPRR: **MSD, HALFWAY HOUSE, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/2.5/0585

Name of medicine: ASPEN LAMOTRIGINE 25 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: **FPRC:** GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0586

Name of medicine: ASPEN LAMOTRIGINE 50 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS INC, **ONTARIO, CANADA**
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS INC, **ONTARIO, CANADA**
LENNON **LTD**, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS **INC, ONTARIO, CANADA**
LENNON LTD, KORSTEN, **PORT ELIZABETH**
SOUTH **AFRICAN** BUREAU OF **STANDARDS**,
GROENKLOOF, PRETORIA, **RSA**
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, **UNIVERSITY**, POTCHEFSTROOM

FPRR: PHARMACARE LTD, **KORSTEN**, PORT ELIZABETH

Shelf-life: **24 months**

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/2.5/0587**

Name of medicine: **ASPEN LAMOTRIGINE 100MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Packer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Laboratory: FPRC: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROEMCLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM**
FPRR: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A3812.510588**

Name of medicine: **ASPEN LAMOTRIGINE 200 MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LAMOTRIGINE **200,0** mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Packer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Laboratory: **F'PRC:** **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM**
FPRR: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/15.4/0592

Name of medicine: **REFRESH LIQUIGEL**

Dosage form: EYE DROPS

Active ingredients: EACH **1,0** ml SOLUTION **CONTAINS :**
CARBOXYMETHYLCELLULOSE SODIUM 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ALLERGAN PHARMACEUTICALS (PTY) LTD

Manufacturer: ALLERGAN INC., WACO, TEXAS

Packer: ALLERGAN INC., WACO, TEXAS

Laboratory: FPRC: ALLERGAN INC., WACO, TEXAS
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: ALLERGAN PHARMACEUTICALS,
HALFWAY HOUSE, RSA

Shelf-life: 18 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/2.6.5/0595**

Name of medicine: **ABILIFY 10MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
ARIPRAZOLE 10,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **BRISTOL-MYERS SQUIBB (PTY) LTD**

Manufacturer: **BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO**

Packer: **BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA**

Laboratory: **FPRC: BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO
BRISTOLMYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL, MANUFACTURER,
WADEVILLE, GERMISTON, RSA
FPRR: BRISTOLMYERS SQUIBB, BEDFORDVIEW, RSA**

Shelf life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A38/2.6.5/0596**

Name of medicine: **ABILIFY 15 MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:**
ARIPRAZOLE 15,0 MG

Conditions of registration: **1,2,3,4,5,6,7**

Applicant: **BRISTOL-MYERS SQUIBB (PTY) LTD**

Manufacturer: **BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO**

Packer: **BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA**

Laboratory: **FPRC:** **BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO
BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA**
FPRR: **BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/2.6.5/0598

Name of medicine: ABILIFY 30 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ARIPRAZOLE 30,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO

Packer: BRISTOL-MYERS SQUIBB AUSTRALIA **PTY** LTD,
NOBLE PARK, VICTORIA, AUSTRALIA

Laboratory: **FPRC:** BRISTOL-MYERS **SQUIBB** MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO
BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE **PARK**, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL **LABORATORIES**,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, **RSA**
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, **RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0632

Name of medicine: REZIDIME 1000 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO
CEFTAZIDIME 1,0 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED HEALTHCARE

Manufacturer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA

Packer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA

Laboratory: FPRC: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD PARK,
DURBAN, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0634

Name of medicine: REZIDIME 2000 INJECTION

Dosage form: **INJECTION**

Active ingredients: EACH VIAL CONTAINS;
CEFTAZIDIME PENTAHYDRATE EQVALENT TO
CEFTAZIDIME 2,0 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: RESMED **HEALTHCARE**

Manufacturer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA

Packer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA

Laboratory: FPRC: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD PARK,
DURBAN, RSA

Shelf-life: 36 ~~months~~

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/13.4.1/0668

Name of medicine: ASPEN MOMETASONE CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g *CREAM* CONTAINS:
MOMETASONE FUROATE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.1.1/0692
Name of medicine:	ZITHROGEN 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN MONOHYDRATE HEMIETHANOLATE EQUIVALENT TO AZITHROMYCIN 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GERARD LABORATORIES, DUBLIN, IRELAND
Packer:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GEWSTON, RSA
Laboratory:	FPRC: GERARD LABORATORIES , DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GEWSTON, RSA SOUTH AFRICAN BUREAU OF STANDARDS , GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY , UNIVERSITY, POTCHEFSTROOM, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/20.1.1/0693**

Name of medicine: **ZITHROGEN 500**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS :
AZITHROMYCIN MONOHYDRATE
HEMIETHANOLATE EQUIVALENT TO
AZITHROMYCIN 500,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **XIXIA PHARMACEUTICALS (PTY) LTD**

Manufacturer: **GERARD LABORATORIES, DUBLIN, IRELAND**

Packer: **GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA**

Laboratory: FPRC: **GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
SOUTH AFRICAN BUREAU OF STANDARDS ,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA**
FPRR: **XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0715

Name of medicine: CIPRODAC 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT
TO CIPROFLOXACIN 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **BE-TABS** PHARMACEUTICALS (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Packer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA

Laboratory: FPRC: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, INDIA
FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, RSA

Shelf-life: 36 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0002

Name of medicine: ASPEN LAMOTRIGINE 25 MG DISPERSIBLE

Dosage fom: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS **Jnc**, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN **PHARMACARE** LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS **Inc**, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, **UNIVERSITY**, POTCHEFSTROOM, **RSA**
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0003

Name of medicine: ASPEN LAMOTRIGINE 50 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARELIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
**SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA**
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0004

Name of medicine: ASPEN LAMOTRIGINE 100 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF *STANDARDS* ,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA

FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: A39/2.5/0006

Name of medicine: ASPEN LAMOTRIGINE 5 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 5,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2,5/0007

Name of medicine: ASPEN LAMOTRIGINE 200 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, **ONTARIO**,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS **Inc**, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN **BUREAU OF** STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE **FOR** PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTR, KORSTEN, PORT ELIZABETH

Shelf-life: **24 months**

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR15)

Registration number: A39/35/0016

Name of medicine: ZEVALIN

Dosage form: INFUSION

Active ingredients: EACH 1,0ml SOLUTION CONTAINS:
IBRITUMOMAB TIUXETAN 1,6 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SCHEIUNG (PTY) LTD

Manufacturer: IDEC PHARMACEUTICALS, SANDIEGO, CA, USA
BAXTER PHARMACEUTICAL SOLUTIONS,
BLOOMINGTON, INDIANA, USA

Packer: BAXTER PHARMACEUTICAL SOLUTIONS,
BLOOMINGTON, INDIANA, USA
SCHERING AG, BERLIN, GERMANY

Laboratory: FPRC: SCHERING AG, BERLIN, GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
FPRR: SCHERING, MIDRAND, RSA

Shelf-life: **12 months** for BULK SOLUTIONS
24 months for KIT SOLUTIONS

Date of registration: 25 **NOVEMBER** 2005

MRF 15 (MBR 15)

Registration number: **A39/20.1.1/0020**

Name of medicine: **MACROZIT 500 MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
AZITHROMYCIN **500,0 mg****

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: **INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA**

Packer: **INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA**

Laboratory: **INTAS PHARMACEUTICALS LTD, MATODA,
GUJARAT, INDIA
**SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
CAMOX PHARMACEUTICALS, ROSEBANK, RSA****

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A39/5.1010062**

Name of medicine: **ASPEN ONDANSETRON 4MG/2 ML**

Dosage form: **INJECTION**

Active ingredients: **EACH 1,0 ml LIQUID CONTAINS :**
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 2,0 mg

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Packer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Laboratory: **FPRC:** **STRIDES ARCOLAB LTD, BANGALORE, INDIA**
FPRR: **LENNON LTD, KORSTEN, PORT ELIZABETH**
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A39/5.10/0063**

Name of medicine: **ASPEN ONDANSETRON 8 MG/4 ML**

Dosage **form**: **INJECTION**

Active ingredients: **EACH 1,0 m LIQUID CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 2,0 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Packer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Laboratory: **FPRC: STRIDES ARCOLAB LTD, BANGALORE, INDIA
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15

Registration number: A39/20.2.8/0088

Name of medicine: REYATAZ **150** MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE EQUIVALENT TO
ATAZANAVIR 150,0 mg

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA

Packer: BRISTOL-MYERS SQUIBB CO, **EVANSVILLE,**
INDIANA, USA
BRISTOL LABORATORIES **INTERNATIONAL,**
EDIFICIO, PANAMA
BRISTOL-MYERS SQUIBB, MEYMAC, FRANCE

Laboratory: FPRC: BRISTOL-MYERS SQUIBB CO, **EVANSVILLE,**
INDIANA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR **STREET,** BOKSBURG, **RSA**
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, **RSA**
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, **RSA**

Shelf-life: **24** months

Date of registration: **25 NOVEMBER 2005**

MRF 15

Registration number: **A39/20.2.8/0089**

Name of medicine: **REYATAZ 200 MG**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE EQUIVALENT TO
ATAZANAVIR 200,0 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **BRISTOL-MYERS SQUIBB (PTY) LTD**

Manufacturer: **BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA**

Packer: **BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
BRISTOL LABORATORIES INTERNATIONAL,
EDIFICIO, PANAMA
BRISTOL-MYERS SQUIBB, MEYMAC, FRANCE**

Laboratory: FPRC: **BRISTOLMYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA**

FPRR: **BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0108

Name of medicine: LISOZIDE 10 (TABLETS)

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LISINOPRIL DIHYDRATE EQUIVALENT TO
LISINOPRIL 10,0 mg
HYDROCHLOROTHIAZIDE 12,5 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA

Packer: **IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA**

Laboratory: **IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA**
SOUTH **AFRICAN** BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
AUSTELL LABORATORIES, SAXONWOLD, RSA

Shelf-life: 24 months

Date of registration: 29 JULY 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0 109
Name of medicine:	LISOZIDE 20 (TABLETS)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 20,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA
Shelf-life:	24 months
Date of registration:	29 JULY 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0141

Name of medicine: **RAMPIL 1,25 MG**

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 **MG**

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM **INC**, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM INC, ETOBICOKE, **ONTARIO**, CANADA
MERCK FARMA y **QUIMICA**, BARCELONA, SPAIN
PHARMACARE LTD, **KORSTEN**, **PORT** ELIZABETH

Laboratory: **F'PRC:** GENPHARM **INC**, ETOBICOKE, **ONTARIO**, CANADA
MERCK FARMA y **QUIMICA**, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU **OF**
STANDARDS, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, **PRETORIA**, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 ~~months~~

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A39/7.1.3/0142**

Name of medicine: **RAMPIL 2,5 MG**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS :**
RAMIPRIL 2,5 MG

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA**
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA**
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: **FPRC** **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA**
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS ,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration number: **A39/7.1.3/0143**

Name of medicine: **RAMPIL 5 MG**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Packer: **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Laboratory: FPRC: **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0144

Name of medicine: RAMPIL 10 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE **CONTAINS:**
RAMIPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM INC, ETOBICOJSE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM **INC**, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUTMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM INC, ETOBICOKE, **ONTARIO**, CANADA
MERCK FARMA y QUTMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA**
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0145
Name of medicine:	MERCK-CARVEDILOL 3,125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 3,125 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN , IRELAND GENEFUCS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECFAR S.A., ATHENS , GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN , IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY , POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0146
Name of medicine:	MERCK-CARVEDILOL 6,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0147
Name of medicine:	MERCK-CARVEDILOL12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENEFUCS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0148
Name of medicine:	MERCK-CARVEDILOL 25
Dosage form:	TABLET
Active ingredients :	EACH TABLET CONTAINS: CARVEDILOL 25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY , IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERIC UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS , GREECE CHANELLE MEDICAL LTD, GALWAY , IRELAND Mc DERMOTT LABORATORIES , DUBLIN, IRELAND GENERIC UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, <i>UNIVERSITY</i> , POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A3913410162

Name of medicine: SABAX LOW GLUCOSE ACID **DIASOL**

Dosage form: **SOLUTION**

Active ingredients: EACH 1000,0 ml SOLUTION **CONTAINS:**

SODIUM CHLORIDE	214,8 G
GLACIAL ACETIC ACID	6,310 G
POTASSIUM CHLORIDE	3,920 G
CALCIUM CHLORIDE DIHYDRATE	7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE	2,135 G
GLUCOSE MONOHYDRATE	38,50 G

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: ADCOCK **INGRAM** CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: **FPRC:** WICKHAM **LABORATORIES**, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**

Shelf-life: **24** months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A3913410163

Name of medicine: *SABAX* LOW MAGNESIUM ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 214,8 G
GLACIAL ACETIC ACID 6,310 G
POTASSIUM CHLORIDE 3,920 G
CALCIUM CHLORIDE DIHYDRATE 7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE 2,135 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL **CARE**, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/34/0164
Name of medicine:	SABAX LIQUID BICARBONATE CONCENTRATE 8,4 %
Dosage form:	SOLUTION
Active ingredients:	EACH 1000,0 ml SOLUTION CONTAINS: SODIUM BICARBONATE 84,0 G
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	ADCOCK INGRAM CRITICAL CARE (PTY) LTD
Manufacturer:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Packer:	ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Laboratory:	FPRC: WICKHAM LABORATORIES, WICKHAM, HAMPSHIRE, U.K. FPRR; ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A3913410165

Name of medicine: **SABAX STANDARD CHRONIC ACID DIASOL**

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 214,8 G
GLACIAL ACETIC ACID 6,310 G
POTASSIUM CHLORIDE **3,920 G**
CALCIUM CHLORIDE DIHYDRATE 7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE 5,340 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK **INGRAM** CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM **LABORATORIES**, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK **INGRAM CRITICAL** CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0 168

Name of medicine: SABAX STANDARD ACUTE ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:

SODIUM CHLORIDE	198,40 G
GLACIAL, ACETIC ACID	6,310 G
POTASSIUM CHLORIDE	3,920 G
CALCIUM CHLORIDE DIHYDRATE	7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE	5,340 G
GLUCOSE MONOHYDRATE	154,00 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL **CARE**, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: **24** months

Date of registration: **25** NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0169

Name of medicine: **SABAX HIGH POTASSIUM ACID DIASOL**

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 198,40 G
GLACIAL ACETIC ACID 6,310 G
POTASSIUM **CHLORIDE** 9,130 G
CALCIUM CHLORIDE DIHYDRATE **7,720 G**
MAGNESIUM CHLORIDE HEXAHYDRATE 5,340 G
GLUCOSE MONOHYDRATE 154,00 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: **ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA**

Packer: **ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA**

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM, HAMPSHIRE, U.K.
FPRR: **ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/2.2/0184

Name of medicine: **MIDAZOLAM-CP 5 MG/5 ML**

Dosage form: INJECTION

Active ingredients: **EACH 5,0 ml AMPOULE CONTAINS :**
MIDAZOLAM 5,0 MG

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Packer: **LABORATORIOS REIG JOFRE, BARCELONA, SPAIN**

Laboratory: FPRC: LABORATORIOS **REIG** JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR **STREET**, BOKSBURG, **RSA**
FPRR: PHARMAPLAN, MIDRAND, **RSA**

Shelf-life: **24** months

Date *of* registration: **25** NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.2/0185

Name of medicine: MIDAZOLAM-CP 15 MG/3 ML

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml AMPOULE CONTAINS :
MIDAZOLAM 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Packer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Laboratory: FPRC: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A3 912210186**

Name of medicine: **MIDAZOLAM-CP 50 MG/10 ML**

Dosage form: **INJECTION**

Active ingredients: **EACH 10,0 ml AMPOULE CONTAINS:
MIDAZOLAM 50,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMAPLAN (PTY) LTD**

Manufacturer: **LABORATORIOS REIG JOFRE, BARCELONA, SPAIN**

Backer: **LABORATORIOS REIG JOFRE, BARCELONA, SPAIN**

Laboratory: **FPRC: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/1.2/02 16

Name of medicine: XET 20 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PAROXETINE HYDROCHLORIDE EQUIVALENT TO
PAROXETINE 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD

Manufacturer: CADILA HEALTHCARE, SANAND, AHMEDABAD,
INDIA

Packer: CADILA HEALTHCARE, SANAND, AHMEDABAD,
INDIA

Laboratory: **F'IRC:** CADILA HEALTHCARE, SANAND, AHMEDABAD,
INDIA
**RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA, RSA**
FPRR: ZYDUS HEALTHCARE, POTCHEFSTROOM, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A3912.81**0228**

Name of medicine: IBUMOL BANANA

Dosage form: SUSPENSION

Active ingredients: EACH 10,0 ml SUSPENSION CONTAINS:
PARACETAMOL **250,0** mg
IBUPROFEN 200,0 mg

Conditions of registration: **1,2,3,4,5,6,7**

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN **PHARMACARE**, WILSONIA, EAST LONDON
FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA**, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA

Shelf-life: **24** months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/2.8/0229

Name of medicine: IBUMOL GRAPE

Dosage form: SUSPENSION

Active ingredients: **EACH 10,0 ml SUSPENSION CONTAINS :**
PARACETAMOL 250,0 mg
IBUPROFEN 200,0 mg

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: **PHARMACARE LTD**, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: **FPRC:** ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE **FOR PHARMACEUTICAL**
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/7.1.3/023 1

Name of medicine: PREXUM 2,5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS :
PERINDOPRIL ARGININE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, **GIDY**,
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, **GIDY**,
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: **LES LABORATOIRES SERVIER INDUSTRIE, GIDY**,
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0232

Name of medicine: PREXUM 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, *GIDY*,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE?, *GIDY*,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: **FPRC:** LES LABORATOIRES SERVIER INDUSTRIE, *GIDY*,
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration **number:** A39/7.1.3/0233

Name of medicine: PREXUM 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVER **INDUSTRIE, GIDY,**
FRANCE
SERVIER **INDUSTRIES LTD, ARKLOW, IRELAND**

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, **IRELAND**
TECHNIKON LABORATORIES, ROBERTVILLE, **RSA**

Laboratory: FPRC: LES LABORATOIRES SERVER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE **M&L, ORMONDE, JOHANNESBURG**
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR15)

Registration number: A39/7.1.3/0234

Name of medicine: **COVERSYL 2,5 MG**

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS :**
PERINDOPRIL ARGININE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD**

Manufacturer: **LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE**
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: **LES LABOMTOIRES SERVIER INDUSTRIE, GIDY, FRANCE**
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORZES, ROBERTVILLE, RSA

Laboratory: **FPRC:** **LES LABORATOIRES SERVIER INDUSTRIE, GIDY, FRANCE**
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: **SERVIER LABORATORIES, RIVONIA, RSA**

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0235

Name of medicine: COVERSYL 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SERVER LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABOMTOIRES SERVER INDUSTRIE, GIDY,
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: LES LABORATOIRES SERVER INDUSTRIE, GIDY,
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: SERVER LABORATORIES, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0236
Name of medicine:	COVERSYL 10MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVER INDUSTRIE, GIDY , FRANCE SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVER INDUSTRIE, GIDY , FRANCE SERVER INDUSTRIES LTD, ARKLOW, IRELAND TECHNIKON LABORATORIES , ROBERTVILLE, RSA
Laboratory:	FPRC: LES LABORATOIRES SERVER INDUSTRIE, <i>GIDY</i> , FRANCE SERVIER INDUSTRIES LTD, ARKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG FPRR: SERVIER LABORATORIES, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A39/20.2.8/0249**

Name of medicine: **ASPEN ZIDOVUDINE 100MG**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:
ZIDOVUDINE 100,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON**

Packer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON**

Laboratory: **FPRC: ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENIUOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration number: A39/20.2.8/0250

Name of medicine: **ASPEN ZIDOVUDINE 250 MG**

Dosage form: **CAPSULE**

Active ingredients: EACH **CAPSULE** CONTAINS:
ZIDOVUDINE 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARELIMITED

Manufacturer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON**

Packer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON**

Laboratory: FPRC: **ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM**
FPRC/FPRR: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0255

Name of **medicine**: **APEX-RANITIDINE 150MG**

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
**RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 150,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: **MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA**

Packer: **MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA**

Laboratory: FPRC: **MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG**
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0256

Name of medicine: APEX-RANITIDINE 300 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 300,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: **FPRC:** MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0276

Name of medicine: CAMOX-RANITIDINE 150MG

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 150,0 MG**

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS(PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
**SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG**
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0277

Name of medicine: CAMOX-RANITIDINE:300 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 300,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: **FPRC:** MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0292

Name of medicine: SANDOZ CLARITHROMYCIN 125 P

Dosage form: *SUSPENSION*

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CLARITHROMYCIN 125,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK d.d., LJUBLJANA, SLOVENIA
KERN PHARMA S.A., VENUS, TERRASSA, SPAIN

Packer: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.110293

Name of medicine: SANDOZ CLARITHROMYCIN 250 P

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CLARITHROMYCIN 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK d.d., LJUBLJANA, SLOVENIA
KERN PHARMA S.A., VENUS, TERRASSA, SPAIN

Packer: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0304

Name of medicine: APEX – RAMIPRIL 1,25 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES LTD, **DADRA** &
NAGAR HAVELI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROEMCLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0305

Name of medicine: **APEX – RAMIPRIL 2,5 MG**

Dosage form: CAPSULE

Active ingredients: EACH **CAPSULE** CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: **IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA**

Packer: **IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA**

Laboratory: **FPRC: IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA**
SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE, RSA

FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration number: A39/7.1.3/0306

Name of medicine: APEX – RAMIPRIL 5 MG

Dosage form: *CAPSULE*

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA &
NAGAR **HAVELI**, INDIA

Packer: IPCA LABORATORIES LTD, **DADRA &**
NAGAR HAVELI, INDIA

Laboratory: FPRC IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA
SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROEMKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, **RSA**
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0307

Name of medicine: APEX - RAMIPRIL 10MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA

Laboratory: **FPRC:** IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROEMKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/2.2/0348
Name of medicine:	MERCK-ZOLPIDEM
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ZOLPIDEM TARTRATE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA MERCK FARMA y QUIMICA SA, BARCELONA, SPAIN
Packer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GEWSTON, RSA MERCK FARMA y QUIMICA SA, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK
Laboratory:	FPRC: MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA MERCK FARMA y QUIMICA SA, BARCELONA, SPAIN GERARD LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: MERCK GENERICS RSA, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0349

Name of medicine: MERCK-FOSINOPRIL 20

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS:**
FOSINOPRIL SODIUM 20,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTDManufacturer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADAPacker: GENPHARM PHARMACEUTICALS INC, **ONTARIO,**
CANADA
GENERICS [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, **U.K.**
GERARD LABORATORIES, DUBLIN, IRELANDLaboratory: FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
GENERICS [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON, **RSA**
RESEARCH INSTITUTE FOR **INDUSTRIAL**
PHARMACY, **UNIVERSITY**, POTCHEFSTROOM
FPRR: MERCK **GENERICS**, MODDERFONTEIN, RSA**Shelf-life:** 24 monthsDate of **registration:** 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registrationnumber: A39/34/0400

Name of medicine: SABAX **LOW CALCIUM ACID DIASOL** (1,25 mmol/l)

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 214,8 G
GLACIAL, ACETIC ACID 6,310 G
POTASSIUM CHLORIDE 3,920 G
CALCIUM CHLORIDE DIHYDRATE 6,430 G
MAGNESIUM CHLORIDE HEXAHYDRATE 2,135 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
ADCOCK INGRAM CRITICAL CARE, AEROTON,
FPRC/FPRR: JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.9/0406

Name of medicine: LOPIDIUM

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOPERAMIDE HYDROCHLORIDE 2,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.9/0407

Name of medicine: CIPLA-LOPERAMIDE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOPERAMIDE HYDROCHLORIDE 2,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR15)

Registration number: A39/5.10/0413

Name of medicine: ODARON 4MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: M J PHARMACEUTICALS LTD, GUJARAT , INDIA

Packer: M J PHARMACEUTICALS LTD, GUJARAT , INDIA

Laboratory: FPRC: M J PHARMACEUTICALS LTD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET , BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration **number:** A39/5.10/0414

Name of medicine: ODARON 8 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Packer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Laboratory: FPRC: M J PHARMACEUTICALS LTD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A39/7.1.3/0441**

Name of medicine: **MERCK-FOSINOPRIL 10**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
FOSINOPRIL SODIUM **10,0 MG****

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **MERCK **GENERICS** RSA (PTY) LTD**

Manufacturer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA**

Packer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
GENERICS [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND**

Laboratory: **FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
GENERICS [UK] LTD, POTTERS BAR,
HERTFORDSHIRE, U.K.
GERARD LABORATORIES, DUBLIN, IRELAND
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR: MERCK **GENERICS**, MODDERFONTEIN, **RSA****

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A39/5.10/0448**

Name of medicine: **ODARON 4 MG INJECTION**

Dosage form: **INJECTION**

Active *ingredients*: **EACH 1,0ml SOLUTION CONTAINS:
ONDASETRON HYDROCHLORIDE EQUIVALENT TO
ONDANSETRON 2,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMAPLAN (PTY) LTD**

Manufacturer: **M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA**

Packer: **M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA**

Laboratory: FPRC: **M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA**
FPRR: **PHARMAPLAN, MIDRAND, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15

Registration number: A39/5.10/0509

Name of medicine: MERCK-ONDANSETRON 4 MG/2 ML

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml AMPOULE CONTAINS:
ONDANSETRON HYDROCHLORIDE
EQUIVALENT TO ONDANSETRON 4,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, **DUBLIN**, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH **INSTITUTE FOR** INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: A39/5.10/0510

Name of medicine: MERCK-ONDANSETRON 8 MG/4 ML

Dosage form: INJECTION

Active ingredients: EACH 4,0 ml **AMPOULE** CONTAINS:
ONDANSETRON HYDROCHLORIDE
EQUIVALENT TO ONDANSETRON 8,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: **PHARMATHEN PHARMACEUTICAL INDUSTRY,**
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR **INDUSTRIAL**
PHARMACY, **UNIVERSITY**, POTCHEFSTROOM
SOUTH **AFRICAN** BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A40/21.2/0006

Name of medicine: DIAGLIM 1

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLIMEPIRIDE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **SANDOZ (PTY) LTD**

Manufacturer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS S.A., **SPARTAN**, KEMPTON PARK, RSA

Laboratory: FPRC: SOUTH ~~AFRICAN~~ BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS **S.A.**, SPARTAN, KEMPTON PARK, RSA
FPRR: **SANDOZ**, SPARTAN, KEMPTON PARK, RSA

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A40/21.2/0007**

Name of medicine: **DIAGLIM 2**

Dosage form: ***TABLET***

Active ingredients: EACH TABLET CONTAINS:
GLIMEPIRIDE 2,0 mg

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: SANDOZ (PTY) LTD

Manufacturer: **NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA**

Packer: NOVARTIS S.A., **SPARTAN**, KEMPTON PARK, RSA

Laboratory: **FPRC:** SOUTH AFRICAN BUREAU OF STANDARDS ,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, **SPARTAN**, KEMPTON PARK

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A40/21.2/0008

Name of medicine: **DIAGLIM 4**

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**
GLIMEPIRIDE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **SANDOZ (PTY) LTD**

Manufacturer: **NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA**

Packer: **NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA**

Laboratory: **FPRC:** SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS S.A., **SPARTAN, KEMPTON PARK, RSA**
FPRR: **SANDOZ, SPARTAN, KEMPTON PARK**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A40/2.7/0255

Name of medicine: **BARRS PARACETAMOL SYRUP**

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
PARACETAMOL 120,0 ml

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BARRS PHARMACEUTICAL INDUSTRIES CC

Manufacturer: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN

Packer: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN

Laboratory: FPRC/FPRR: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN
FPRC: SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROENKLOOF, PRETORIA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005
