

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 MONOHYDRATE EQUIVALENT 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: 35/7.1/0 179

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:
PREDNISONE 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, JOHANNESBURGPacker: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURGLaboratory: FPRC: BODENE, KORSTEN, PORT ELIZABETH
PHARMA-Q, INDUSTRIA, JOHANNESBURG
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETHShelf-life: **48** monthsDate 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: F'PRC: 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, LABORATORTES, 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 M G
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
FPRR:	SYNTHON, NIJMEGEN, THE NETHERLANDS 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 PHARMACEUTIC NV, 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: 37/2.6.5/0 189

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, GERMANYPacker: **HEXAL AG**, HOLZKIRCHEN, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA
PHARMA Q, INDUSTRIA **WEST, RSA**Laboratory: 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 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: 37/7.1.3/0225

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**, USAPacker: GENSIASICOR PHARMACEUTICALS, **IRVINE**, USALaboratory: 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
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: 37/26/0359

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:	CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA
FPRC:	CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA
FPRR:	
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 1,0 G

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
FPRR: ANALYTICON, KEMPTON PARK, GAUTENG, RSA
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: DNPHARM 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 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: 37/7.1.3/0601

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: <table><tr><td>VITAMIN A</td><td>4000,0 iu</td></tr><tr><td>THIAMINE HYDROCHLORIDE</td><td>1,6 mg</td></tr><tr><td>RIBOFLAVINE</td><td>1,8 mg</td></tr><tr><td>NICOTINAMIDE</td><td>19,0 mg</td></tr><tr><td>CALCIUM PANTOTHENATE</td><td>10,0 mg</td></tr><tr><td>PYRIDOXINE HYDROCHLORIDE</td><td>2,6 mg</td></tr><tr><td>BIOTIN</td><td>200,0 ug</td></tr><tr><td>FOLIC ACID</td><td>0,8 mg</td></tr><tr><td>CYANOCOBALAMIN</td><td>4,0 ug</td></tr><tr><td>ASCORBIC ACID</td><td>100,0 mg</td></tr><tr><td>CHOLECALCIFEROL</td><td>100,0 iu</td></tr><tr><td>a- TOCOPHEROL ACETATE</td><td>15,0 mg</td></tr><tr><td>CALCIUM</td><td>125,0 mg</td></tr><tr><td>COPPER</td><td>1,0 mg</td></tr><tr><td>IRON</td><td>60,0 mg</td></tr><tr><td>MAGNESIUM</td><td>100,0 mg</td></tr><tr><td>MANGANESE</td><td>1,0 mg</td></tr><tr><td>PHOSPHORUS</td><td>125,0 mg</td></tr><tr><td>ZINC</td><td>7,5 mg</td></tr></table>	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	a- 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
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CHOLECALCIFEROL	100,0 iu																																						
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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**
FPRR: **ANALYTICON, KEMPTON PARK, RSA**
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
FPRR: RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
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 (MBR15)

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, ROSENPARK, 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 **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 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:	38/2.5/0135
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 months

Date 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 EQUIVALENT 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: 3813410**144**

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, **SODERTAWE**, SWEDEN

Packer: ASTWENEC A AB, SODERTAWE, SWEDEN
ASTRAZENECA U.K., MACCLESFIELD, **CHESHIRE**,
UK
ASTRAZENECA, ALRODE, ALBERTON, RSA
JANSSEN PHARMACEUTICA, HALFWAY HOUSE,
RSA

Laboratory: FPRC: ASTRAZENECA AB, SODERTAWE, 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
