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## GENERAL NOTICE ALGEMENE KENNISGEWING

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### NOTICE 1300 OF 2005

#### MEDICINES CONTROL COUNCIL

#### CONDITIONS OF REGISTRATION OF A MEDICINE INTERMS 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)**

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Registration number: 01/20.1.2/10

Name of medicine: LINCOJECT INJECTION

**Dosage form:** INJECTION

Active **ingredients:** EACH VIAL **CONTAINS:**  
LINCOMYCIN HYDROCHLORIDE **EQUIVALENT TO**  
LINCOMYCIN 100,0 mg

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

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

Manufacturer: NORBROOK LABORATORIES LTD, NEWRY,  
NORTHERN IRELAND

Packer: NORBROOK LABORATORIES LTD, NEWRY,  
NORTHERN IRELAND

Laboratory: NORBROOK LABORATORIES LTD, **NEWRY ,**  
NORTHERN **IRELAND**  
NORBROOK LABORATORIES, CENTURION, **RSA**

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 02/17.1.1.2/14

Name of medicine: CEPOREX 50 MG TABLETS

Dosage form: TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
CEPHALEXIN MONOHYDRATE EQUIVALENT TO  
CEPHALEXIN 50,0 mg

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

Applicant: SCHERING-PLOUGH (PTY) LTD

Manufacturer: GALEN LTD, SEAGOE INDUSTRIAL ESTATE,  
ARMAGH, NORTHERN IRELAND

**Packer:** **GALEN LTD, SEAGOE INDUSTRIAL ESTATE,**  
ARMAGH, NORTHERN IRELAND  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA

Laboratory: GALEN LTD, SEAGOE INDUSTRIAL ESTATE,  
ARMAGH, NORTHERN IRELAND  
SCHERING-PLOUGH, ISANDO, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 02/21.1/18

**Name of medicine:** CEFA-VET 50 MG

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
CEFADROXIL 50,0 mg

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

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

**Manufacturer:** INTERVET LAB, DUBLIN, IRELAND

**Packer:** INTERVET LAB, DUBLIN, IRELAND

**Laboratory:** INTERVET INTERNATIONAL B.V., BOXMEER,  
THE NETHERLANDS  
INTERVET S.A., KEMPTON PARK, RSA

**Shelf-life:** 60 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 ( MBR €5)**

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**Registration number:** 02121.1119**Name of medicine:** CEFA-VET 200 MG**Dosage form:** TABLET**Active ingredients:** EACH TABLET CONTAINS:  
CEFADROXIL 200,0 mg**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7**Applicant:** INTERVET S.A.(PTY) LTD**Manufacturer:** INTERVET LAB, DUBLIN, IRELAND**Packer:** INTERVET LAB, DUBLIN, IRELAND**Laboratory:** INTERVET INTERNATIONAL B.V., BOXMEER,  
THENETHERLANDS  
INTERVET S.A., KEMPTON PARK, RSA**Shelf-life:** 60 months**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 02/21.1/20

Name of medicine: CEFA-VET 1000MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
CEFADROXIL 1000,0 mg

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

Applicant: INTERVET S.A. (PTY) LTD

Manufacturer: INTERVET LAB, DUBLIN, IRELAND

*Packer:* INTERVET LAB, DUBLIN, IRELAND

Laboratory: INTERVET INTERNATIONAL B.V., BOXMEER,  
THENETHERLANDS  
INTERVET S.A., KEMPTON PARK, RSA

Shelf-life: 60 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 03/2 1116

**Name of medicine:** NOROCLAV INJECTION

**Dosage form:** INJECTION

**Active ingredients:** EACH 1,0 ml SUSPENSION CONTAINS:  
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 140,0 mg  
POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 35,0 mg

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

**Applicant:** NORBROOK LABORATORIES S.A. (PTY) LTD

**Manufacturer:** NORBROOK LABORATORIES LTD, NEWRY,  
NORTHERN IRELAND

**Packer:** NORBROOK LABORATORIES LTD, NEWRY,  
NORTHERN IRELAND

**Laboratory:** NORBROOK LABORATORIES LTD, NEWRY,  
NORTHERN IRELAND  
NORBROOK LABORATORIES, CENTURION, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 03/3.1/7

Name of medicine: QUADRISOL 1 GEL

Dosage form: GEL

Active ingredients: EACH 1,0 ml GEL **CONTAINS:**  
VEDAPROFEN 1,0 mg

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

Applicant: INTERVET S.A. (PTY) LTD

Manufacturer: INTERVET INTERNATIONAL B.V., BOXMEER,  
THE NETHERLANDS

Packer: **INTERVET** INTERNATIONAL B.V., BOXMEER,  
THE NETHERLANDS

Laboratory: INTERVET INTERNATIONAL B.V., BOXMEER,  
THE NETHERLANDS  
INTERVET S.A., KEMPTON PARK, RSA

Shelf-life: **24 months**

Date of registration: 23 SEPTEMBER 2005

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MRF 15 (MBR 15)

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Registration number: A03/2I. 1/11

Name of medicine: EXCENEL RTU SUSPENSION FOR INJECTION

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:  
CEFTIOFUR HYDROCHLORIDE EQUIVALENT TO  
CEFTIOFUR 50,0 mg

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

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

Manufacturer: **PHARMACIA & UPJOHN CO, KALAMAZOO,  
MICHIGAN, USA  
ISOMEDIX INC, LIBERTYVILLE, ILLINOIS, USA**

Packer: **PHARMACIA & UPJOHN CO, KALAMAZOO,  
MICHIGAN, USA**

Laboratory: **PHARMACIA & UPJOHN CO, KALAMAZOO,  
MICHIGAN, USA  
KHULULEKANI LABORATORY SERVICES,  
MIDRAND, RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
PHARMACIA S.A., MIDRAND, RSA**

Shelf-life: **24 months**

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A03/3.1.2/14

Name of medicine: PREVICOX 57 MG CHEWABLE TABLET

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
FIROCOXIB 57,0 mg

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

Applicant: MERIAL SOUTH AFRICA (PTY) LTD

Manufacturer: PATHEON INC., **ONTARIO**, CANADA

Packer: PATHEON INC., ONTARIO, CANADA

Laboratory: MERIAL S.A.S., CEDEX, FRANCE  
STAINER LABORATORY SERVICES FERNDALE,  
**RANDBURG**, RSA  
MERIAL, HALFWAY HOUSE, RSA

Shelf-life: **24 months**

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** A03/3.1.2/15

**Name of medicine:** PREVICOX 227 MG CHEWABLE TABLET

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
FIROCOXIB 227,0 mg

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

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

**Manufacturer:** PATHEON INC., ONTARIO, CANADA

**Packer:** PATHEON INC., ONTARIO, CANADA

**Laboratory:** MERIAL S.A.S., CEDEX, FRANCE  
STAINER LABORATORY SERVICES, FERNDALE,  
RANDBURG, RSA  
M E W , HALFWAY HOUSE, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **32/2.8/0320**

Name of medicine: **GRAND-PA HEADACHE POWDERS LEMON  
FLAVOUR**

Dosage form: **POWDER**

Active ingredients: **EACH POWDER CONTAINS:**  
**ASPIRIN 453,6 mg**  
**PARACETAMOL 324,0 mg**  
**CAFFEINE 64,8 mg**

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

Applicant: **GROUP LABORATORIES S.A. (PTY) LTD**

Manufacturer: **GLAXOSMITHKLINE, EPPING, CAPE TOWN**

Packer: **GLAXOSMITHKLINE, EPPING, CAPE TOWN**

Laboratory: **GLAXOSMITHKLINE, EPPING, CAPE TOWN  
GROUP LABORATORIES, EPPING, CAPE TOWN**

Shelf-life: **12 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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<b>Registration number:</b>	32/34/0423
<b>Name of medicine:</b>	OVANTA
<b>Dosage form:</b>	TABLET
<b>Active ingredients:</b>	EACH TABLET CONTAINS: RALOXIFENE HYDROCHLORIDE 60,0 mg
<b>Conditions of registration:</b>	1, 2, 3, 4, 5, 6, 7
<b>Applicant:</b>	ELI LILLY (S.A.) (PTY) LTD
<b>Manufacturer:</b>	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO
<b>Packer:</b>	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, U.K.
<b>Laboratory:</b>	ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, U.K. LILLY DEL CARIBE, CAROLINA, PUERTO RICO CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA ELI LILLY, BRYANSTON, RSA
<b>Shelf-life:</b>	24 months
<b>Date of registration:</b>	23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 33/21.12/05 17

**Name of medicine:** TAMOXIHEXAL 10

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS :  
TAMOXIFEN CITRATE EQUIVALENT TO  
TAMOXIFEN 10,0 mg

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

**Applicant:** HEXAL PHARMA (SA) (PTY) LTD

**Manufacturer:** SALUTAS PHARMA GmbH, BARLEBEN, GERMANY

**Packer:** SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA

**Laboratory:** SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
HEXAL PHARMA, WESTMEAD, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 ( MBR 15)**

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Registration number: **33/21.12/05 18**

Name of medicine: **TAMOXIHEXAL 20**

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

Active Ingredients: **EACH TABLET CONTAINS:  
TAMOXIFEN CITRATE EQUIVALENT TO  
TAMOXIFEN **20,0 mg****

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

Applicant: **HEXAL PHARMA (SA) (PTY) LTD**

Manufacturer: **SALUTAS PHARMA GmbH, BARLEBEN, GERMANY**

Packer: **SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA**

Laboratory: **SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
HEXAL PHARMA, WESTMEAD, RSA**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: 34/7.1/0284

Name of medicine: CARDOSIN 1

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
DOXAZOSIN MESYLATE EQUIVALENT TO  
DOXAZOSIN 1,0 mg

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

Applicant: H E W PHARMA (S.A.) (PTY) LTD

Manufacturer: LAB PHARMACEUTICAL RESEARCH  
INTERNATIONAL, QUEBEC, CANADA

Packer: LAB PHARMACEUTICAL RESEARCH  
INTERNATIONAL, QUEBEC, CANADA  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG, RSA

Laboratory: LAB PHARMACEUTICAL RESEARCH  
INTERNATIONAL, QUEBEC, CANADA  
CONSULTING CHEMICAL LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
H E W PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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MRF 15 (MBR 15)

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Registration number: 34/7.1/0285

Name of medicine: **CARDOSIN 2**

**Dosage** form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
DOXAZOSIN MESYLATE EQUIVALENT TO  
**DOXAZOSIN 2,0 mg**

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

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

**Manufacturer:** **LAB PHARMACEUTICAL RESEARCH  
INTERNATIONAL, QUEBEC, CANADA**

Packer: LAB PHARMACEUTICAL RESEARCH  
INTERNATIONAL, QUEBEC, CANADA  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, **JOHANNESBURG, RSA**

Laboratory: LAB PHARMACEUTICAL RESEARCH  
INTERNATIONAL, QUEBEC, CANADA  
CONSULTING **CHEMICAL** LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
**HEXAL PHARMA, WESTMEAD, RSA**

Shelf-life: **24 months**

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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<b>Registration number:</b>	<b>34/7.1/0286</b>
<b>Name of medicine:</b>	<b>CARDOSIN 4</b>
<b>Dosage form:</b>	<b>TABLET</b>
<b>Active ingredients:</b>	<b>EACH TABLET CONTAINS : DOXAZOSIN MESYLATE EQUIVALENT TO DOXAZOSIN 4,0 mg</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>HEXAL PHARMA (S.A.)(PTY) LTD</b>
<b>Manufacturer:</b>	<b>LAB PHARMACEUTICAL RESEARCH INTERNATIONAL, QUEBEC, CANADA</b>
<b>Packer:</b>	<b>LAB PHARMACEUTICAL RESEARCH INTERNATIONAL, QUEBEC, CANADA DIVPHARM MANUFACTURING &amp;PACKAGING, LONGDALE, JOHANNESBURG, RSA</b>
<b>Laboratory:</b>	<b>LAB PHARMACEUTICAL RESEARCH INTERNATIONAL, QUEBEC, CANADA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA HEXAL PHARMA, WESTMEAD, RSA</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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MRF 15 (MBR 15)

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Registration number: 34/24/0369

**Name** of medicine: EUROMED DEXTROSE 50 % SOLUTION

Dosage form: SOLUTION

Active ingredients: EACH **1,0** ml SOLUTION CONTAINS:  
DEXTROSE MONOHYDRATE 500,0 mg

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

Applicant: LEBASI PHARMACEUTICALS CC

Manufacturer: EUROMED LABORATORIES, CAVITE, PHILIPPINES

Packer: EUROMED LABORATORIES, CAVITE, PHILIPPINES

Laboratory: EUROMED LABORATORIES, CAVITE, **PHILIPPINES**  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA, **RSA** ,  
LEBASI PHARMACEUTICALS, **POTCHEFSTROOM,**  
**RSA**

Shelf-life: **48** months

**Date of registration:** 23 SEPTEMBER 2005

**MRF 15 (MBR 15)**

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Registration number: **3512.210321**

Name of medicine: **MIDAZOLAM – HEXAL 5 MG/ML**

Dosage form: **INJECTION**

Active ingredients: **EACH 1,0 ml AMPOULE CONTAINS:  
MIDAZOLAM HYDROCHLORIDE EQUIVALENT TO  
MIDAZOLAM 5,0 mg**

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

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

Manufacturer: **SOLUPHARM, MELSUNGEN, GERMANY**

Packer: **SOLUPHARM, MELSUNGEN, GERMANY  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA**

Laboratory: **SOLUPHARM, MELSUNGEN, GERMANY  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
ANALYTICON, KEMPTON PARK, RSA  
H E W PHARMA, WESTMEAD, RSA**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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MRF 15 (MBR 15)

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Registration number: 35/2.2/0322

Name of medicine: MIDAZOLAM – HEXAL 15 MG/3 ML

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml AMPOULE CONTAINS:  
**MIDAZOLAM HYDROCHLORIDE EQUIVALENT TO**  
MIDAZOLAM 15,0 mg

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

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

Manufacturer: SOLUPHARM, MELSUNGEN, GERMANY

Packer: SOLUPHARM, MELSUNGEN, GERMANY  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA

Laboratory: **SOLUPHARM, MELSUNGEN, GERMANY**  
CONSULTING CHEMICAL **LABORATORIES**,  
STAR STREET, BOKSBURG, RSA  
ANALYTICON, KEMPTON PARK, RSA  
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 ~~months~~

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 36/20.1.1/0222

Name of medicine: **ERYKO-250**

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: KOPRAN LTD, KHALAPUR, **RAIGAD**, INDIA  
BE-TABS PHARMACEUTICALS, ROODEPOORT, **RSA**

Shelf-life: **24** months

Date of registration: **23** SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **36/15.410357**

Name of medicine: **SPERSALLERG SDU (SINGLE DOSE UNIT)**

Dosage form: **DROPS**

Active ingredients: **EACH 0,3 ml SOLUTION CONTAINS:**  
**ANTAZOLINE HYDROCHLORIDE 0,15 mg**  
**TETRYZOLINE HYDROCHLORIDE 0,12 mg**

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

Applicant: **ADCOCK INGRAM LIMITED**

Manufacturer: **LABORATOIRES CIBA VISION, ANNONAY, CEDEX, FRANCE**

Packer: **LABORATOIRES CIBA VISION, ANNONAY, CEDEX, FRANCE**  
**NOVO NORDISK, MAIN STREET, JOHANNESBURG**

Laboratory: **LABORATOIRES CIBA VISION, ANNONAY, CEDEX, FRANCE**  
**NOVARTIS OPHTHALMICS AG, HETTLINGEN, SWITZERLAND**  
**ADCQCK INGRAM LTD, BRYANSTON, RSA**  
**NOVO NORDISK, MAIN STREET, JOHANNESBURG**  
**ADCOCK INGRAM HEALTHCARE, WADEVILLE, GERMISTON, RSA**

Shelf-life: **36 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number:	<b>36/17.1/0431</b>
Name of medicine:	MUSCURON
Dosage form:	INJECTION
Active ingredients:	EACH <b>AMPOULE</b> CONTAINS: <b>VECURONIUM BROMIDE</b> <b>4,0 mg</b>
Conditions of registration:	<b>1, 2, 3, 4, 5, 6, 7</b>
Applicant:	MC PHARMA (PTY) LTD
Manufacturer:	M J PHARMACEUTICALS LTD, HALOL, GUJARAT, INDIA
Packer:	M J PHARMACEUTICALS LTD, HALOL, GUJARAT, INDIA
Laboratory:	M J PHARMACEUTICALS LTD, HALOL, GUJARAT, INDIA MC PHARMA, LYTTTELTON MANOR, CENTURION, RSA
Shelf-life:	<b>24 months</b>
Date of registration:	<b>23 SEPTEMBER 2005</b>

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**MRF 15 (MBR 15)**

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**Registration number:** 36/10.2.1/0443

**Name of medicine:** FORAMET DRY POWDER

**Dosage form:** CAPSULE

**Active ingredients:** EACH CAPSULE CONTAINS:  
FORMOTEROL FUMARATE 0,012 mg

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

**Applicant:** ADCOCK INGRAM LIMITED

**Manufacturer:** LICONSA S.A, AZUQUECA DE HENARES,  
GUADALAJARA, SPAIN

**Packer:** LICONSA S.A, AZUQUECA DE HENARES,  
GUADALAJARA, SPAIN

**Laboratory:** LICONSA S.A, AZUQUECA DE HENARES,  
GUADALAJARA, SPAIN  
ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
GERMISTON, RSA  
ADCOCK INGRAM HEALTHCARE,  
OLIFANTSFONTEIN, CLAYVILLE, RSA  
ADCOCK INGRAM LTD, BRYANSTON, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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<b>Registration number</b>	<b>37/20.1.2/0003</b>
<b>Name of medicine:</b>	<b>AUSTELL – AMOXICILLIN 250 MG</b>
<b>Dosage form:</b>	<b>CAPSULE</b>
<b>Active ingredients:</b>	<b>EACH CAPSULE CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250,0 mg</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>AUSTELL LABORATORIES (PTY) LTD</b>
<b>Manufacturer:</b>	<b>IPCA LABORATORIES LTD, GUJARAT, INDIA</b>
<b>Packer:</b>	<b>IPCA LABORATORIES LTD, GUJARAT, INDIA</b>
<b>Laboratory:</b>	<b>IPCA LABORATORIES LTD, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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**MRF 15 ( MBR 15)**

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**Registration number:** 37/20.1.2/0004

**Name of medicine:** AUSTELL – AMOXICILLIN 500 MG

**Dosage form:** CAPSULE

**Active ingredients:** EACH CAPSULE CONTAINS :  
AMOXICILLIN TRIHYDRATE EQUIVALENT TO  
AMOXICILLIN 500,0 mg

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

**Applicant:** AUSTELL LABORATORIES (PTY) LTD

**Manufacturer:** IPCA LABORATORIES LTD, GUJARAT, INDIA

**Packer:** P C A LABORATORIES LTD, GUJARAT, INDIA

**Laboratory:** IPCA LABORATORIES LTD, GUJARAT, INDIA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
AUSTELL LABORATORIES, SAXONWOLD, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 37/1.2/0083

**Name of medicine:** FLUTINOL

**Dosage form:** CAPSULE

**Active ingredients:** EACH CAPSULE CONTAINS:  
FLUOXETINE HYDROCHLORIDE EQUIVALENT TO  
FLUOXETINE 20,0 mg

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

**Applicant:** MC PHARMA (PTY) LTD

**Manufacturer:** M J PHARMACEUTICALS LTD, GUJARAT, INDIA

**Packer:** M J PHARMACEUTICALS LTD, GUJARAT, INDIA

**Laboratory:** M J PHARMACEUTICALS LTD, GUJARAT, INDIA  
MC PHARMA, MEYERSPARK, PRETORIA, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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MRF 15

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Registration number: **37/34/0088**Name of medicine: ACIDIC BICARBONATE HAEMODIALYSIS  
CONCENTRATE SW 95A

Dosage form: SOLUTION

Active ingredients: EACH 100,0 ml **SOLUTION** CONTAINS:  
SODIUM CHLORIDE 210,68 g  
POTASSIUM CHLORIDE 5,22 g  
CALCIUM CHLORIDE 9,01 g  
MAGNESIUM CHLORIDE HEXAHYDRATE 3,56 g  
GLACIAL ACETIC ACID 6,31 g

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

Applicant: B. BRAUN MEDICAL (PTY) LTD

Manufacturer: **B. BRAUN SCHIWA GmbH & CO, GLANDORF,  
GERMANY**Packer: **B. BRAUN SCHIWA GmbH & CO, GLANDORF,  
GERMANY**Laboratory: B. BRAUN SCHIWA GmbH & CO, GLANDORF,  
GERMANY  
INSPECTORATE M&L, ORMONDE,  
JOHANNESBURG, RSA  
B. BRAUN MEDICAL, HONEYDEW, RANDBURG

Shelf-life: 36 months

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15**

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**Registration number:** 37/34/0089

**Name of medicine:** ALKALINE BICARBONATEHAEMODIALYSIS  
CONCENTRATE 8,4% SOLUTION

**Dosage form:** SOLUTION

**Active ingredients:** EACH 100,0 ml SOLUTION CONTAINS:  
SODIUM BICARBONATE 84,0 g

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

**Applicant:** B. BRAUN MEDICAL (PTY) LTD

**Manufacturer:** B. BRAUN SCHWA GmbH & CO, GLANDORF,  
GERMANY

**Packer:** B. BRAUN SCHWA GmbH & CO, GLANDORF,  
GERMANY

**Laboratory:** B. BRAUN SCHWA GmbH & CO, GLANDORF,  
GERMANY  
INSPECTORATE M&L, ORMONDE,  
JOHANNESBURG, RSA  
B.BRAUN MEDICAL, HONEYDEW, RANDBURG

**Shelf-life:** 36 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 37/1.2/0156

Name of medicine: NUZAK 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 LIFE SCIENCES (PTY) LTD

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

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

Laboratory: CIPLA LTD, SATARA, INDIA  
CIPLA LTD, VIKHROLI, BOMBAY, INDIA  
CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months

Date of registration: 12 NOVEMBER 2004

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**MRF 15 (MBR 15)**

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Registration number: 37/20.1.1/0222

Name of medicine: AP AZITHROMYCIN 500 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
AZITHROMYCIN MONOHYDRATE EQWALENT  
TO AZITHROMYCIN 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: LENNON LTD, KORSTEN, PORT ELIZABETH  
SAD SELF MEDICATION, WILSONIA, EAST  
LONDON  
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 37/7.1/0230

Name of medicine: DILEM 30 MG

Dosage **form**: TABLET

Active ingredients: EACH TABLET **CONTAINS** :  
DILTIAZEM HYDROCHLORIDE 30,0 mg

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

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, **NEW ZEALAND**

Packer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, **NEW ZEALAND**

Laboratory: DOUGLAS PHARMACEUTICALS **LTD**, LINCOLN,  
AUCKLAND, **NEW ZEALAND**  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
**PHARMAPLAN**, MIDRAND, RSA

Shelf-life: **48 months**

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 37/7.1/0231

Name of medicine: DILEM 60 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
DILTIAZEM HYDROCHLORIDE 60,0 mg

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

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, **NEW ZEALAND**

Packer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, **NEW ZEALAND**

Laboratory: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, **NEW ZEALAND**  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
PHARMAPLAN, MIDRAND, RSA

Shelf-life: 48 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 37/26/0256

Name of medicine: VINCRISTINE RTU 1

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:  
VINCRISTINE SULPHATE 1,0 mg

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

Applicant: PHARMACHEMIE (PTY) LTD

Manufacturer: PHARMACHEMIE BV, HAARLEM,  
THE NETHERLANDS

Packer: PHARMACHEMIE BV, HAARLEM,  
THE NETHERLANDS

Laboratory: PHARMACHEMIE BV, HAARLEM,  
THE NETHERLANDS  
CONSULTING CHEMICAL LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
RESEARCH INSTITUTE FOR **INDUSTRIAL**  
PHARMACY, UNIVERSITY, POTCHEFSTROOM  
PHARMACHEMIE, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 37/26/0257

**Name of medicine:** VINCRISTINE RTU 2

**Dosage form:** INJECTION

**Active ingredients:** EACH 2,0 ml SOLUTION CONTAINS:  
VINCRISTINE SULPHATE 2,0 mg

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

**Applicant:** PHARMACHEMIE (PTY) LTD

**Manufacturer:** PHARMACHEMIE BV, HAARLEM,  
THE NETHERLANDS

**Packer:** PHARMACHEMIE BV, HAARLEM,  
THE NETHERLANDS

**Laboratory:** PHARMACHEMIE BV, HAARLEM,  
THE NETHERLANDS  
CONSULTING CHEMICAL LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, UNIVERSITY, POTCHEFSTROOM  
PHARMACHEMIE, MIDRAND, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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MRF 15 (MBR 15)

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Registration number: 37/18.1/0291

**Name of medicine:** DIFROSID

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
FUROSEMIDE 40,0 mg

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

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, **NEW** ZEALAND

Packer: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, NEW ZEALAND

Laboratory: DOUGLAS PHARMACEUTICALS LTD, LINCOLN,  
AUCKLAND, **NEW** ZEALAND  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, **RSA**  
PHARMAPLAN, MIDRAND, **RSA**

Shelf-life: 48 months

Date of registration: 23 SEPTEMBER 2005

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## MRF 15 (MBR 15)

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Registration number:	37/21.2/0407
Name of medicine:	DIABETMIN 850
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: METFORMIN HYDROCHLORIDE 850,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GULF DRUG COMPANY (PTY) LTD
Manufacturer:	HOVID SDN., PERAK, MALAYSIA
Packer:	HOVID SDN., PERAK, MALAYSIA
Laboratory:	HOVID SDN., PERAK, MALAYSIA WRAPSA, CENTURION, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA CONSULTING MICROBIOLOGICAL LAB, MOREWILL, BEYERSPARK, RSA GULF DRUG CO, MOUNT EDGEcombe, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

MRF 15 (MBR 15)

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Registration number: 37/21.10/0408

Name of medicine: GONAPEPTYL DEPOT POWDER FOR INJECTION

Dosage form: INJECTION

Active ingredients: EACH **VIAL** CONTAINS:  
TRIPTORELIN 3,75 mg

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

Applicant: FERRING PHARMACEUTICALS (PTY) LTD

Manufacturer: FERRING GmbH, WITTLAND, KIEL, GERMANY

Packer: FERRING GmbH, WITTLAND, KIEL, GERMANY

Laboratory: FERRING GmbH, WITTLAND, KIEL, GERMANY  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
FERRING PHARMACEUTICALS, KEMPTON PARK,  
RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 37/34/0409

Name of medicine: GONAPEPTYL DEPOT INJECTION VEHICLE

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SUSPENSION CONTAINS:  
DEXTRAN 104,0 mg  
WATER FOR INJECTION to 1,0 ml

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

Applicant: FERRING PHARMACEUTICALS (PTY) LTD

Manufacturer: FERRING GmbH, WITTLAND, KIEL, GERMANY

Packer: FERRING GmbH, WITTLAND, KIEL, GERMANY

Laboratory: FERRING GmbH, WITTLAND, KIEL, GERMANY  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
FERRING PHARMACEUTICALS, KEMPTON PARK,  
RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 37/18.1/0432

**Name of medicine:** AUSTELL-FUROSEMIDE 20 MG

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
FUROSEMIDE 20,0 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  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
INSPECTORATE M&L, ORMONDE,  
JOHANNESBURG, RSA  
AUSTELL LABORATORIES, ROSEBANK, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 37/18.1/0433

**Name of medicine:** AUSTELL-FUROSEMIDE 40 MG

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
FUROSEMIDE 40,0 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  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
INSPECTORATE M&L, ORMONDE,  
JOHANNESBURG, RSA  
AUSTELL LABORATORIES, ROSEBANK, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **37/1 6.410435**

Name of medicine: **L.C.C. THROAT LOZENGES - MENTHOL**

Dosage form: **LOZENGE**

Active ingredients: **EACH LOZENGE CONTAINS:  
CETYLPYRIDINIUM CHLORIDE **1,47 mg**  
BENZYL ALCOHOL **6,5 mg****

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

Applicant: **ADCOCK **INGRAM** LIMITED**

Manufacturer: **ADCOCK INGRAM HEALTHCARE, CLAYVILLE,  
OLIFANTSFONTEIN, **RSA****

Packer: **ADCOCK INGRAM HEALTHCARE, CLAYVILLE,  
OLIFANTSFONTEIN, RSA**

Laboratory: **ADCOCK **INGRAM** HEALTHCARE, CLAYVILLE,  
OLIFANTSFONTEIN, RSA  
ADCOCK INGRAM LTD, BRYANSTON, RSA**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number:	<b>37/25.2/0501</b>
Name of medicine:	OLICLINOMELN4-550 E
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) <b>5,5 % AMINO ACIDS SOLUTION</b> compartment with electrolytes. b) <b>20 % GLUCOSE SOLUTION</b> compartment with electrolyte calcium. c) <b>10 % LIPID EMULSION</b> compartment  SEE ADDENDUM
Conditions of registration:	<b>1, 2, 3, 4, 5, 6, 7</b>
Applicant:	ADCOCK <b>INGRAM</b> CRITICAL CARE (PTY) LTD
Manufacturer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM
Packer:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, <b>RSA</b>
Laboratory:	CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL <b>CARE</b> , AEROTON, JOHANNESBURG, <b>RSA</b>
Shelf-life:	<b>24 months</b>
Date of registration:	<b>23 SEPTEMBER 2005</b>

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**ADDENDUM**

- a) **5,5 % AMINO ACIDS SOLUTION** compartment with electrolytes, containing per 1,0 litre:

L-alanine	11,39 g
L-arginine	6,33 g
Glycine	5,67 g
L-histidine	2,64 g
Gisoleucine	3,30 g
L-leucine	4,02 g
L-lysine	3,19 g
L-methionine	2,20 g
L-phenylalanine	3,08 g
L-proline	3,74 g
Eserine	2,75 g
<b>L-threonine</b>	2,31 g
<b>L-tryptophan</b>	0,99 g
L-tyrosine	0,22 g
L-valine	3,19 g
Sodium acetate	2,45 g
<b>Sodium</b> glycerophosphate	5,36 g
Potassium chloride	2,98 g
Magnesium chloride	1,12 g

- b) **20 % GLUCOSE SOLUTION** compartment with electrolyte calcium containing per 1,0 litre:

<del>Glucose</del> monohydrate equivalent to	
Glucose	200,00 g
Calcium chloride	0,74 g

- c) **10% LIPID EMULSION** compartment containing per 1,0 litre:

Refined soya-bean oil +	
Refined olive oil	100,00 g

MRF 15 (MBR 15)

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Registration number: 37/25.2/0502

Name of medicine: OLICLINOMEL N5-800 E

Dosage form: INFUSION

Active ingredients: EACH BAG **CONTAINS:**  
a) 7 % **AMINO** ACIDS SOLUTION compartment with electrolytes.  
b) 25 % **GLUCOSE** SOLUTION compartment with electrolyte cdcium.  
c) 20 % **LIPID** EMULSION compartment  
  
SEE ADDENDUM

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

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: CLINTEC PARENTERAL S.A., CEDEX, FRANCE  
BAXTER S.A., LESSINES, BELGIUM

Packer: CLINTEC PARENTERAL S.A., CEDEX, **FRANCE**  
BAXTER S.A., LESSINES, BELGIUM  
ADCOCK INGRAM CRITICAL CARE, AEROTON,  
JOHANNESBURG, RSA

Laboratory: CLINTEC PARENTERAL S.A., CEDEX, **FRANCE**  
BAXTER **S.A.**, LESSINES, BELGIUM  
ADCOCK INGRAM CRITICAL CARE, **AEROTON**,  
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**ADDENDUM**

- a) **7% AMINO ACIDS SOLUTION** compartment with electrolytes, containing per 1,0 litre:

L-alanine	14,49 g
L-arginine	8,05 g
Glycine	7,21 g
L-histidine	3,36 g
L-isoleucine	4,20 g
L-leucine	5,11 g
L-lysine	4,06 g
L-methionine	2,80 g
L-phenylalanine	3,92 g
L-proline	4,76 g
L-serine	3,50 g
L-threonine	2,94 g
L-tryptophan	1,26 g
L-tyrosine	0,28 g
L-valine	4,06 g
<b>Sodium</b> acetate	6,12 g
<b>Sodium</b> glycerophosphate	5,36 g
<b>Potassium</b> chloride	4,47 g
Magnesium chloride	1,12 g

- b) **25% GLUCOSE SOLUTION** compartment with electrolyte calcium containing per 1,0 litre:

Glucose monohydrate equivalent to	
Glucose	250,00 g
Calcium chloride	0,74 g

- c) **20% LIPID EMULSION** compartment Containing per **1,0** litre:

Refined soya-bean oil +	
Refined olive oil	200,00 g

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**MRF 15 (MBR 15)**

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<b>Registration number:</b>	<b>37/25.2/0503</b>
<b>Name of medicine:</b>	<b>OLICLINOMEL N6-900 E</b>
<b>Dosage form:</b>	<b>INFUSION</b>
<b>Active ingredients:</b>	<b>EACH BAG CONTAINS :</b> a) <b>8,5 % AMINO ACIDS SOLUTION</b> compartment with electrolytes. b) <b>30 % GLUCOSE SOLUTION</b> compartment with electrolyte calcium. c) <b>20 % LIPID EMULSION</b> compartment  <b>SEE ADDENDUM</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>ADCOCK INGRAM CRITICAL CARE (PTY) LTD</b>
<b>Manufacturer:</b>	<b>CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM</b>
<b>Packer:</b>	<b>CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA</b>
<b>Laboratory:</b>	<b>CLINTEC PARENTERAL, S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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**ADDENDUM**

- a) 8,5 % **AMINO** ACIDS SOLUTION compartment with electrolytes, containing per **1,0** litre:

L-alanine	17,60 g
L-arginine	9,78 g
Glycine	8,76 g
L-histidine	4,08 g
L-isoleucine	5,10 g
L-leucine	6,21 g
L-lysine	4,93 g
L-methionine	3,40 g
L-phenylalanine	4,76 g
L-proline	5,78 g
L-serine	4,25 g
L-threonine	3,57 g
L-tryptophan	1,53 g
L-tyrosine	0,34 g
L-valine	4,93 g
Sodium acetate	6,12 g
Sodium glycerophosphate	5,36 g
Potassium chloride	4,47 g
Magnesium chloride	1,12 g

- b) **30 %** GLUCOSE SOLUTION compartment with electrolyte calcium containing per **1,0** litre:

Glucose monohydrate equivalent to	
Glucose	300,00 g
Calcium chloride	0,74 g

- c) **20 %** **LIPID** EMULSION compartment containing per 1,0 litre:

Refined soya-bean oil +	
Refined olive oil	200,00 g

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**MRF 15 ( MBR15)**

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Registration number:	<b>37/25.2/0504</b>
Name of medicine:	<b>OLICLINOMELN7-1000 E</b>
Dosage <i>form</i> :	<b>INFUSION</b>
Active ingredients:	<b>EACH BAG CONTAINS:</b> a) 10% <b>AMINO</b> ACIDS SOLUTION compartment with electrolytes. b) <b>40 %</b> GLUCOSE SOLUTION compartment with electrolyte calcium. c) <b>20 %</b> LIPID EMULSION compartment  <b>SEE ADDENDUM</b>
Conditions of registration:	<b>1, 2, 3, 4, 5, 6, 7</b>
Applicant:	<b>ADCOCK INGRAM CRITICAL CARE (PTY) LTD</b>
Manufacturer:	<b>CLINTEC PARENTEW S.A., CEDEX, FRANCE BAXTER <b>S.A.</b>, LESSINES, BELGIUM</b>
<b>Packer:</b>	<b>CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA</b>
Laboratory:	<b>CLINTEC PARENTERAL S.A., CEDEX, FRANCE BAXTER S.A., LESSINES, BELGIUM ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA</b>
Shelf-life:	<b>24 months</b>
Date of registration:	<b>23 SEPTEMBER 2005</b>

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**ADDENDUM**

- a) **10 % AMINO ACIDS SOLUTION** compartment with electrolytes, containing per 1,0 litre:

L-alanine	20,70 g
L-arginine	11,50 g
Glycine	10,30 g
L-histidine	4,80 g
L-isoleucine	6,00 g
L-leucine	7,30 g
L-lysine	5,80 g
L-methionine	4,00 g
L-phenylalanine	5,60 g
L-proline	6,80 g
L-serine	5,00 g
L-threonine	4,20 g
L-tryptophan	1,80 g
L-tyrosine	0,40 g
L-valine	5,80 g
Sodium acetate	6,12 g
<b>Sodium</b> glycerophosphate	5,36 g
Potassium chloride	4,47 g
Magnesium chloride	1,12 g

- b) **40 % GLUCOSE SOLUTION** compartment with electrolyte calcium containing per 1,0 litre:

Glucose monohydrate equivalent to	
Glucose	400,00 g
Calcium chloride	0,74 g

- c) **20 % LIPID EMULSION** compartment containing per **1,0**litre:

Refined soya-bean oil +	
Refined olive oil	200,00 g

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**MRF 15 (MBR 15)**

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Registration number: 3712.910532

**Name of medicine:** DOLOTRAM CAPSULES

Dosage form: CAPSULES

Active ingredients: EACH *CAPSULE* CONTAINS:  
TRAMADOL HYDROCHLORIDE 50,0 mg

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

Applicant: MC PHARMA (PTY) LTD

Manufacturer: M.J. PHARMACEUTICALS LTD, HALOL, GUJARAT,  
INDIA

Packer: M.J. PHARMACEUTICALS LTD, HALOL, GUJARAT,  
INDIA

Laboratory: M.J. PHARMACEUTICALS LTD, HALOL, GUJARAT,  
INDIA  
MC PHARMA, CENTURION, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 ( MBR15)**

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Registration number: **37/5.8/0556**

Name of medicine: **COLCAPS CHILDREN'S SYRUP ORANGE FLAVOUR**

Dosage form: **SYRUP**

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:  
PARACETAMOL 120,0 mg  
CODEINE PHOSPHATE 5,0 mg  
PSEUDOEPHEDRINE HCL 20,0 mg

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

Applicant: **ADCOCK INGRAM LIMITED**

Manufacturer: **ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
GERMISTON, RSA  
PHARMA-Q, INDUSTRIA, RSA**

Packer: **ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
GERMISTON, RSA  
PHARMA-Q, INDUSTRIA, RSA**

Laboratory: **ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
GERMISTON, RSA  
PHARMA-Q, INDUSTRIA, RSA  
ADCOCK INGRAM LTD, BRYANSTON, RSA**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15** (MBR 15)

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Registration number: 37/20.2.2/0559

Name of medicine: ADCO-SPOROZOLE

Dosage form: CAPSULE

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

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

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: LICONSA S.A., AZUQUECA DE HENARES,  
GUADALAJARA, SPAIN

Packer: LICONSA S.A., AZUQUECA DE HENARES,  
GUADALAJARA, **SPAIN**

Laboratory: LICONSA S.A., AZUQUECA DE HENARES,  
GUADALAJARA, **SPAIN**  
ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
GERMISTON, RSA  
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,  
OLIFANTSFONTEIN, RSA  
ADCOCK INGRAM LTD, BRYANSTON, **RSA**

**Shelf-life:** **24 months**

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **37121.210570**

Name of medicine: **ARROW METFORMIN HCL 500 MG**

Dosage form: **TABLET**

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

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

Applicant: **ARROW PHARMA SOUTH AFRICA (PTY) LTD**

Manufacturer: **LABORATOIRE ELAIAPHARM, CEDEX, FRANCE**

Packer: **LABORATOIRE ELAIAPHARM, CEDEX, FRANCE  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG**

Laboratory: **LABORATOIRE ELAIAPHARM, CEDEX, FRANCE  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, UNIVERSITY, POTCHEFSTROOM  
SEDEK AGRKEM, KAMEEL DRIFT, PRETORIA  
ARROW PHARMA, WADEVILLE, RSA**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: **37/21.2/0571**

Name of medicine: **ARROW METFORMIN HCL 850 MG**

Dosage form: **TABLET**

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

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

Applicant: **ARROW PHARMA SOUTH AFRICA (PTY) LTD**

Manufacturer: **LABORATOIRE ELAIAPHARM, CEDEX, FRANCE**

Packer: **LABORATOIRE ELAIAPHARM, CEDEX, FRANCE  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG**

Laboratory: **LABORATOIRE ELAIAPHARM, CEDEX, FRANCE  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, UNIVERSITY, POTCHEFSTROOM  
SEDEK AGRIKEM, KAMEEL DRIFT, PRETORIA  
ARROW PHARMA, WADEVILLE, RSA**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15**

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**Registration number:** 37/20.1.1/0648

**Name of medicine:** SAFELINE – AMIKACIN SULPHATE 1 G

**Dosage form:** INJECTION

**Active ingredients:** EACH 4,0 ml SOLUTION CONTAINS:  
AMIKACIN SULPHATE 1000,0 mg

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

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

**Manufacturer:** LISAPHARMA S.p.A., VIA LICINIO, ERBA, ITALY

**Packer:** LISAPHARMA S.p.A., VIA LICINIO, ERBA, ITALY

**Laboratory:** LISAPHARMA S.p.A., VIA LICINIO, ERBA, ITALY  
ANALYTICON, KEMPTON PARK, RSA  
SAFELINE PHARMACEUTICALS, FLORIDA, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 37/21.5.1/0652

**Name of medicine:** BECLATE 100 HFA

**Dosage form:** INHALER

**Active ingredients:** EACH ACTUATION DELIVERS:  
BECLOMETHASONE DPROPIONATE 100,0 ug

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

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

**Manufacturer:** MEDISPRAY LABORATORIES, KUNDIAM, GOA,  
INDIA

**Packer:** MEDISPRAY LABORATORIES, KUNDIAM, GOA,  
INDIA

**Laboratory:** MEDISPRAY LABORATORIES, KUNDIAM, GOA,  
INDIA  
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 37/21.5.1/0653

**Name of medicine:** BECLATE 200 HFA

**Dosage form:** INHALER

**Active ingredients:** EACH ACTUATION DELIVERS:  
BECLOMETHASONE DPROPIONATE 200,0 ug

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

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

**Manufacturer:** MEDISPRAY LABORATORIES, KUNDIAM, GOA,  
INDIA

**Packer:** MEDISPRAY LABORATORIES, KUNDIAM, GOA,  
INDIA

**Laboratory:** MEDISPRAY LABORATORIES, KUNDIAM, GOA,  
INDIA  
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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<b>Registration number:</b>	<b>37/21.5.1/0654</b>
<b>Name of medicine:</b>	<b>BECLATE 250 HFA</b>
<b>Dosage form:</b>	<b>INHALER</b>
<b>Active ingredients:</b>	<b>EACH ACTUATION DELIVERS: BECLOMETHASONEDPROPIONATE 250,0 ug</b>
<b>Conditions of registration:</b>	<b>1,2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>CIPLA-MEDPRO(PTY) LTD</b>
<b>Manufacturer:</b>	<b>MEDISPRAY LABORATORIES, KUNDIAM, GOA, INDIA</b>
<b>Packer:</b>	<b>MEDISPRAY LABORATORIES, KUNDIAM, GOA, INDIA</b>
<b>Laboratory:</b>	<b>MEDISPRAY LABORATORIES, KUNDIAM, GOA, INDIA CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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**MRF 15 (MBR 15)**

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Registration number: **37/20.2.3/0667**Name of medicine: **MYRIN-P FORTE**Dosage form: **TABLET**

Active ingredients: EACH TABLET CONTAINS:

PYRAZINAMIDE	400,0 mg
ETHAMBUTOL HYDROCHLORIDE	<b>275,0 mg</b>
RIFAMPICIN	150,0 mg
<b>ISONIAZID</b>	<b>75,0 mg</b>

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**Applicant: **WYETH SOUTH AFRICA (PTY) LTD**Manufacturer: **WYETH PAKISTAN, KARACHI, PAKISTAN**Packer: **WYETH PAKISTAN, KARACHI, PAKISTAN  
TECHNIKON LABORATORIES, FLORIDA, RSA**Laboratory: **WYETH PAKISTAN, KARACHI, PAKISTAN  
CONSULTING CHEMICAL LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
PHARMA-Q, INDUSTRIA, JOHANNESBURG  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
WYETH, VORNA VALLEY, MIDRAND, RSA**Shelf-life: **24 months**Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: 38/20.1.2/0003

Name of medicine: APEX-CLAWTIN 625 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO  
AMOXYCILLIN 500,0 mg  
POTASSIUM CLAVULANATE EQUIVALENT TO  
CLAVULANIC ACID 125,0 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: 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  
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

Shelf-life: **24** months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 38/5.10/0045

**Name of medicine:** AUSTELL – ONDANSETRON 4 MG TABLETS

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
ONDANSETRON HYDROCHLORIDE DIHYDRATE  
EQUVALENT TO ONDANSETRON 4,0 mg

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

**Applicant:** AUSTELL LABORATORIES (PTY) LTD

**Manufacturer:** IPCA LABORATORIES LMITES, DADRA AND  
NAGAR HAVELI, INDIA

**Packer:** IPCA LABORATORIES LIMITES, DADRA AND  
NAGAR HAVELI, INDIA

**Laboratory:** IPCA LABORATORIES LIMITES, DADRA AND  
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:** 23 SEPTEMBER 2005

**MRF 15 (MBR 15)**

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<b>Registration number</b>	<b>38/5.10/0046</b>
<b>Name of medicine:</b>	<b>AUSTELL – ONDANSETRON 8 MG TABLETS</b>
<b>Dosage form:</b>	<b>TABLET</b>
<b>Active ingredients:</b>	<b>EACH TABLET CONTAINS : ONDANSETRON HYDROCHLORIDE DIHYDRATE EQVALENT TO ONDANSETRON 8,0 mg</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>AUSTELL LABORATORIES (PTY) LTD</b>
<b>Manufacturer:</b>	<b>IPCA LABORATORIES LIMITES, DADRA AND NAGAR HAVELI, INDIA</b>
<b>Packer:</b>	<b>IPCA LABORATORIES LIMITES, DADRA AND NAGAR HAVELI, INDIA</b>
<b>Laboratory:</b>	<b>IPCA LABORATORIES LIMITES, DADRA AND NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&amp;L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>



**MRF 15 (MBR 15)**

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Registration number: 38/1.2/0068

Name of medicine: SERRAPRESS 30

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
PAROXETINE HYDROCHLORIDE EQVALENT TO  
PAROXETINE 30,0 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

**Manufacturer:** DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG, RSA  
TECHNIKON LABORATORIES, FLORIDA, RSA  
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

Laboratory: DELTA LTD, HAFNARFJORDUR, ICELAND  
CONSULTING CHEMICAL LABORATORIES,  
**STAR STREET, BOKSBURG, RSA**  
**PHARMA DYNAMICS, WESTLAKE, RSA**

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number:	<b>38/12/0069</b>
Name of medicine:	<b>SERRAPRESS 20</b>
Dosage form:	<b>TABLET</b>
Active ingredients:	<b>EACH TABLET CONTAINS: PAROXETINE HYDROCHLORIDE EQUIVALENT TO PAROXETINE 20,0 mg</b>
Conditions of registration:	<b>1, 2, 3, 4, 5, 6, 7</b>
Applicant:	<b>PHARMA DYNAMICS (PTY) LTD</b>
Manufacturer:	<b>DELTA LTD, HAFNARFJORDUR, ICELAND</b>
Packer:	<b>DELTA LTD, HAFNARFJORDUR, ICELAND DIVPHARM MANUFACTURING &amp; PACKAGING, LONGDALE, JOHANNESBURG, RSA TECHNIKON LABORATORIES, FLORIDA, RSA PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN</b>
Laboratory:	<b>DELTA LTD, HAFNARFJORDUR, ICELAND CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA PHARMA DYNAMICS, WESTLAKE, RSA</b>
Shelf-life:	<b>36 months</b>
Date of registration:	<b>23 SEPTEMBER 2005</b>

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MRF 15 (MBR 15)

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**Registration number:** 38/1.2/0072

**Name of medicine:** PHARMA DYNAMICS PAROXETINE 20

**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:** PHARMA DYNAMICS (PTY) LTD

**Manufacturer:** DELTA LTD, HAFNARFJORDUR, ICELAND

**Packer:** DELTA LTD, HAFNARFJORDUR, ICELAND  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG, RSA  
TECHNIKON LABORATORIES, FLORIDA, RSA  
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

**Laboratory:** DELTA LTD, HAFNARFJORDUR, ICELAND  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
PHARMA DYNAMICS, WESTLAKE, RSA

**Shelf-life:** 36 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 38/1.2/0074

Name of medicine: PHARMA DYNAMICS PAROXETINE 30

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
PAROXETINE HYDROCHLORIDE EQUIVALENT TO  
PAROXETINE 30,0 mg

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

Applicant: PHARMA DYNAMICS (PTY) LTD

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG, RSA  
TECHNIKON LABORATORIES, FLORIDA, RSA  
PHARMACEUTICAL ENTERPRISES, N'DABENI, KZN

Laboratory: DELTA LTD, HAFNARFJORDUR, ICELAND  
CONSTJLTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 38/21.1/0084

Name of medicine: LEVEMIR

Dosage form: INJECTION

Active ingredients: EACH €0 ml SOLUTION CONTAINS:  
**INSULIN DETEMIR** 100,0 units

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

Applicant: NOVO NORDISK (PTY) LTD

Manufacturer: NOVO NORDISK, BAGSVAERD, DENMARK

Packer: NOVO NORDISK, BAGSVAERD, DENMARK  
NOVO NORDISK, KALUNDBORG, DENMARK  
NOVO NORDISK, HILLEROD, DENMARK

Laboratory: NOVO NORDISK, BAGSVAERD, DENMARK  
NOVO NORDISK, GENTOFTE, DENMARK  
NOVO **NORDISK**, SOEBORG, DENMARK  
NOVO NORDISK, FREDERIKSBERG, DENMARK  
NOVO NORDISK, SANDTON, RSA

**Shelf-life:** 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number:	<b>38/5.7.1/0087</b>
Name of medicine:	<b>CLARINESE SYRUP</b>
Dosage form:	<b>SYRUP</b>
Active ingredients:	<b>EACH 5,0 ml SYRUP CONTAINS: LORATADINE            5,0 mg</b>
Conditions of registration:	<b>1, 2, 3, 4, 5, 6, 7</b>
Applicant:	<b>PHARMACARE LIMITED</b>
Manufacturer:	<b>PHARMACARE LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA, EAST LONDON</b>
Packer:	<b>PHARMACARE LTD, KORSTEN, PORT <b>ELIZABETH</b> SAD SELF MEDICATION, WILSONIA, EAST LONDON</b>
Laboratory:	<b>PHARMACARE LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA, EAST LONDON SOUTH AFRICAN <b>BUREAU</b> OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM</b>
Shelf-life:	<b>24 months</b>
Date of registration:	<b>23 SEPTEMBER 2005</b>

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**MRF 15 (MBR 15)**

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Registration number: 38/7.5/0123

**Name of medicine:** ASPEN PRAVASTATIN 10MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
PRAVASTATIN SODIUM 10,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM Inc, ONTARIO, CANADA  
PHARMACARE LTD, KORSTEN, PORT ELIZABETHPacker: GENPHARM Inc, ONTARIO, CANADA  
PHARMACARE LTD, KORSTEN, PORT ELIZABETHLaboratory: GENPHARM Inc, ONTARIO, CANADA  
PHARMACARE LTD, KORSTEN, PORT ELIZABETH  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
RESEARCH INSTITUTE FOR PHARMACEUTICAL  
SERVICES, UNIVERSITY, POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 38/20.1.1/0127

**Name of medicine:** CEFASYN-500

**Dosage form:** TABLET

**Active ingredients:** *EACH TABLET CONTAINS:*  
CEFUROXIME AXETIL EQUIVALENT TO  
CEFUROXIME 500,0 MG

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

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

**Manufacturer:** OKASA PHARMA PVT. LTD, SATARA, INDIA

**Packer:** OKASA PHARMA PVT. LTD, SATARA, INDIA

**Laboratory:** OKASA PHARMA PVT. LTD, SATARA, INDIA  
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

**Shelf-life:** 18 months

**Date of registration:** 8 APRIL 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 38/20.1.1/0133**Name of medicine:** CEFASYN-250**Dosage form:** TABLET**Active ingredients:** EACH TABLET CONTAINS :  
CEFUROXIME AXETIL EQUIVALENT TO  
CEFUROXIME 250,0 MG**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7**Applicant:** CPLA-MEDPRO (PTY) LTD**Manufacturer:** OKASA PHARMA PVT. LTD, SATARA, INDIA**Packer:** OKASA PHARMA PVT. LTD, SATARA, INDIA**Laboratory:** OKASA PHARMA PVT. LTD, SATARA, INDIA  
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA**Shelf-life:** 18 months**Date of registration:** 8 APRIL 2005

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MRF 15 (MBR 15)

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**Registration number:** 38/7.5/0139

**Name of medicine:** ASPEN PRAVASTATIN **20 MG**

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
PRAVASTATIN SODIUM 20,0 mg

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

**Applicant:** PHARMACARE LIMITED

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

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

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

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 38/7.5/0140**Name of medicine:** ASPEN PRAVASTATIN 40 MG**Dosage form:** TABLET**Active ingredients:** EACH TABLET CONTAINS:  
PRAVASTATIN SODIUM 40,0 mg**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7**Applicant:** PHARMACARE LIMITED**Manufacturer:** GENPHARM Inc, ONTARIO, CANADA  
PHARMACARE LTD, KORSTEN, PORT ELIZABETH**Packer:** GENPHARM Inc, ONTARIO, CANADA  
PHARMACARE LTD, KORSTEN, PORT ELIZABETH**Laboratory:** GENPHARM Inc, ONTARIO, CANADA  
PHARMACARE LTD, KORSTEN, PORT ELIZABETH  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
RESEARCH INSTITUTE FOR PHARMACEUTICAL  
SERVICES, UNIVERSITY, POTCHEFSTROOM**Shelf-life:** 34 months**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 38/30.1/0182

**Name of medicine:** MENOMUNE

**Dosage form:** INJECTION

**Active ingredients:** EACH 0,5 ml DOSE CONTAINS:  
NEISSERIA MENINGITIDES GROUP A 50,0 ug  
NEISSERIA MENINGITIDES GROUP C 50,0 ug  
NEISSERIA MENINGITIDES GROUP Y 50,0 ug  
NEISSERIA MENINGITIDES GROUP W-135 50,0 ug

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

**Applicant:** AVENTIS PHARMA (PTY) LTD

**Manufacturer:** AVENTIS PASTEUR, SWIFTWATER, PA, USA

**Packer:** AVENTIS PASTEUR, SWIFTWATER, PA, USA

**Laboratory:** AVENTIS PASTEUR, SWIFTWATER, PA, USA  
AVENTIS PHARMA, WALTLOO, PRETORIA, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: 38/21.5.1/0186

Name of medicine: BECLATE 50 HFA

Dosage form: INHALER

Active ingredients: EACH ACTUATION DELIVERS:  
BECLOMETHASONE DIPROPIONATE 50,0 ug

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

Applicant: CIPLA-MEDPRO (PTY) LTD

Manufacturer: MEDISPRAY LABORATORIES, **KUNDIAM**, GOA,  
INDIA

Packer: MEDISPRAY LABORATORIES, **KUNDIAM**, GOA,  
INDIA

Laboratory: MEDISPRAY LABORATORIES, **KUNDIAM**, GOA,  
INDIA  
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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MRF 15 (MBR 15)

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Registration number: 38/21.8.2/0248

Name of medicine: ADCO-FEM 35

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
CYPROTERONE ACETATE 2,0 mg  
ETHINYLOESTRADIOL 0,035 mg

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

Applicant: ADCOCK **INGRAM** LIMITED

Manufacturer: DOUGLAS MANUFACTURING LTD, LINCOLN,  
AUCKLAND, NEW ZEALAND

Packer: DOUGLAS MANUFACTURING LTD, LINCOLN,  
AUCKLAND, NEW ZEALAND  
ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
GERMISTON, RSA  
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,  
OLIFANTSFONTEIN, RSA

Laboratory: DOUGLAS MANUFACTURING LTD, LINCOLN,  
AUCKLAND, NEW ZEALAND  
ADCOCK **INGRAM** HEALTHCARE, WADEVILLE,  
GERMISTON, RSA  
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,  
OLIFANTSFONTEIN, RSA  
ADCOCK INGRAM LTD, BRYANSTON, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

**MRF 15 (MBR 15)**

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Registration number: 38/34/0263

Name of medicine: PEG-INTRON 80 MICROGRAM

Dosage form: INJECTION

Active ingredients: EACH **VIAL** CONTAINS:  
PEGINTERFERON ALFA-2b 80,0 mcg

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

Applicant: SCHERING-PLOUGH(PTY) LTD

**Manufacturer:** SCHERING-PLOUGH (BRINNY), COUNTY CORK,  
IRELAND  
VETTER PHARMA-FERTIGUNG GmbH,  
LANGENARGEN, GERMANY

Packer: SCHERING-PLOUGH (BRINNY), COUNTY CORK,  
IRELAND  
VETTER PHARMA-FERTIGUNG GmbH,  
LANGENARGEN, GERMANY  
SCHERING-PLOUGH LABO, HEIST-OP-DEN-BERG,  
BELGIUM  
SCHERING-PLOUGH LTD, EDMUNDS, SUFFOLK,  
U.K.  
SCHERING-PLOUGH, ISANDO, RSA

Laboratory: SCHERING-PLOUGH (BRINNY), COUNTY CORK,  
IRELAND  
VETTER PHARMA-FERTIGUNG GmbH,  
LANGENARGEN, GERMANY  
SCHERING-PLOUGH, ISANDO, RSA

Shelf-life: 18 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 38/20.I.2/0266

**Name of medicine:** APEX-CLAWTIN 375 MG TABLETS

**Dosage form:** TABLET

**Active ingredients:** **EACH TABLET CONTAINS:**  
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 250,0 mg  
POTASSIUM CLAWLANATE EQUIVALENT TO CLAVULANIC ACID 125,0 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:** MEDREICH STERILAB LTD, VIRWNAGAR, BANGALORE, INDIA  
SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA  
INSPECTORATE M&L, ORMONDE, JOHANNESBURG  
CAMOX PHARMACEUTICALS, SAXONWOLD, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** 38/7.1/0271

**Name of medicine:** ISTIN 5 MG

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS :  
AMLODIPINE BESYLATE EQUIVALENT TO  
AMLODIPINE 5,0 mg

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

**Applicant:** PFIZER LABORATORIES (PTY) LTD

**Manufacturer:** PFIZER LABORATORIES, PIETERMARITZBURG,  
RSA  
WARNER-LAMBERT, RETREAT, RSA

**Packer:** PFIZER LABORATORIES, PIETERMARITZBURG,  
RSA  
WARNER-LAMBERT, RETREAT, RSA

**Laboratory:** PFIZER LABORATORIES, PIETERMARITZBURG,  
RSA  
WARNER-LAMBERT, RETREAT, RSA

**Shelf-life:** 48 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 ( MBR 15)**

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Registration number: 38/7.1/0272

Name of medicine: **ISTIN 10MG**

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
AMLODIPINE BESYLATE EQUIVALENT TO  
AMLODIPINE 10,0 **mg**

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

Applicant: PFIZER LABORATORIES (PTY) LTD

Manufacturer: PFIZER LABORATORIES, PIETERMARITZBURG,  
**RSA**  
WARNER-LAMBERT, RETREAT, RSA

Packer: PFIZER LABORATORIES, PIETERMARITZBURG,  
**RSA**  
WARNER-LAMBERT, RETREAT, RSA

Laboratory: PFIZER LABORATORIES, PIETERMARITZBURG,  
**RSA**  
WARNER-LAMBERT, RETREAT, **RSA**

Shelf-life: **48** months

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: **38/34/0329**

Name of medicine: **PEG-INTRON 120 MICROGRAM**

Dosage form: **INJECTION**

Active ingredients: **EACH VIAL, CONTAINS:  
PEGINTERFERON ALFA-2b      120,0 mcg**

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

Applicant: **SCHERING-PLOUGH (PTY) LTD**

Manufacturer: **SCHERING-PLOUGH (BRINNY), COUNTY CORK,  
IRELAND  
VETTER PHARMA-FERTIGUNG GmbH,  
LANGENARGEN, GERMANY**

Packer: **SCHERING-PLOUGH (BRINNY), COUNTY CORK,  
IRELAND  
VETTER PHARMA-FERTIGUNG GmbH,  
LANGENARGEN, GERMANY  
SCHERING-PLOUGH LABO, HEIST-OP-DEN-BERG,  
BELGIUM  
SCHERING-PLOUGH LTD, EDMUNDS, SUFFOLK,  
U.K.  
SCHERING-PLOUGH, ISANDO, RSA**

Laboratory: **SCHERING-PLOUGH (BRINNY), COUNTY CORK,  
IRELAND  
VETTER PHARMA-FERTIGUNG GmbH,  
LANGENARGEN, GERMANY  
SCHERING-PLOUGH, ISANDO, RSA**

Shelf-life: **18 months**

Date of registration: **23 SEPTEMBER 2005**

**MRF 15 (MBR 15)**

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**Registration number:** A38/1.2/0403**Name of medicine:** PROLAX TABLETS**Dosage form:** TABLET**Active ingredients:** EACH TABLET CONTAINS:  
FLUOXETINE HYDROCHLORIDE EQUIVALENT TO  
FLUOXETINE 20,0 mg**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7**Applicant:** GENERIX INTERNATIONAL S.A. (PTY) LTD**Manufacturer:** SIEGFRIED LTD, ZOFINGEN, SWITZERLAND**Packer:** SIEGFRIED LTD, ZOFINGEN, SWITZERLAND**Laboratory:** SIEGFRIED LTD, ZOFINGEN, SWITZERLAND  
CONSULTING CHEMICAL, LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
GENERIX INTERNATIONAL, INDUSTRIA,  
CAPE TOWN, RSA**Shelf-life:** 36 months**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/1.2/04 13

Name of medicine: PROLAX CAPSULES

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:  
FLUOXETINE HYDROCHLORIDE EQUIVALENT TO  
FLUOXETINE 20,0 mg

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

Applicant: GENERIX INTERNATIONAL S.A. (PTY) LTD

Manufacturer: SIEGFRIED LTD, ZOFINGEN, SWITZERLAND

Packer: SIEGFRIED LTD, ZOFINGEN, SWITZERLAND

Laboratory: SIEGFRIED LTD, ZOFINGEN, SWITZERLAND  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
GENERIX INTERNATIONAL, INDUSTRIA,  
**CAPE TOWN, RSA**

Shelf-life: 36 months

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number:	A38/8.2/0422
Name of medicine:	CIPLA-WARFARIN 5 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: WARFARIN SODIUM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CIPLA-MEDPRO (PTY) LTD
Manufacturer:	CIPLA LTD, PATALGANGA, <b>MAHARASHTRA, INDIA</b>
Packer:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA CIPLA-MEDPRO, ROSENPARK, BELLVILLE, <b>RSA</b>
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/20.1.1/0448

Name of medicine: APEX CIPROFLOXACIN 250 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT  
TO CIPROFLOXACIN 250,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

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

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

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

Shelf-life: **24** months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration **number**: A38/20.1.1/0449

Name of medicine: **APEX** CIPROFLOXACIN 500 MG TABLETS

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: CAMOX PHARMACEUTICALS (PTY) LTD

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

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

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

Shelf-life: 24 months

Date of registration: **23 SEPTEMBER 2005**

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MRF 15(MBR 15)

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Registration number: A38/20.1.1/0450

Name of medicine: APEX CIPROFLOXACIN 750 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT  
TO CIPROFLOXACIN 750,0 mg

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

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: INTAS PHARMACEUTICALS, MATODA, GUJARAT,  
INDIA

Packer: INTAS PHARMACEUTICALS, MATODA, GUJARAT,  
INDIA

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

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number:	A38/20.1.1/0467
Name of medicine:	RESMED CEFUROXIME 750 INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL CONTAINS: CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg
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:	ASTRAL PHARMACEUTICAL INDUSTRIES, GUJARAT, INDIA RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA
Shelf-life:	36 months
Date of registration:	23 SEPTEMBER 2005

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**MRF 15(MBR 15)**

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Registration number: A38/13.4.1/0473

**Name** of medicine: LOCATOP

Dosage form: CREAM

Active ingredients: EACH 100,0 g **CREAM** CONTAINS:  
DESONIDE 100,0 mg

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

Applicant: PHARMACO DISTRIBUTION (PTY) LTD

Manufacturer: PIERRE **FABRE** MEDICAMENT PRODUCTION  
PROGIPHARM, **GIEN**, FRANCE

**Packer:** PIERRE FABRE **MEDICAMENT** PRODUCTION  
PROGIPHARM, GIEN, FRANCE  
PHARMA-Q, **INDUSTRIA** WEST, **RSA**  
ROCHE PRODUCTS, **ISANDO**, **RSA**

Laboratory: PIERRE FABRE MEDICAMENT PRODUCTION  
PROGIPHARM, **GIEN**, FRANCE  
PHARMA-Q, **INDUSTRIA** WEST, **RSA**  
ROCHE PRODUCTS, **ISANDO**, **RSA**  
PHARMACO **DISTRIBUTION**, SANDTON, **RSA**

Shelf-life: **24** months

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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**Registration number:** A38/1.2/0474

**Name of medicine:** APEX – PAROXETINE 20 MG 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:** CAMOX PHARMACEUTICALS (PTY) LTD

**Manufacturer:** FARMACEUTISCH ANALYTISCH LABORATORIUM  
B.V., DUIVEN, THE NETHERLANDS

**Packer:** FARMACEUTISCH ANALYTISCH LABORATORIUM  
B.V., DUIVEN, THE NETHERLANDS

**Laboratory:** FARMACEUTISCH ANALYTISCH LABORATORIUM  
B.V., DWEN, THE NETHERLANDS  
SOUTH AFRICAN BUREAU OF STANDARDS ,  
GROENKLOOF, PRETORIA, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
INSPECTORATE M&L, ORMONDE ,  
JOHANNESBURG, RSA  
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15**

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Registration number: A38/7.3/0480

Name of medicine: *MITREX 50*

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**  
SUMATRIPTAN SUCCINATE EQUIVALENT TO  
SUMATREPTAN 50,0 mg

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

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXO OPERATIONS U.K., WARE,  
HERTFORDSHIRE, **U.K.**

Packer: GLAXO OPERATIONS U.K., WARE,  
**HERTFORDSHIRE, U.K.**  
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Laboratory: GLAXO OPERATIONS U.K., WARE,  
HERTFORDSHIRE, U.K.  
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15**

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Registration number: A38/7.3/0481

Name of medicine: **IMITREX 100**

**Dosage form:** TABLET

Active ingredients: EACH TABLET CONTAINS:  
SUMATRIPTAN SUCCINATE EQUIVALENT TO  
SUMATRIPTAN 100,0 mg

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

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXO OPERATIONS U.K., WARE,  
HERTFORDSHIRE, U.K.

Packer: GLAXO OPERATIONS U.K., WARE,  
HERTFORDSHIRE, U.K.  
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Laboratory: GLAXO OPERATIONS U.K., WARE,  
HERTFORDSHIRE, U.K.  
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/5.2/050 1

Name of medicine: TENOPRESS 25 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
ATENOLOL 25,0 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, **RSA**  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, **RSA**  
AUSTELL LABORATORIES, ROSEBANK, **RSA**

Shelf-life: **24** months

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: A38/5.2/0502

**Name** of medicine: TENOPRESS 50 MG TABLETS

Dosage form: TABLET

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

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

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATOIRES 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, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES  
BARDENE, BOKSBURG, RSA  
AUSTELL LABORATORIES, ROSEBANK, RSA

Shelf-life: **24 months**

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/5.2/0503

Name of medicine: TENOPRESS 100MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
ATENOLOL 100,0 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, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
AUSTELL LABORATORIES, ROSEBANK, **RSA**

Shelf-life: **24** months

Date of registration: **23** SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **A38/21.2/0504**

Name of medicine: **AUSTELL-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: **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, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, **RSA**  
AUSTELL LABORATORIES, ROSEBANK, **RSA****

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: **A38/21.2/0505**

Name of medicine: **AUSTELL-METFORMIN 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: **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, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
AUSTELL LABORATORIES, ROSEBANK, **RSA****

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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**Registration number:** A3812610532

**Name of medicine:** KEMOCARB 150

**Dosage form:** INJECTION

**Active ingredients:** EACH VIAL CONTAINS:  
CARBOPLATIN 150,0 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  
CIPLA-MEDPRO, ROSENPARK, BELLVILLE, RSA

**Shelf-life:** 18 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/26/0533

Name of medicine: KEMOCARB 450

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:  
CARBOPLATIN 450,0 mg

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

Applicant: CPLA-MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

Packer: CIPLA LTD, KURKUMBH, MAHARASHTRA, INDIA

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

Shelf-life: 18 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/2.7/0561

Name of medicine: PERFALGAN 1 G

Dosage *form*: SOLUTION

Active ingredients: EACH 100,0 ml VIAL CONTAINS:  
PARACETAMOL 1,0 g

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

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: LABORATORIES RENAUDIN, ITXASSOU, FRANCE  
BRISTOL-MYERS SQUIBB, ANAGNI, ITALY

Packer: LABORATORIES RENAUDIN, ITXASSOU, FRANCE  
BRISTOL-MYERS SQUIBB, ANAGNI, ITALY  
MERCK PHARMACEUTICAL MANUFACTURING,  
WADEVILLE, GERMISTON, RSA

Laboratory: BRISTOL-MYERS SQUIBB, ANAGNI, ITALY  
BRISTOL-MYERS SQUIBB, AGEN, FRANCE  
MERCK PHARMACEUTICAL MANUFACTURING,  
WADEVILLE, GERMISTON, RSA  
CONSULTING CHEMICAL LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: 24 ~~months~~

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **A38/2 1.8.210563**

Name of medicine: **ESTALIS 25/125**

Dosage form: **TRANSDERMAL PATCH**

Active ingredients: **EACH PATCH CONTAINS:  
ESTRADIOL HEMIHYDRATE EQUIVALENT TO  
ESTRADIOL 0,256 mg  
NORETHISTERONE ACETATE 2,40 mg**

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

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

Manufacturer: **NOVEN PHARMACEUTICALS, MIAMI, FLORIDA,  
USA**

Packer: **NOVEN PHARMACEUTICALS, MIAMI, FLORIDA,  
USA  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA**

Laboratory: **NOVEN PHARMACEUTICALS, MIAMI, FLORIDA,  
USA  
NOVARTIS PHARMA SAS, HUNINGUE, FRANCE  
NOVARTIS PHARMA, **STEIN, SWITZERLAND**  
NORTHVIEW LABORATORIES, NORTHBROOK,  
**ILLINOIS, USA**  
**INSPECTORATE M&L, ORMONDE, JOHANNESBURG**  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA**

Shelf-life: **21 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number:	A38/20.1.1/0580
Name of medicine:	RES-CEFOTAX 500 INJECTION
Dosage form:	INJECTION
Active ingredients:	EACH VIAL <b>CONTAINS:</b> CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 500,0 mg.
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	RESMED HEALTHCARE
Manufacturer:	ASTRAL PHARMACEUTICAL INDUSTRIES, VADODARA, GUJARAT, INDIA
Packer:	ASTRAL PHARMACEUTICAL INDUSTRIES, VADODARA, <b>GUJARAT</b> , INDIA
Laboratory:	ASTRAL PHARMACEUTICAL INDUSTRIES, VADODARA, <b>GUJARAT</b> , INDIA RESMED HEALTHCARE, SPRINGFIELDPARK, DURBAN, <b>RSA</b>
Shelf-life:	36 months
Date of registration:	23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/20.1.1/0581

Name of medicine: RES-CEFOTAX 1000 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:  
CEFOTAXIME SODIUM EQUIVALENT TO  
CEFOTAXIME 1000,0 mg

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

Applicant: RESMED HEALTHCARE

Manufacturer: ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

Packer: ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA .

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

Shelf-life: **36 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: A38/20.1.1/0582

Name of medicine: REZONE 250 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:  
CEFTRIAXONE SODIUM EQUIVALENT TO  
CEFTRIAXONE 250,0 mg

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

Applicant: RESMED HEALTHCARE

Manufacturer: ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

Packer: ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

Laboratory: ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA  
RESMED HEALTHCARE, SPRINGFIELD, DURBAN,  
RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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MRF 15(MBR 15)

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Registration number: A38/20.1.1/0583

Name of medicine: **REZONE 500 INJECTION**

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:  
CEFTRIAXONE SODIUM **EQUIVALENT TO**  
CEFTRIAXONE 500,0 mg

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

Applicant: RESMED HEALTHCARE

Manufacturer: **ASTRAL PHARMACEUTICAL INDUSTRIES,**  
VADODARA, GUJARAT, INDIA

Packer: **ASTRAL PHARMACEUTICAL INDUSTRIES,**  
VADODARA, GUJARAT, **INDIA**

Laboratory: **ASTRAL PHARMACEUTICAL INDUSTRIES,**  
**VADODARA, GUJARAT, INDIA**  
RESMED HEALTHCARE, **SPRINGFIELD, DURBAN,**  
RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/21.2/0590

Name of medicine: **DIAFORMIN 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: 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  
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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MRF 15(MBR 15)

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Registration number: A38/21.2/0591

Name of medicine: DIAFORMIN FORTE 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, VRGONAGAR,  
BANGALORE, INDIA

Laboratory: 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**  
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

Shelf-life: 24 months

Date of registration: **23** SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/26/0593

Name of medicine: ENDOXAN 50 MG TABLETS

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**  
CYCLOPHOSPHAMIDE MONOHYDRATE  
EQVALENT TO CYCLOPHOSPHAMIDE 50,0 mg

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

Applicant: AVENTIS PHARMA (PTY) LTD

Manufacturer: ALMIRALL PRODESFARMA, BARCELONA, SPAIN

Packer: ALMIRALL PRODESFARMA, BARCELONA, SPAIN  
**AVENTIS PHARMA, WALTLOO, PRETORIA, RSA**

Laboratory: ALMIRALL PRODESFARMA, BARCELONA, SPAIN  
AVENTIS PHARMA, WALTLOO, PRETORIA, RSA  
BAXTER ONCOLOGY GmbH, HALLE, GERMANY  
**AVENTIS PHARMA, MIDRAND, RSA**

Shelf-life: **36 months**

Date of registration: **23 SEPTEMBER 2005**

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MRF 15 (MBR 15)

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Registration number: A38/20.1.1/0606

Name of medicine: CEFOTAXIME-COMBINOPHARM 1 G

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:  
CEFOTAXIME SODIUM *EQUIVALENT* TO  
CEFOTAXIME 1,0 g

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

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: **REIG JOFRE S.A., BESOS, SPAIN**

Packer: **REIG JOFRE S.A., BESOS, SPAIN**

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

Shelf-Kfe: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: **A38/20.1.1/0607**

Name of medicine: **CEFOTAXIME-COMBINOPHARM 500 MG**

Dosage form: **INJECTION**

Active ingredients: **EACH VIAL CONTAINS:  
CEFOTAXIME SODIUM EQUIVALENT TO  
CEFOTAXIME 500,0 mg**

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

Applicant: **PHARMAPLAN (PTY) LTD**

Manufacturer: **REIG JOFRE S.A., BESOS, SPAIN**

Packer: **REIG JOFRE S.A., BESOS, SPAIN**

Laboratory: **REIG JOFRE S.A., BESOS, SPAIN  
COMBINOPHARM S.L., BARCELONA, SPAIN  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG, RSA  
PHARMAPLAN, MIDRAND, RSA**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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MRF 15 (MBR 15)

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Registration number: A38/5.7.2/0625

Name of medicine: **EMEND COMBI PACK**

Dosage form: CAPSULE

Active ingredients: **EACH PACK CONTAINS :**  
1 x OPAQUE **CAPSULE** CONTAINING:  
APREPITANT 125,0 mg  
2 x WHITE **CAPSULES** CONTAINING:  
APREPITANT 80,0 mg

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

Applicant: **MSD (PTY) LTD**

Manufacturer: MERCK & CO, SUMNEYTOWN PIKE, WEST POINT,  
PA. USA

Packer: MERCK *SHARP* & DOHME, HAARLEM,  
THE NETHERLANDS  
PCI/CARDINAL HEALTH, CORBY, NORTHANTS, UK  
MSD, HALFWAY HOUSE, RSA

Laboratory: MERCK & CO, SUMNEYTOWN ~~PIKE~~, WEST POINT,  
PA. USA  
MERCK *SHARP* & DOHME, HAARLEM, j  
THE NETHERLANDS  
MERCK SHARP & DOHME, CRAMLINGTON,  
NORTHUMBERLAND, UK  
MSD, HALFWAY HOUSE, RSA

Shelf-life: 24 months

Date of registration: **23 SEPTEMBER 2005**

## MRF 15 (MBR 15)

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Registration number:	A38/5.7.2/0626
Name of medicine:	EMEND 80
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: APREPITANT <b>80,0 mg</b>
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MSD (PTY) LTD
Manufacturer:	MERCK & CO, SUMNEYTOWN PIKE, WEST POINT, PA. USA
Packer:	MERCK SHARP & DOHME, HAARLEM, THE <b>NETHERLANDS</b> PCI/CARDINAL HEALTH, CORBY, NORTHANTS, UK MSD, HALFWAY HOUSE, RSA
Laboratory:	MERCK & CO, SUMNEYTOWN PIKE, WEST POINT, <b>PA. USA</b> MERCK SHARP & DOHME, HAARLEM, THE NETHERLANDS MERCK SHARP & DOHME, CRAMLINGTON, NORTHUMBERLAND, UK MSD, HALFWAY HOUSE, RSA
Shelf-life:	<b>24 months</b>
Date of registration:	23 SEPTEMBER 2005

MRF 15 (MBR 15)

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Registration number: A38/5.7.2/0627

Name of medicine: **EMEND 125**

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:  
APREPITANT 125,0 mg

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

**Applicant:** MSD (PTY) LTD

Manufacturer: MERCK & CO, SUMNEYTOWN PIKE, WEST POINT,  
PA. USA

Packer: MERCK SHARP & DOHME, HAARLEM,  
THE NETHERLANDS  
PCYCARDINAL HEALTH, CORBY, NORTHANTS, UK  
**MSD, HALFWAY HOUSE, RSA**

Laboratory: MERCK & CO, SUMNEYTOWN PIKE, WEST POINT,  
PA. USA  
MERCK **SHARP** & DOHME, HAARLEM,  
THE NETHERLANDS  
MERCK **SHARP** & DOHME, CRAMLINGTON,  
NORTHUMBERLAND, UK  
MSD, HALFWAY HOUSE, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

**MRF 15 (MBR 15)**

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<b>Registration number:</b>	<b>A38/20.1.1/0633</b>
<b>Name of medicine:</b>	<b>RESMED CEFUROXIME 250 INJECTION</b>
<b>Dosage form:</b>	<b>INJECTION</b>
<b>Active ingredients:</b>	<b>EACH VIAL CONTAINS : CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 250,0 mg</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>RESMED HEALTHCARE</b>
<b>Manufacturer:</b>	<b>ASTRAL PHARMACEUTICAL INDUSTRIES, VADODARA, GUJARAT, INDIA</b>
<b>Packer:</b>	<b>ASTRAL PHARMACEUTICAL INDUSTRIES, VADODARA, GUJARAT, INDIA</b>
<b>Laboratory:</b>	<b>ASTRAL PHARMACEUTICAL INDUSTRIES, VADODARA, GUJARAT, INDIA RESMED HEALTHCARE, SPRINGFIELD PARK, DURBAN, RSA</b>
<b>Shelf-life:</b>	<b>36 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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**MRF 15 (MBR 15)**

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Registration number: A38/20.1.1/0665

Name of medicine: CLARIDE 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
CLARITHROMYCIN 250,0 mg

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

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS, ETOBICOKE,  
ONTARIO, CANADA  
PHARMACARE LTD, KORTSEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS, ETOBICOKE,  
ONTARIO, CANADA  
PHARMACARE LTD, KORTSEN, PORT ELIZABETH

Laboratory: GENPHARM PHARMACEUTICALS, ETOBICOKE,  
ONTARIO, CANADA  
PHARMACARE LTD, KORTSEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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MRF 15(MBR 15)

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Registration number: A38/20.1.1/0666

Name of medicine: CLARIDE 500

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
CLARITHROMYCIN 500,0 mg

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

Applicant: PHARMACARE LIMITED

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

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

Laboratory: GENPHARM PHARMACEUTICALS ETOBICOKE,  
ONTARIO, CANADA  
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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MRF 15 (MBR 15)

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Registration number: A3813410669

Name of medicine: STROMOS 1 G

Dosage form: GRANULES

Active ingredients: EACH SACHET CONTAINS:  
STRONTIUM RANELATE 1,0 g

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

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVER INDUSTRIE, **GIDY**,  
FRANCE  
E. PHARMA, G N A T , FRANCEPacker: LES LABORATOIRES SERVER INDUSTRIE, **GIDY**,  
FRANCE  
E. PHARMA, BESSAY, FRANCE  
TECHNIKON LABORATORIES, ROBERTVILLE,  
FLORIDA, RSALaboratory: LES LABORATOIRES SERVIER INDUSTRIE, **GIDY**,  
FRANCE  
INSPECTORATE M&L, ORMONDE, JOHANNESBURG  
BIOGARAN, RIVONIA, **RSA**

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/34/0670

Name of medicine: STROMOS 2 G

Dosage form: GRANULES

Active ingredients: EACH SACHET CONTAINS:  
STRONTIUM RANELATE 2,0 g

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

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABOMTOIRES SERVER INDUSTRIE, GIDY,  
FRANCE  
E. PHARMA, GANNAT, FRANCE

Packer: LES LABOMTOIRES SERVIER INDUSTRIE, GIDY,  
FRANCE  
E. PHARMA, BESSAY, FRANCE  
TECHNIKON LABORATORIES, ROBERTVILLE,  
FLORIDA, RSA

Laboratory: LES LABOMTOIRES SERVIER INDUSTRIE, **GIDY**,  
FRANCE  
INSPECTORATE M&L, ORMONDE, JOHANNESBURG  
BIOGARAN, RIVONIA, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A38/34/0671

Name of medicine: PAROSTAN 1 G

Dosage form: GRANULES

Active ingredients: EACH SACHET CONTAINS:  
STRONTIUM RANELATE 1,0 g

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

Applicant: EGIS PHARMACEUTICALS S.A. (PTY) LTD

Manufacturer: LES LABORATOIRES SERVER INDUSTRIE, GIDY,  
FRANCE  
E. PHARMA, G N A T , FRANCE

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,  
FRANCE  
E. PHARMA, BESSAY, FRANCE  
TECHNIKON LABORATORIES, ROBERTVILLE,  
FLORIDA, RSA

Laboratory: LES LABORATOIRES SERVER INDUSTRIE, GIDY,  
FRANCE  
INSPECTORATE M&L, ORMONDE, JOHANNESBURG  
EGIS PHARMACEUTICALS, RIVONIA, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number:	A38/34/0672
Name of medicine:	PAROSTAN 2 G
Dosage form:	GRANULES
Active ingredients:	EACH SACHET CONTAINS: <b>STRONTIUM RANELATE</b> 2,0 g
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	EGIS PHARMACEUTICALS S.A. (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVER INDUSTRIE, GIDY, FRANCE E. PHARMA, GANNAT, FRANCE
Packer:	LES LABORATOIRES SERVER INDUSTRIE, GIDY, FRANCE E. PHARMA, BESSAY, FRANCE TECHNIKON LABORATORIES, ROBERTVILLE, FLORIDA, RSA
Laboratory:	LES LABORATOIRES SERVER INDUSTFUE, GIDY, FRANCE INSPECTORATE M&L, ORMONDE, JOHANNESBURG EGIS PHARMACEUTICALS, RIVONIA, RSA
Shelf-life:	36 months
Date of registration:	23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **A38/3410673**

Name of medicine: **PROTOS 1G**

Dosage form: **GRANULES**

Active ingredients: **EACH SACHET CONTAINS:  
STRONTIUM RANELATE 1,0 g**

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

Applicant: **SERVER LABORATORIES SOUTH AFRICA (PTY) LTD**

Manufacturer: **LES LABORATOIRES SERVIER **INDUSTRIE**, GIDY,  
FRANCE  
E. PHARMA, G N A T , FRANCE**

Packer: **LES LABORATOIRES SERVIER INDUSTRIE, GIDY,  
FRANCE  
E. PHARMA, BESSAY, FRANCE  
TECHNIKON LABORATORIES, ROBERTVILLE,  
FLORIDA, RSA**

Laboratory: **LES LABORATOIRES SERVER INDUSTRIE, GIDY,  
FRANCE  
INSPECTORATE M&L, ORMONDE, **JOHANNESBURG**  
SERVIER LABORATORIES, RIVONIA, RSA**

Shelf-life: **36 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: A3813410674

Name of medicine: PROTOS 2 G

Dosage form: GRANULES

**Active ingredients:** EACH SACHET CONTAINS:  
STRONTIUM RANELATE 2,0 g

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

Applicant: SERVER LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVER INDUSTRIE, GIDY,  
FRANCE  
E. PHARMA, GANNAT, FRANCE

Packer: LES LABORATOIRES SERVER INDUSTRIE, GIDY,  
FRANCE  
E. PHARMA, BESSAY, FRANCE  
TECHNIKON LABORATORIES, ROBERTVILLE,  
FLORIDA, RSA

Laboratory: LES LABORATOIRES SERVER INDUSTRIE, GIDY,  
FRANCE  
INSPECTORATE M&L, ORMONDE, JOHANNESBURG  
SERVER LABORATORIES, RIVONIA, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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## MRF 15 (MBR 15)

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Registration number:	A38/20.2.2/0691
<b>Name</b> of medicine:	MERCK-TERBINAFINE 250 MG (TABLET)
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:	XIXIA PHARMACEUTICALS' (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA
Packer:	GENPHARM PHARMACEUTICALS, ETOBICOKE, ONTARIO, CANADA <b>GENERIC</b> S U.K., STATION CLOSE, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, <b>RSA</b>
Laboratory:	GENPHARM PHARMACEUTICALS, ETOBICOKE, <b>ONTARIO</b> , CANADA GENERIC S U.K., STATION CLOSE, HERTFORDSHIRE, U.K. GERARD LABORATORIES, <b>DUBLIN</b> , <b>IRELAND</b> MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, <b>RSA</b> RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM SOUTH AFRICAN <b>BUREAU OF STANDARDS</b> , GROENKLOOF, PRETORIA, <b>RSA</b> XIXIA PHARMACEUTICALS, MODDERFONTEIN, <b>RSA</b>
Shelf-life:	<b>24 months</b>
Date <b>of</b> registration:	23 SEPTEMBER 2005

**MRF 15 (MBR 15)**

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Registration number: A38/1.2/0706

Name of medicine: PAXOTENE 20 MG 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: CAMOX PHARMACEUTICALS (PTY) LTD

**Manufacturer:** FARMACEUTISCH ANALYTISCH LABORATORIUM  
B.V., DUIVEN, THE NETHERLANDS

Packer: FARMACEUTISCH ANALYTISCH LABORATORIUM  
B.V., DUIVEN, THE NETHERLANDS

Laboratory: FARMACEUTISCH ANALYTISCH LABORATORIUM  
B.V., DUIVEN, THE NETHERLANDS  
SOUTH AFRICAN BUREAU OF **STANDARDS**,  
**GROENKLOOF**, PRETORIA, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
INSPECTORATE M&L, **ORMONDE**,  
JOHANNESBURG, RSA  
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: **A39/21.2/0023**

Name of medicine: **GLIMEHEXAL 1**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:  
GLIMEPIRIDE **1,0 mg****

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

Applicant: **HEXAL PHARMA (SA) (PTY) LTD**

Manufacturer: **SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
HEXAL A/S, HVIDOVRE, DENMARK**

Packer: **SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
HEXAL A/S, HVIDOVRE, DENMARK  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA**

Laboratory: **SALUTASPHARMA GmbH, BARLEBEN, GERMANY  
H E W A/S, HVIDOVRE, DENMARK  
CONSULTING CHEMICAL **LABORATORIES**, STAR  
STREET, BOKSBURG, **RSA**  
ANALYTICON, KEMPTON PARK, **RSA**  
HEXAL PHARMA, WESTMEAD, **RSA****

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: A39/21.2/0024

Name of medicine: GLIMEHEXAL 2

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
GLIMEPIRIDE 2,0 mg

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

Applicant: **HEXAL PHARMA (SA) (PTY) LTD**

Manufacturer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
H E W A/S, HVIDOVRE, DENMARK

Packer: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
H E W A/S, HVIDOVRE, DENMARK  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA

Laboratory: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY  
**HEXAL A/S, HVIDOVRE, DENMARK**  
CONSULTING CHEMICAL LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
ANALYTICON, KEMPTON PARK, **RSA**  
H E W PHARMA, WESTMEAD, **RSA**

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A39/21.2/0025

Name of medicine: GLIMEHEXAL 4

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
GLIMEPIRIDE 4,0 mg

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

Applicant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer: SALUTAS PHARMA GmbH, **BARLEBEN, GERMANY**  
H E X A/S, HVIDOVRE, DENMARK

Packer: SALUTAS PHARMA GmbH, **BARLEBEN, GERMANY**  
HEXAL A/S, HVIDOVRE, DENMARK  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, RSA

Laboratory: SALUTAS PHARMA GmbH, **BARLEBEN, GERMANY**  
HEXAL A/S, HVIDOVRE, DENMARK  
CONSULTING CHEMICAL **LABORATORIES, STAR**  
**STREET, BOKSBURG, RSA**  
ANALYTICON, KEMPTON PARK, RSA  
H E X PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A39/20.2.8/0030

Name of medicine: KIVEXA

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
ABACAVIR SULPHATEEQUIVALENT TO  
ABACAVIR 600,0 mg  
LAMIVUDINE 300,0 mg

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

Applicant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD

Manufacturer: GLAXO OPERATIONS UK, WARE,  
HERTFORDSHIRE, U.K.

Packer: GLAXO OPERATIONS UK, WARE,  
HERTFORDSHIRE, U.K.  
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Laboratory: GLAXO OPERATIONS UK, WARE,  
HERTFORDSHIRE, U.K.  
GLAXOSMITHKLINE, EPPING, CAPE TOWN

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A39/20.1.1/0044

Name of medicine: CAMOX-CIPROFLOXACIN 250 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:  
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT  
TO CIPROFLOXACIN 250,0 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  
INSPECTORATE M&L LABORATORIES, ORMONDE,  
JOHANNESBURG, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
CAMOX PHARMACEUTICALS, CROWNMINES, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

**MRF 15 (MBR 15)**

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Registration number: A39/20.1.1/0045

Name of medicine: CAMOX-CIPROFLOXACIN 500 MG

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: 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,  
GROENIUOOF, PRETORIA, RSA  
INSPECTORATE M&L LABORATORIES, ORMONDE,  
JOHANNESBURG, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, **RSA**  
CAMOX PHARMACEUTICALS, CROWN MINES, **RSA**

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

**MRF 15 (MBR 15)**

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**Registration number:** A39/20.1.1/0046

**Name of medicine:** CAMOX-CIPROFLOXACIN 750 MG

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS:  
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT  
TO CIPROFLOXACIN 750,0 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  
INSPECTORATE M&L LABORATORIES, ORMONDE,  
JOHANNESBURG, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
BARDENE, BOKSBURG, RSA  
CAMOX PHARMACEUTICALS, CROWN MINES, RSA

**Shelf-life:** **24 months**

**Date of registration:** **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: A39/20.1.2/0070

Name of medicine: CURAM BD SUSPENSION

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:  
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 400,0 mg  
POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 57,0 mg

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: **SANDOZ** GmbH, KUNDL, AUSTRIA

Packer: SANDOZ GmbH, KUNDL, AUSTRIA

Laboratory: SANDOZ GmbH, KUNDL, AUSTRIA  
NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Shelf-life: **24** months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: A39/20.1.2/0071

Name of medicine: **SANDOZ CO-AMOXYCLAV BD SUSPENSION**

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION **CONTAINS :**  
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO  
AMOXYCILLIN 400,0 mg  
POTASSIUM CLAVULANATE EQUIVALENT TO  
CLAVULANIC ACID 57,0 mg

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: SANDOZ GmbH, KUNDL, AUSTRIA

Packer: SANDOZ GmbH, KUNDL, AUSTRIA

Laboratory: SANDOZ GmbH, KUNDL, AUSTRIA  
NOVARTIS S.A., SPARTAN, **KEMPTON PARK**, RSA

Shelf-life: 24 months

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15**

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Registration number: A3911910074

Name of medicine: **SPEC-OXYTOCIN 10**

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml AMPOULE **CONTAINS:**  
OXYTOCIN 10,0 i.u.

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

Applicant: SPECPHARM (PTY) LTD

Manufacturer: ROTEX-MEDICA, BUNSENSTRASS, TRITTAN

Packer: ROTEX-MEDICA, BUNSENSTRASS, TRITTAN

Laboratory: ROTEX-MEDICA, BUNSENSTRASS, TRITTAN  
ANALYTICON, KEMPTON PARK, RSA  
SPECPHARM, SANDTON, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** A39/20.1.1/0113

**Name of medicine:** REZOLIN 500 INJECTION

**Dosage form:** INJECTION

**Active ingredients:** EACH VIAL CONTAINS:  
CEFAZOLIN SODIUM EQUIVALENT TO  
CEFAZOLIN 500,0 mg

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

**Applicant:** RESMED HEALTHCARE

**Manufacturer:** ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

**Packer:** ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

**Laboratory:** ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA  
RESMED HEALTHCARE, SPRINGFIELD, DURBAN,  
RSA

**Shelf-life:** 36 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** A39/20.1.1/0114

**Name of medicine:** REZOLIN 1000 INJECTION

**Dosage form:** INJECTION

**Active ingredients:** EACH VIAL CONTAINS :  
CEFAZOLIN SODIUM EQUIVALENT TO  
CEFAZOLIN 1000,0 mg

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

**Applicant:** RESMED HEALTHCARE

**Manufacturer:** ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

**Packer:** ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

**Laboratory:** ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA  
RESMED HEALTHCARE, SPRINGFIELD, DURBAN,  
RSA

**Shelf-life:** 36 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **A39/5.4.1/0124**

Name of medicine: **PARKILYNE**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:  
SELEGILINE HYDROCHLORIDE 5,0 mg**

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

Applicant: **GENERIX INTERNATIONAL SA (PTY) LTD**

Manufacturer: **SIEGFRIED LTD, ZOFINGEN, SWITZERLAND**

Packer: **SIEGFRIED LTD, ZOFINGEN, SWITZERLAND**

Laboratory: **SIEGFRIED LTD, ZOFINGEN, SWITZERLAND  
CONSULTING CHEMICAL LABORATORIES, STAR  
STREET, BOKSBURG, RSA  
GENERIX INTERNATIONAL SA, INDUSTRIA,  
CAPE TOWN, RSA**

Shelf-life: **48 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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Registration number: A39/20.1.1/0179

Name of medicine: REZONE 2000 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:  
CEFTRIAZONE SODIUM EQUIVALENT  
CEFTRIAZONE 2000,0 mg

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

Applicant: RESMED HEALTHCARE

Manufacturer: ASTRAL PHARMACEUTICAL INDUSTRIES (P) LTD,  
VADODARA, GUJARAT, INDIA

Packer: ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA

Laboratory: ASTRAL PHARMACEUTICAL INDUSTRIES,  
VADODARA, GUJARAT, INDIA  
RESMED HEALTHCARE, SPRINGFIELD, DURBAN  
RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** A39/2.8/0237

**Name of medicine:** MYBULEN SUSPENSION

**Dosage form:** SUSPENSION

**Active ingredients:** EACH 10,0 ml SUSPENSION CONTAINS:  
IBUPROFEN 200,0 mg  
CODEINE PHOSPHATE 10,0 mg  
PARACETAMOL 250,0 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:** PHARMACARE LTD, KORSTEN, PORT ELIZABETH  
ASPEN PHARMACARE, WILSONIA, EAST LONDON  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, UNIVERSITY, POTCHEFSTROOM

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** A39/1 1,510260

**Name of medicine:** LENNON LACTULOSE PEACH

**Dosage form:** SOLUTION

**Active ingredients:** EACH 5,0 ml SOLUTION CONTAINS:  
LACTULOSE ANHYDROUS 3,250 g

**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:** PHARMACARE LTD, KORSTEN, PORT ELIZABETH  
ASPEN PHARMACARE, WILSONIA, EAST LONDON  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, UNIVERSITY, POTCHEFSTROOM

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number: **A39/11.5/0263**

Name of medicine: **LENNON LACTULOSE LEMON**

Dosage form: **SOLUTION**

Active ingredients: **EACH 5,0 ml SOLUTION CONTAINS:  
LACTULOSE ANHYDROUS **3,250 g****

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: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH  
ASPEN PHARMACARE, WILSONIA, EAST LONDON  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, UNIVERSITY, POTCHEFSTROOM**

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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**Registration number:** A39/20.2.8/0280

**Name of medicine:** DAS-LAMIVUDINE 150 MG

**Dosage form:** TABLET

**Active ingredients:** EACH TABLET CONTAINS :  
LAMIVUDINE 150,0 mg

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

**Applicant:** STRIDES SA (PTY) LTD

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

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

**Laboratory:** STRIDES ARCOLAB LTD, ANEKAL TALUK,  
BANGALORE, INDIA  
COLUMBIA PGARMACEUTICALS, BARDENE,  
BOKSBURG, RSA  
INSTITUTE FOR PHARMACEUTICAL SERVICES,  
SILVERTONDALE, RSA  
NOVARTIS SA, SPARTAN, KEMPTON PARK, RSA  
STRIDES, ARCADIA, PRETORIA, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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MRF 15 (MBR 15)

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**Registration number:** A39/10.2.1/0373

**Name of medicine:** SABAX COMBINEB

**Dosage form:** INHALATION SOLUTION

**Active ingredients:** EACH 2,5 ml SOLUTION CONTAINS:  
IPRATROPIUM BROMIDE 0,520 mg  
SALBUTAMOL SULPHATE 3,010 mg

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

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

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

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

**Laboratory:** ADCOCK INGRAM CRITICAL CARE, AEROTON,  
JOHANNESBUGR, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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<b>Registration number:</b>	<b>A39/18.1/0399</b>
<b>Name of medicine:</b>	<b>RIDAQ-12,5</b>
<b>Dosage form:</b>	<b>TABLET</b>
<b>Active ingredients:</b>	<b>EACH TABLET CONTAINS: HYDROCHLOROTHIAZIDE 12,5 mg</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>PHARMACARE LIMITED</b>
<b>Manufacturer:</b>	<b>PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON</b>
<b>Packer:</b>	<b>PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON</b>
<b>Laboratory:</b>	<b>PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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**MRF 15 (MBR 15)**

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Registration number: A39/2.5/0473

**Name** of medicine: **SANDOZ LAMOTRIGINE 25**

Dosage **form**: TABLET

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

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

Applicant: **SANDOZ (PTY) LTD**

Manufacturer: NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH

Packer: NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA  
**SOUTH AFRICAN BUREAU OF STANDARDS,**  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON **PARK, RSA**  
SANDOZ, SPARTAN, KEMPTON PARK

**Shelf-life:** **24 months**

Date of registration: 23 ~~SEPTEMBER~~ 2005

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**MRF 15 (MBR 15)**

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Registration number: **A39/2.5/0474**

Name of medicine: **SANDOZ 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: **SANDOZ (PTY) LTD**

Manufacturer: **NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH**

Packer: **NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEWTON PARK, RSA**

Laboratory: **NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEWTON PARK, RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON PARK, RSA  
**SANDOZ, SPARTAN, KEMPTON PARK****

Shelf-life: **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 ( MBR 15)**

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**Registration number:** A39/2.5/0475

**Name of medicine:** SANDOZ 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:** SANDOZ (PTY) LTD

**Manufacturer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH

**Packer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

**Laboratory:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON PARK, RSA  
SANDOZ, SPARTAN, KEMPTON PARK

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** A39/2.5/0476

**Name of medicine:** SANDOZ 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:** SANDOZ (PTY) LTD

**Manufacturer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH

**Packer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

**Laboratory:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON PARK, RSA  
SANDOZ, SPARTAN, KEMPTON PARK

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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**Registration number:** A39/2.5/0513

**Name of medicine:** LAMEPTIL 25

**Dosage form:** TABLET

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

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

**Applicant:** SANDOZ (PTY) LTD

**Manufacturer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH

**Packer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

**Laboratory:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA  
SOUTH AFRICAN BUREAU OF STANDARDS'  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON PARK, RSA  
SANDOZ, SPARTAN, KEMPTON PARK, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 ( MBR 15)**

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Registration number: **A39/2.5/0514**

Name of medicine: **LAMEPTIL 50**

Dosage form: **TABLET**

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

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

Applicant: **SANDOZ(PTY) LTD**

Manufacturer: **NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH**

Packer: **NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA**

Laboratory: **NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON PARK, RSA  
SANDOZ, SPARTAN, KEMPTON PARK, RSA**

**Shelf-life:** **24 months**

Date of registration: **23 SEPTEMBER 2005**

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**MRF 15 (MBR 15)**

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**Registration number:** A39/2.5/05 15

**Name of medicine:** LAMEPTIL 100

**Dosage form:** TABLET

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

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

**Applicant:** SANDOZ (PTY) LTD

**Manufacturer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH

**Packer:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS , SPARTAN, KEMPTON PARK, RSA

**laboratory:** NOVARTIS BANGLADESH LTD, GAZIPUR,  
BANGLADESH  
NOVARTIS, SPARTAN, KEMPTON PARK, RSA  
SOUTH AFRICAN BUREAU OF *STANDARDS* ,  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON PARK, RSA  
SANDOZ, SPARTAN ,KEMPTON PARK, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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<b>Registration number:</b>	<b>A39/2.5/0516</b>
<b>Name of medicine:</b>	<b>LAMEPTIL 200</b>
<b>Dosage form:</b>	<b>TABLET</b>
<b>Active ingredients:</b>	<b>EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>SANDOZ (PTY) LTD</b>
<b>Manufacturer:</b>	<b>NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH</b>
<b>Packer:</b>	<b>NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH NOVARTIS, SPARTAN, KEMPTON PARK, RSA</b>
<b>Laboratory:</b>	<b>NOVARTIS BANGLADESH LTD, GAZIPUR, BANGLADESH NOVARTIS, SPARTAN, KEMPTON PARK, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA ANALYTICON, KEMPTON PARK, RSA SANDOZ, SPARTAN, KEMPTON PARK, RSA</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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MRF 15 (MBR 15)

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Registration number: A40/3.1/0028

Name of medicine: AITHROCOX 15

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS:**  
MELOXICAM 15,0 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: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
GROENKLOOF, PRETORIA, RSA  
ANALYTICON, KEMPTON PARK, RSA  
**SANDOZ**, SPARTAN, KEMPTON PARK, RSA

Shelf-life: **24** months

Date of registration: 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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Registration number:	A40/2.2/0054
Name of medicine:	ZOLAMID 5 MG/5 ML
Dosage form:	INJECTION
Active ingredients:	EACH <b>AMPOULE</b> CONTAINS: MIDAZOLAM 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	GENERIX INTERNATIONAL S.A (PTY) LTD
Manufacturer:	CRISTALIA PRODUTOS QUIMICOS FARMACEUTICOS, BUTANTA, SAO PAULO
Packer:	CRISTALIA PRODUTOS QUIMICOS FARMACEUTICOS, BUTANTA, SAO PAULO
Laboratory:	CRISTALIA PRODUTOS QUIMICOS FARMACEUTICOS, BUTANTA, SAO PAULO CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA GENERIX INTERNATIONAL, INDUSTRIA, CAPE TOWN, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

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**MRF 15 ( MBR15)**

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**Registration number:** A40/2.2/0055

**Name of medicine:** ZOLAMID 15 MG/3 ML

**Dosage form:** INJECTION

**Active ingredients;** EACH AMPOULE CONTAINS :  
MIDAZOLAM 15,0 mg

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

**Applicant:** GENERIX INTERNATIONAL S.A (PTY) LTD

**Manufacturer:** CRISTALIA PRODUTOS QUIMICOS  
FARMACEUTICOS, BUTANTA, SAO PAULO

**Packer:** CRISTALIA PRODUTOS QUIMICOS  
FARMACEUTICOS, BUTANTA, SAO PAULO

**Laboratory:** CRISTALIA PRODUTOS QUIMICOS  
FARMACEUTICOS, BUTANTA, SAO PAULO  
CONSULTING CHEMICAL LABORATORIES,  
STAR STREET, BOKSBURG ,RSA  
GENERIX INTERNATIONAL, INDUSTRIA,  
CAPE TOWN, RSA

**Shelf-life:** 24 months

**Date of registration:** 23 SEPTEMBER 2005

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**MRF 15 (MBR 15)**

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<b>Registration number:</b>	<b>A40/2.2/0056</b>
<b>Name of medicine:</b>	<b>ZOLAMID 50MG/10 ML</b>
<b>Dosage form:</b>	<b>INJECTION</b>
<b>Active ingredients:</b>	<b>EACH AMPOULE CONTAINS: MIDAZOLAM 50,0 mg</b>
<b>Conditions of registration:</b>	<b>1, 2, 3, 4, 5, 6, 7</b>
<b>Applicant:</b>	<b>GENERIX INTERNATIONAL S.A (PTY) LTD</b>
<b>Manufacturer:</b>	<b>CRISTALIA PRODUTOS QUIMICOS FARMACEUTICOS, BUTANTA, SAO PAULO</b>
<b>Packer:</b>	<b>CRISTALIA PRODUTOS QUIMICOS FARMACEUTICOS, BUTANTA, SAO PAULO</b>
<b>Laboratory:</b>	<b>CRISTALIA PRODUTOS QUIMICOS FARMACEUTICOS, BUTANTA, SAO PAULO CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA GENERIX INTERNATIONAL, INDUSTRIA, CAPE TOWN, RSA</b>
<b>Shelf-life:</b>	<b>24 months</b>
<b>Date of registration:</b>	<b>23 SEPTEMBER 2005</b>

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