

**REPUBLIC OF SOUTH AFRICA
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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1300 OF 2005

MEDICINES CONTROL COUNCIL

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

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

KENNISGEWING 1300 VAN 2005**MEDISYNEBEHEERRAAD****VOORWAARDES VIR DIE REGISTRASIE VAN 'N MEDISYNE IN TERME VAN DIE BEPALINGS VAN ARTIKEL 15(7) VAN DIE WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET No. 101 VAN 1965)**

1. Die applikant sal verseker dat die medisyne vervaardig en beheer word ooreenkomstig huldige Goeie Vervaardigingspraktyke soos bepaal deur die Medisynebeheerraad.
2. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs, aangestel ingevolge Artikel 26 van die Wet, om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
3. Die inligting soos vervat in die voubiljet moet op 'n gereelde grondslag opgedateer word in ooreenstemming met 'n voubiljet wat onlangs deur die Raad goedgekeur is.
4. Die applikant moet voldoen aan alle wetlike vereistes van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
5. Die registrasie van hierdie medisyne is onderhewig aan gereelde hersiening rakende kwaliteit, veiligheid en effektiwiteit, en die registrasie van hierdie medisyne kan gewysig word onderhewig aan kwessies soos goedgegink deur die Raad.
6. Die eerste twee produksielotte moet ten volle gevalideer word ooreenkomstig die breedvoerige prosesvalidasie protokol wat ingedien is ten tye van die aansoek om registrasie, en die validasieverslag moet binne die bestek van een maand na die voltooiing van die validasie ingedien word.
7. Die registrasie-aansoek is onderhewig aan hersiening met tussenposes soos deur die Raad bepaal.
8. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslike vervaardigde produk uitgevoer word.
9. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
10. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die ingevoerde produk uitgevoer word.
11. Bemaking van die produk mag slegs in aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
12. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die massalot en die vulloot sowel as ses kopieë van die vrystellingsertifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken, sal gewysig word deur 'n verklaring by te voeg dat die virusstamme tans vir Suid-Afrikaanse gebruik gedurende die gespesifiseerde jaar aanbeveel word.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 02/21.1/19

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,
THE NETHERLANDS
INTERVET S.A., KEMPTON PARK, RSA

Shelf-life: 60 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: 02/21.1/20

Name of medicine: CEFA-VET 1000 MG

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,
THE NETHERLANDS
INTERVET S.A., KEMPTON PARK, RSA

Shelf-life: 60 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: 03/21.1/6

Name of medicine: NOROCLAV INJECTION

Dosage form: INJECTION

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

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A03/21.1/11

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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, FERNDAL, RANDBURG, RSA
MERIAL, HALFWAY HOUSE, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 32/34/0423

Name of medicine: OVANTA

Dosage form: TABLET

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

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

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

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

Packer: ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE,
U.K.

Laboratory: 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

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: 33/21.12/0517

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

MRF 15 (MBR 15)

Registration number: 33/21.12/0518

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

MRF 15 (MBR 15)

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:	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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 34/7.1/0286

Name of medicine: CARDOSIN 4

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
DOXAZOSIN MESYLATE EQUIVALENT TO
DOXAZOSIN 4,0 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

MRF 15 (MBR 15)

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)

Registration number: 35/2.2/0321

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
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 36/15.4/0357

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
ADCOCK 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

MRF 15 (MBR 15)

Registration number: 36/17.1/0431

Name of medicine: MUSCURON

Dosage form: INJECTION

Active ingredients: EACH AMPOULE CONTAINS:
VECURONIUM BROMIDE 4,0 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, LYTTTELTON MANOR, CENTURION,
RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 37/20.1.2/0003

Name of medicine: AUSTELL – AMOXICILLIN 250 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
AMOXICILLIN TRIHYDRATE EQUIVALENT TO
AMOXICILLIN 250,0 mg

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

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, GUJARAT, INDIA

Packer: IPCA 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

MRF 15 (MBR 15)

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: IPCA 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

MRF 15 (MBR 15)

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

MRF 15

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

MRF 15

Registration number: 37/34/0089

Name of medicine: ALKALINE BICARBONATE HAEMODIALYSIS
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 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 37/20.1.1/0222

Name of medicine: AP AZITHROMYCIN 500 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AZITHROMYCIN MONOHYDRATE EQUIVALENT
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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 37/16.4/0435

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

MRF 15 (MBR 15)

Registration number:	37/25.2/0501
Name of medicine:	OLICLINOMEL N4-550 E
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) 5,5 % AMINO ACIDS SOLUTION compartment with electrolytes. b) 20 % GLUCOSE SOLUTION compartment with electrolyte calcium. c) 10 % 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

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
L-isoleucine	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
L-serine	2,75 g
L-threonine	2,31 g
L-tryptophan	0,99 g
L-tyrosine	0,22 g
L-valine	3,19 g
Sodium acetate	2,45 g
Sodium 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:

Glucose 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)

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 calcium. 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

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
Sodium acetate	6,12 g
Sodium glycerophosphate	5,36 g
Potassium 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

MRF 15 (MBR 15)

Registration number:	37/25.2/0503
Name of medicine:	OLICLINOMEL N6-900 E
Dosage form:	INFUSION
Active ingredients:	EACH BAG CONTAINS: a) 8,5 % AMINO ACIDS SOLUTION compartment with electrolytes. b) 30 % GLUCOSE SOLUTION compartment with electrolyte calcium. 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

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

MRF 15 (MBR 15)

Registration number: 37/25.2/0504

Name of medicine: OLICLINOMEL N7-1000 E

Dosage form: INFUSION

Active ingredients: EACH BAG CONTAINS:
a) 10 % AMINO ACIDS SOLUTION compartment with electrolytes.
b) 40 % GLUCOSE SOLUTION compartment with electrolyte calcium.
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

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
Sodium 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

MRF 15 (MBR 15)

Registration number: 37/2.9/0532

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 37/21.2/0570

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 AGRIKEM, KAMEEL DRIFT, PRETORIA
ARROW PHARMA, WADEVILLE, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15

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 1 000,0 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

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0652

Name of medicine: BECLATE 100 HFA

Dosage form: INHALER

Active ingredients: EACH ACTUATION DELIVERS:
BECLOMETHASONE DIPROPIONATE 100,0 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

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0653

Name of medicine: BECLATE 200 HFA

Dosage form: INHALER

Active ingredients: EACH ACTUATION DELIVERS:
BECLOMETHASONE DIPROPIONATE 200,0 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

MRF 15 (MBR 15)

Registration number: 37/21.5.1/0654

Name of medicine: BECLATE 250 HFA

Dosage form: INHALER

Active ingredients: EACH ACTUATION DELIVERS:
BECLOMETHASONE DIPROPIONATE 250,0 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

MRF 15 (MBR 15)

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 275,0 mg
RIFAMPICIN 150,0 mg
ISONIAZID 75,0 mg

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

MRF 15 (MBR 15)

Registration number: 38/20.1.2/0003

Name of medicine: APEX-CLAVUTIN 625 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO 500,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO 125,0 mg
CLAVULANIC ACID

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

MRF 15 (MBR 15)

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
EQUIVALENT TO ONDANSETRON 4,0 mg

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

Applicant: AUSTELL LABORATORIES (PTY) LTD

Manufacturer: IPCA LABORATORIES LIMITES, 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)

Registration number:	38/5.10/0046
Name of medicine:	AUSTELL – ONDANSETRON 8 MG TABLETS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ONDANSETRON HYDROCHLORIDE DIHYDRATE EQUIVALENT TO ONDANSETRON 8,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LIMITES, 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)

Registration number: 38/1.2/0068

Name of medicine: SERRAPRESS 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
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/1.2/0069

Name of medicine: SERRAPRESS 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
PHARMA DYNAMICS, WESTLAKE, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/21.1/0084

Name of medicine: LEVEMIR

Dosage form: INJECTION

Active ingredients: EACH 1,0 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

MRF 15 (MBR 15)

Registration number: 38/5.7.1/0087

Name of medicine: CLARINESE SYRUP

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
LORATADINE 5,0 mg

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

Applicant: PHARMACARE LIMITED

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

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

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

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: 38/7.5/0123

Name of medicine: ASPEN PRAVASTATIN 10 MG

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 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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: 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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)

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

MRF 15 (MBR 15)

Registration number: 38/20.1.2/0266

Name of medicine: APEX-CLAVUTIN 375 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO 250,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO 125,0 mg
CLAVULANIC ACID

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, SAXONWOLD, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: 38/7.1/0272

Name of medicine: ISTIN 10 MG

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

MRF 15 (MBR 15)

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)

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

MRF 15 (MBR 15)

Registration number: A38/1.2/0413

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

MRF 15 (MBR 15)

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, MAHARASHTRA, INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA

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

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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: 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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., 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

MRF 15

Registration number: A38/7.3/0480

Name of medicine: *IMITREX 50*

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SUMATRIPTAN SUCCINATE EQUIVALENT TO
SUMATRIPTAN 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

MRF 15

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

MRF 15 (MBR 15)

Registration number: A38/5.2/0501

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

MRF 15 (MBR 15)

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 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

MRF 15 (MBR 15)

Registration number: A38/5.2/0503

Name of medicine: TENOPRESS 100 MG 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A38/26/0532

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

MRF 15 (MBR 15)

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: 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A38/21.8.2/0563

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

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0580

Name of medicine: RES-CEFOTAX 500 INJECTION

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: 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0583

Name of medicine: REZONE 500 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAZONE SODIUM EQUIVALENT TO
CEFTRIAZONE 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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, 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

MRF 15 (MBR 15)

Registration number: A38/26/0593

Name of medicine: ENDOXAN 50 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
CYCLOPHOSPHAMIDE MONOHYDRATE
EQUIVALENT 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

MRF 15 (MBR 15)

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-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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,
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)

Registration number:	A38/5.7.2/0626
Name of medicine:	EMEND 80
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: 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, 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)

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
PCI/CARDINAL 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)

Registration number: A38/20.1.1/0633

Name of medicine: RESMED CEFUROXIME 250 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFUROXIME SODIUM EQUIVALENT TO
CEFUROXIME 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 PARK,
DURBAN, RSA

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A38/34/0669

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 SERVIER INDUSTRIE, GIDY,
FRANCE
E. PHARMA, GANNAT, FRANCE

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

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

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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 LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
E. PHARMA, GANNAT, FRANCE

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

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

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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 SERVIER INDUSTRIE, GIDY,
FRANCE
E. PHARMA, GANNAT, FRANCE

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

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

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/34/0672

Name of medicine: PAROSTAN 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: EGIS PHARMACEUTICALS S.A. (PTY) LTD

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

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

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

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/34/0673

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: SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD

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

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

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

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/34/0674

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: SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD

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

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

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

Shelf-life: 36 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
HEXAL 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

MRF 15 (MBR 15)

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 HEXAL 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 HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

MRF 15 (MBR 15)

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
HEXAL 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
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.2.8/0030

Name of medicine: KIVEXA

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ABACAVIR SULPHATE EQUIVALENT 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

MRF 15 (MBR 15)

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, CROWN MINES, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

MRF 15 (MBR 15)

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,
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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A39/20.1.2/0071

Name of medicine: SANDOZ CO-AMOXICLAV BD SUSPENSION

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 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

MRF 15

Registration number: A39/19/0074

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A39/20.1.1/0179

Name of medicine: REZONE 2000 INJECTION

Dosage form: INJECTION

Active ingredients: EACH VIAL CONTAINS:
CEFTRIAXONE SODIUM EQUIVALENT TO
CEFTRIAXONE 2000,0 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A39/11.5/0260

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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,
JOHANNESBURG, RSA

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

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

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/18.1/0399

Name of medicine: RIDAQ-12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
HYDROCHLOROTHIAZIDE 12,5 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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, 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A39/2.5/0515

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

MRF 15 (MBR 15)

Registration number: A39/2.5/0516

Name of medicine: LAMEPTIL 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, RSA

Shelf-life: 24 months

Date of registration: 23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: A40/3.1/0028

Name of medicine: ARTHROCOX 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

MRF 15 (MBR 15)

Registration number: A40/2.2/0054

Name of medicine: ZOLAMID 5 MG/5 ML

Dosage form: INJECTION

Active ingredients: EACH AMPOULE 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

MRF 15 (MBR 15)

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

MRF 15 (MBR 15)

Registration number: A40/2.2/0056

Name of medicine: ZOLAMID 50 MG/10 ML

Dosage form: INJECTION

Active ingredients: EACH AMPOULE CONTAINS:
MIDAZOLAM 50,0 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
