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GENERAL NOTICE ALGEMENE KENNISGEWING

NOTICE 1680 OF 2006

MEDICINES CONTROL COUNCIL

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

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

KENNISGEWING 1680 VAN 2006**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 huidige 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 goedgevind 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 vullot 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

Registration number: A04/2.1/9

Name of medicine: RAPINOVET INJECTION

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml EMULSION CONTAINS:
Propofol 10,0 mg

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

Applicant: SCHERING-PLOUGH (PTY) LTD

Manufacturer: SICOR PHARMACEUTICALS INC, IRVINE,
CALIFORNIA, USA

Packer: SICOR PHARMACEUTICALS INC, IRVINE,
CALIFORNIA, USA
SCHERING-PLOUGH, BRAY, WICKLOW, IRELAND
SCHERING-PLOUGH, ISANDO, RSA

Laboratory:FPRC: SICOR PHARMACEUTICALS INC, IRVINE,
CALIFORNIA, USA
SCHERING-PLOUGH, BRAY, WICKLOW, IRELAND
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK, RSA
FPRR: SCHERING-PLOUGH, ISANDO, RSA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 34/7.1.3/0137

Name of medicine: CONCOR 5 PLUS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
BISOPROLOL FUMARATE 5,0 mg
HYDROCHLOROTHIAZIDE 12,5 mg

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

Applicant: MERCK (PTY) LTD

Manufacturer: MERCK KGaA, DARMSTADT, GERMANY

Packer: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON

Laboratory:FPRC: MERCK KGaA, DARMSTADT, GERMANY
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON
FPRR: MERCK, MODDERFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	34/7.1.3/0138
Name of medicine:	CONCOR 10 PLUS
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BISOPROLOL FUMARATE 10,0 mg HYDROCHLOROTHIAZIDE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	MERCK (PTY) LTD
Manufacturer:	MERCK KGaA, DARMSTADT, GERMANY
Packer:	MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
Laboratory:FPRC:	MERCK KGaA, DARMSTADT, GERMANY MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON
FPRR:	MERCK, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: 36/7.1.3/0383

Name of medicine: TAREG 40

Dosage form: TABLET

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

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

Applicant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND

Packer: NOVARTIS PHARMA STEIN AG, STEIN,
SWITZERLAND
KONPHARMA AG, PRATTELN, SWITZERLAND
ALLPACK AG, MUTTENZ, SWITZERLAND
NOVARTIS PHARMA GmbH, WEHR/BADEN,
GERMANY
NOVARTIS, SPARTAN, KEMPTON PARK

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

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 37/7.1.3/0327

Name of medicine: BIO-ENALAPRIL MALEATE 5 mg

Dosage form: TABLET

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

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

Applicant: BIOTECH LABORATORIES (PTY) LTD

Manufacturer: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA

Packer: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA

FPRR: BIOTECH LABORATORIES, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 37/7.1.3/0328

Name of medicine: BIO-ENALAPRIL MALEATE 10 mg

Dosage form: TABLET

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

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

Applicant: BIOTECH LABORATORIES (PTY) LTD

Manufacturer: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA

Packer: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA

FPRR: BIOTECH LABORATORIES, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 37/7.1.3/0329

Name of medicine: BIO-ENALAPRIL MALEATE 20 mg

Dosage form: TABLET

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

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

Applicant: BIOTECH LABORATORIES (PTY) LTD

Manufacturer: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA

Packer: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: LEK PHARMACEUTICAL & CHEMICAL COMPANY,
VEROVSKOVA, SLOVENIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA

FPRR: BIOTECH LABORATORIES, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 37/7.1.4/0339

Name of medicine: IMOTRATE 60 mg SR

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ISOSORBIDE-5-MONONITRATE 60,0 mg

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

Applicant: COMPUPHARM (PTY) LTD

Manufacturer: VALPHARMA INTERNATIONAL S.p.A, PENNABILLI,
ITALY
EUDERMA S.p.A, RIMINI, ITALY

Packer: VALPHARMA INTERNATIONAL S.p.A, PENNABILLI,
ITALY
EUDERMA S.p.A, RIMINI, ITALY

Laboratory:FPRC: VALPHARMA INTERNATIONAL S.p.A, PENNABILLI,
ITALY
EUDERMA S.p.A, RIMINI, ITALY
SEDEK AGRIKEM, KAMEELDRIFT, PRETORIA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE

FPRR: COMPUPHARM, LYNNWOOD, PRETORIA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	37/7.1.4/0340
Name of medicine:	VALPHARMA ISOSORBIDE-5-MONONITRATE 60 mg SR
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ISOSORBIDE-5-MONONITRATE 60,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	COMPUPHARM (PTY) LTD
Manufacturer:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY
Packer:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY
Laboratory:FPRC:	VALPHARMA INTERNATIONAL S.p.A, PENNABILLI, ITALY EUDERMA S.p.A, RIMINI, ITALY SEDEK AGRKEM, KAMEELDRIFT, PRETORIA INSTITUTE FOR PHARMACEUTICAL SERVICES, SILVERTONDALE
FPRR:	COMPUPHARM, LYNNWOOD, PRETORIA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: 37/7.1/0378

Name of medicine: OROVASC 5

Dosage form: TABLET

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

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Packer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 37/7.1/0379

Name of medicine: OROVASC 10

Dosage form: TABLET

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

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Packer: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
NOVARTIS SA, SPARTAN, KEMPTON PARK

Laboratory:FPRC: NOVARTIS LTD, TONGI, GAZIPUR,
BANGLADESH
FPRC/FPRR: NOVARTIS SA, SPARTAN, KEMPTON PARK

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	38/7.5/0225
Name of medicine:	BEZACHOLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: BEZAFIBRATE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES, DUBLIN, IRELAND GENERIC (UK) LTD, STATION CLOSE, HERTFORDSHIRE, U.K.
Laboratory:FPRC:	ALPHAPHARM, BRISBANE, QUEENSLAND, AUSTRALIA GERARD LABORATORIES, DUBLIN, IRELAND GENERIC (UK) LTD, STATION CLOSE, HERTFORDSHIRE, U.K. SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A38/7.1.3/0392

Name of medicine: QUINAZIDE 10/12,5

Dosage form: TABLET

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

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

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

Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND

Packer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA, PINETOWN, KZN

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A38/7.1.3/0393

Name of medicine: QUINAZIDE 20/12,5

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
QUINAPRIL HYDROCHLORIDE EQUIVALENT TO
QUINAPRIL 20,0 mg
HYDROCHLOROTHIAZIDE 12,5 mg

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

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

Manufacturer: ACTAVIS hf, HAFNARFJORDUR, ICELAND

Packer: ACTAVIS hf, HAFNARFJORDUR, ICELAND
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: ACTAVIS hf, HAFNARFJORDUR, ICELAND
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK
FPRR: HEXAL PHARMA, PINETOWN, KZN

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A38/1.2/0482
Name of medicine:	ASPEN SERTRALINE 50 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 50,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/1.2/0483
Name of medicine:	ASPEN SERTRALINE 100 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SERTRALINE HYDROCHLORIDE EQUIVALENT TO SERTRALINE 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory:FPRC:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A38/21.2/0560

Name of medicine: ALEMBIC GLICLAZIDE 80

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLICLAZIDE 80,0 mg

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

Applicant: GULF DRUG COMPANY (PTY) LTD

Manufacturer: ALEMBIC LTD, PANCHMAHALS, GUJARAT,
INDIA

Packer: ALEMBIC LTD, PANCHMAHALS, GUJARAT,
INDIA

Laboratory:FPRC: ALEMBIC LTD, PANCHMAHALS, GUJARAT,
INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE,
JOHANNESBURG, RSA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
PHARMA-Q, INDUSTRIA, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
CONSULTING MICROBIOLOGICAL
LABORATORY, MOREWILL, BEYERSPARK, RSA
FPRR: GULF DRUG CO, MOUNT EDGECOMBE, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A38/7.1.3/0639
Name of medicine:	PHARMAPRESS 2,5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 2,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES LTD, DUBLIN, IRELAND GENERIC (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:FPRC:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A38/7.1.3/0640
Name of medicine:	PHARMAPRESS 5 mg
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ENALAPRIL MALEATE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN PHARMACARE LTD, KORSTEN, PORT ELIZABETH GERARD LABORATORIES LTD, DUBLIN, IRELAND GENERIC (UK) LTD, STATION CLOSE, HERTFORDSHIRE, UK
Laboratory:FPRC:	GENPHARM INC, ETOBICOKE, ONTARIO, CANADA MERCK FARMA y QUIMICA S.A, BARCELONA, SPAIN SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A38/30.1/0717

Name of medicine: IMOVAX POLIO

Dosage form: INJECTION

Active ingredients: EACH 0,5 ml DOSE CONTAINS:
POLIO VIRUS TYPE 1 (MAHONEY) 40,0 ANTIGEN D UNITS
POLIO VIRUS TYPE 2 (MEF-1) 8,0 ANTIGEN D UNITS
POLIO VIRUS TYPE 3 (SAUKETT) 32,0 ANTIGEN D UNITS

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

Applicant: AVENTIS PHARMA (PTY) LTD

Manufacturer: AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE

Packer: AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE

Laboratory:FPRC: AVENTIS PASTEUR, MARCY L'ETOILE, FRANCE
FPRR: AVENTIS PHARMA, WALTLOO, PRETORIA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/21.12/0258

Name of medicine: FINAHEXAL 5

Dosage form: TABLET

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

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

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

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, TERENCE, KEMPTON PARK
FPRR: HEXAL PHARMA, PINETOWN, KZN

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/21.12/0259

Name of medicine: FINASTERIDE HEXAL 5

Dosage form: TABLET

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

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

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

Manufacturer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA

Packer: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
TECHNIKON LABORATORIES, ROBERTVILLE,
FLORIDA

Laboratory:FPRC: CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, TERENURE, KEMPTON PARK
FPRR: HEXAL PHARMA, PINETOWN, KZN

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/24/0312

Name of medicine: 0,9 % w/v SODIUM CHLORIDE INJECTION B BRAUN

Dosage form: INJECTION

Active ingredients: EACH 100,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 0,9 g

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Packer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Laboratory:FPRC: B BRAUN MELSUNGEN AG, BERLIN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG,RSA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/34/0313

Name of medicine: WATER FOR INJECTIONS B BRAUN

Dosage form: SOLUTION

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

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Packer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Laboratory:FPRC: B BRAUN MELSUNGEN AG, BERLIN, GERMANY
FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/20.1.1/0334

Name of medicine: CIPROFLOXACIN – SAFELINE 100

Dosage form: INFUSION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CIPROFLOXACIN LACTATE EQUIVALENT TO
CIPROFLOXACIN 2,0 mg

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

Applicant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Laboratory:FPRC: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/20.1.1/0335

Name of medicine: CIPROFLOXACIN – SAFELINE 200

Dosage form: INFUSION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CIPROFLOXACIN LACTATE EQUIVALENT TO
CIPROFLOXACIN 2,0 mg

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

Applicant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Laboratory:FPRC: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/20.1.1/0336

Name of medicine: CIPROFLOXACIN – SAFELINE 400

Dosage form: INFUSION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
CIPROFLOXACIN LACTATE EQUIVALENT TO
CIPROFLOXACIN 2,0 mg

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

Applicant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Laboratory:FPRC: DEMO S.A. PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: SAFELINE PHARMACEUTICALS, FLORIDA, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A39/21.10/0357
Name of medicine:	MENOPUR POWDER FOR SOLUTION FOR INJECTION
Dosage form:	POWDER
Active ingredients:	EACH VIAL CONTAINS: MENOTROPHIN EQUIVALENT TO FOLLICLE STIMULATING HORMONE 75,0 iu LUTEINISING HORMONE 75,0 iu
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	FERRING (PTY) LTD
Manufacturer:	DR RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM, GERMANY PATHEON ITALIA S.p.A, MONZA, ITALY FERRING GmbH, KIEL, GERMANY
Packer:	DR RENTSCHLER BIOTECHNOLOGIE GmbH, LAUPHEIM, GERMANY PATHEON ITALIA S.p.A, MONZA, ITALY FERRING GmbH, KIEL, GERMANY
Laboratory:FPRC:	FERRING GmbH, KIEL, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING, IRENE, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A39/8.2/0375

Name of medicine: ENOXAPARIN-HEXAL 40 PRE-FILLED SYRINGE

Dosage form: INJECTION

Active ingredients: EACH 0,4 ml SOLUTION CONTAINS:
ENOXAPARIN SODIUM 40,0 mg

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

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

Manufacturer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLIBEN/ORTSTEIL TORNAU, GERMANY

Packer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLIBEN/ORTSTEIL TORNAU, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENCE, KEMPTON PARK
HEXAL PHARMA , PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/8.2/0376

Name of medicine: ENOXAPARIN-HEXAL 60 PRE-FILLED SYRINGE

Dosage form: INJECTION

Active ingredients: EACH 0,6 ml SOLUTION CONTAINS:
ENOXAPARIN SODIUM 60,0 mg

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

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

Manufacturer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLBEN/ORTSTEIL TORNAU, GERMANY

Packer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLBEN/ORTSTEIL TORNAU, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENCE, KEMPTON PARK
HEXAL PHARMA , PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/8.2/0377

Name of medicine: ENOXAPARIN-HEXAL 80 PRE-FILLED SYRINGE

Dosage form: INJECTION

Active ingredients: EACH 0,8 ml SOLUTION CONTAINS:
ENOXAPARIN SODIUM 80,0 mg

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

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

Manufacturer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLIBEN/ORTSTEIL TORNAU, GERMANY

Packer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLIBEN/ORTSTEIL TORNAU, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENURE, KEMPTON PARK
HEXAL PHARMA , PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/8.2/0378

Name of medicine: ENOXAPARIN-HEXAL 100 PRE-FILLED SYRINGE

Dosage form: INJECTION

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

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

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

Manufacturer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLIBEN/ORTSTEIL TORNAU, GERMANY

Packer: IMPFSTOFFWERK DESSAU-TORNAU GmbH,
RODLIBEN/ORTSTEIL TORNAU, GERMANY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, JOHANNESBURG

Laboratory:FPRC: SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: ANALYTICON, TERENCE, KEMPTON PARK
HEXAL PHARMA , PINETOWN, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0379
Name of medicine:	ENOXAPARIN-HEXAL 40 AMPOULES
Dosage form:	INJECTION
Active ingredients:	EACH 0,4 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPfstoffwerk Dessau-Tornau GmbH, Rodleben/Ortsteil Tornau, Germany
Packer:	IMPfstoffwerk Dessau-Tornau GmbH, Rodleben/Ortsteil Tornau, Germany DivPharm Manufacturing & Packaging, Longdale, Johannesburg
Laboratory:FPRC:	SALUTAS PHARMA GmbH, Barleben, Germany Consulting Chemical Laboratories, Star Street, Boksburg, RSA
FPRR:	ANALYTICON, Terenure, Kempton Park HEXAL PHARMA, Pinetown, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/8.2/0380
Name of medicine:	ENOXAPARIN-HEXAL 300 MULTI-DOSE VIAL
Dosage form:	INJECTION
Active ingredients:	EACH 3,0 ml SOLUTION CONTAINS: ENOXAPARIN SODIUM 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	IMPSTOFFWERK DESSAU-TORNAU GmbH, RODLBEN/ORTSTEIL TORNAU, GERMANY
Packer:	IMPSTOFFWERK DESSAU-TORNAU GmbH, RODLBEN/ORTSTEIL TORNAU, GERMANY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG
Laboratory:FPRC:	SALUTAS PHARMA GmbH, BARLEBEN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	ANALYTICON, TERENCE, KEMPTON PARK HEXAL PHARMA , PINETOWN, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/5.7.1/0395
Name of medicine:	ALLERCHLOR 2 mg/5 ml LIQUID
Dosage form:	LIQUID
Active ingredients:	EACH 5,0 ml LIQUID CONTAINS: CHLORPHENAMINE MALEATE 2,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH ASPEN PHARMACARE, WILSONIA, EAST LONDON
Laboratory:FPRC:	SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM ASPEN PHARMACARE, WILSONIA, EAST LONDON
FPRC/FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/34/0412
Name of medicine:	MENOPUR SOLVENT FOR SOLUTION FOR INJECTION
Dosage form:	SOLUTION
Active ingredients:	EACH AMPOULE CONTAINS: WATER FOR INJECTIONS 1,0 ml
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	FERRING (PTY) LTD
Manufacturer:	WEIMAR PHARMA GmbH, RASTATT, GERMANY WULFING PHARMA GmbH, GRONAU, GERMANY
Packer:	WEIMAR PHARMA GmbH, RASTATT, GERMANY WULFING PHARMA GmbH, GRONAU, GERMANY
Laboratory:FPRC:	FERRING GmbH, KIEL, GERMANY CONSULTING CHEMICAL LABORATORIES, ATLASVILLE, BOKSBURG, RSA
FPRR:	FERRING, IRENE, RSA
Shelf-life:	36 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A39/4/0436
Name of medicine:	LIGNOCAINE-HCl B BRAUN 1 % 5 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Laboratory:FPRC:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A39/4/0437

Name of medicine: LIGNOCAINE-HCl B BRAUN 2 % 5 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
LIGNOCAINE HYDROCHLORIDE 20,0 mg

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Packer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Laboratory:FPRC: B BRAUN MELSUNGEN AG, BERLIN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A39/2.7/0440

Name of medicine: ZYDUS-PARACETAMOL 500 mg TABLETS

Dosage form: TABLET

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

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

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

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA

Laboratory:FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,
AHMEDABAD, INDIA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL
SERVICES, SILVERTONDALE, RSA
INSTITUTE FOR INDUSTRIAL PHARMACY,
UNIVERSITY, POTCHEFSTROOM
FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK,
POTCHEFSTROOM

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A39/7.1.3/0531
Name of medicine:	MAVIK 4 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: TRANDOLAPRIL 4,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	ABBOTT LABORATORIES S.A. (PTY) LTD
Manufacturer:	ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY
Packer:	ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY
Laboratory:FPRC: FPRC/FPRR:	ABBOTT GmbH & Co, LUDWIGSHAFEN, GERMANY ABBOTT LABORATORIES, CONSTANTIA KLOOF, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A39/20.2.2/0617

Name of medicine: TRISPORAL

Dosage form: CAPSULE

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

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

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer: JANSSEN PHARMACEUTICA NV, BEERSE,
BELGIUM
JANSSEN PHARMACEUTICA NV, OLEN, BELGIUM
ETHYPHARM INDUSTRIES, CHATEAUNEUF-en-
THYMERAI, FRANCE

Packer: JANSSEN-CILAG SpA, LATINA, ITALY
JANSSEN PHARMACEUTICA, WOODMEAD, RSA

Laboratory:FPRC: JANSSEN PHARMACEUTICA NV, BEERSE,
BELGIUM
FPRR: JANSSEN PHARMACEUTICA, WOODMEAD, RSA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/28/0001

Name of medicine: PRIMOVIST 5 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
GADOXETIC ACID 181,43 mg

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

Applicant: SCHERING (PTY) LTD

Manufacturer: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY

Packer: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY

Laboratory:FPRC: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY
SOUTH AFRICAN BUREUA OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: SCHERING, RANDJES PARK, MIDRAND

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/28/0002

Name of medicine: PRIMOVIST 7,5 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
GADOXETIC ACID 181,43 mg

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

Applicant: SCHERING (PTY) LTD

Manufacturer: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY

Packer: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY

Laboratory:FPRC: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY
SOUTH AFRICAN BUREUA OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: SCHERING, RANDJESPARK, MIDRAND

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/28/0003

Name of medicine: PRIMOVIST 10 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
GADOXETIC ACID 181,43 mg

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

Applicant: SCHERING (PTY) LTD

Manufacturer: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY

Packer: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY

Laboratory:FPRC: SCHERING AG CHARLOTTENBURG, BERLIN,
GERMANY
SCHERING AG WEDDING, BERLIN, GERMANY
SOUTH AFRICAN BUREUA OF STANDARDS,
GROENKLOOF, PRETORIA
FPRR: SCHERING, RANDJES PARK, MIDRAND

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A40/2.5/0158
Name of medicine:	EPLEPTIN 100 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 100,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Packer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Laboratory:FPRC:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
FPRR:	CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number:	A40/2.5/0159
Name of medicine:	EPLEPTIN 300 mg
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: GABAPENTIN 300,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	PHARMAPLAN (PTY) LTD
Manufacturer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Packer:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA
Laboratory:FPRC:	MJ PHARMACEUTICALS LTD, PANCHMAHAL, GUJARAT, INDIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	PHARMAPLAN, MIDRAND, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A40/2.5/0160

Name of medicine: EPLEPTIN 400 mg

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
GABAPENTIN 400,0 mg

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

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: MJ PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA

Packer: MJ PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA

Laboratory:FPRC: MJ PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months (provisional)

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.1/0212
Name of medicine:	SANDOZ CEFUROXIME 125 mg/5 ml
Dosage form:	SUSPENSION
Active ingredients:	EACH 5,0 ml SUSPENSION CONTAINS: CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 125,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	GfM GESELLSCHAFT FÜR MIKRONISIERUNG GmbH, BREMEN, GERMANY PENCEF PHARMA GmbH, GOTTINGEN, GERMANY
Packer:	PENCEF PHARMA GmbH, GOTTINGEN, GERMANY NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	PENCEF PHARMA GmbH, GOTTINGEN, GERMANY NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A40/7.1/0283

Name of medicine: KLODIP-5

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

Applicant: DEZZO TRADING (PTY) LTD t/a INDO PHARMA

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory:FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG, RSA
FPRR: DEZZO TRADING, ANCHORVILLE,
LENASIA, JOHANNESBURG, RSA

Shelf-life: 24 months (provisional)

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/21.12/0304

Name of medicine: BICADEX

Dosage form: TABLET

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

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

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, VIRGONAR, BANGALORE, INDIA
CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA

Packer: CIPLA LTD, VIRGONAR, BANGALORE, INDIA
CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA

Laboratory:FPRC: CIPLA LTD, VIRGONAR, BANGALORE, INDIA
CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE

Shelf-life: 24 months (provisional)

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/21.12/0305

Name of medicine: CIPLA-BICALUTAMIDE

Dosage form: TABLET

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

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, VIRGONAR, BANGALORE, INDIA
CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA

Packer: CIPLA LTD, VIRGONAR, BANGALORE, INDIA
CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA

Laboratory:FPRC: CIPLA LTD, VIRGONAR, BANGALORE, INDIA
CIPLA LTD, UNIT VI, SALCETTE, GOA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE

Shelf-life: 24 months (provisional)

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/20.1.2/0331

Name of medicine: AMYN 250

Dosage form: CAPSULE

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

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

Applicant: DEZZO TRADING (PTY) LTD t/a INDO PHARMA

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory:FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
FPRR: DEZZO TRADING, ANCHORVILLE, LENASIA,
JOHANNESBURG, RSA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/20.1.2/0332

Name of medicine: AMYN 500

Dosage form: CAPSULE

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

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

Applicant: DEZZO TRADING (PTY) LTD t/a INDO PHARMA

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory:FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
FPRR: DEZZO TRADING, ANCHORVILLE, LENASIA,
JOHANNESBURG, RSA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A40/7.5/0397
Name of medicine:	CIPLA-SIMVASTATIN 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: SIMVASTATIN 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	CIPLA LIFE SCIENCES (PTY) LTD
Manufacturer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Packer:	CIPLA LTD, KURKUMBH, PUNE, INDIA
Laboratory:FPRC: FPRR:	CIPLA LTD, KURKUMBH, PUNE, INDIA CIPLA LIFE SCIENCES, ROSENPARK, BELLVILE
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A40/7.5/0398

Name of medicine: CIPLA-SIMVASTATIN 20

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
SIMVASTATIN 20,0 mg

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

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, KURKUMBH, PUNE, INDIA

Packer: CIPLA LTD, KURKUMBH, PUNE, INDIA

Laboratory:FPRC: CIPLA LTD, KURKUMBH, PUNE, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILE

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/26/0416

Name of medicine: MABCAMPATH 30 mg/ml

Dosage form: SOLUTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
ALEMTUZUMAB 30,0 mg

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

Applicant: SCHERING (PTY) LTD

Manufacturer: BOEHRINGER INGELHEIM PHARMA GmbH,
BIBERACH AN DER RISS, GERMANY

Packer: BOEHRINGER INGELHEIM PHARMA GmbH,
BIBERACH AN DER RISS, GERMANY
SCHERING AG, BERLIN, GERMANY

Laboratory:FPRC: BOEHRINGER INGELHEIM PHARMA GmbH,
BIBERACH AN DER RISS, GERMANY
SCHERING AG, BERLIN, GERMANY
FPRR: SCHERING, RANDJESPAK, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: A40/20.1.1/0525

Name of medicine: SANDOZ LEVOFLOXACIN 250

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LEVÓFLOXACIN HEMIHYDRATE EQUIVALENT TO
LEVÓFLOXACIN 250,0 mg

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

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK PHARMACEUTICALS d.d., VEROVSKOVA,
SLOVENIA

Packer: LEK PHARMACEUTICALS d.d., VEROVSKOVA,
SLOVENIA
NOVARTIS, SPARTAN, KEMPTON PARK

Laboratory:FPRC: LEK PHARMACEUTICALS d.d., VEROVSKOVA,
SLOVENIA
NOVARTIS, SPARTAN, KEMPTON PARK
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA

FPRR: SANDOZ, SPARTAN, KEMPTON PAR

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A40/20.1.1/0526
Name of medicine:	SANDOZ LEVOFLOXACIN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO LEVOFLOXACIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	SANDOZ (PTY) LTD
Manufacturer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA
Packer:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK
Laboratory:FPRC:	LEK PHARMACEUTICALS d.d., VEROVSKOVA, SLOVENIA NOVARTIS, SPARTAN, KEMPTON PARK SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA
FPRR:	SANDOZ, SPARTAN, KEMPTON PARK
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A40/20.2.8/0531

Name of medicine: AURO-STAVUDINE CAPSULES 30 mg

Dosage form: CAPSULES

Active ingredients: EACH CAPSULE CONTAINS:
STAVUDINE 30,0 mg

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

Applicant: AUROBINDO PHARMA (PTY) LTD

Manufacturer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Packer: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA

Laboratory:FPRC: AUROBINDO PHARMA LTD, ANDHRA PRADESH,
INDIA
FPRR: AUROBINDO PHARMA, ROSEBANK,
JOHANNESBURG, RSA

Shelf-life: 24 months (provisional)

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	A40/20.2.8/0532
Name of medicine:	AURO-STAVUDINE CAPSULES 40 mg
Dosage form:	CAPSULES
Active ingredients:	EACH CAPSULE CONTAINS: STAVUDINE 40,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	AUROBINDO PHARMA (PTY) LTD
Manufacturer:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
Packer:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
Laboratory:FPRC:	AUROBINDO PHARMA LTD, ANDHRA PRADESH, INDIA
FPRR:	AUROBINDO PHARMA, ROSEBANK, JOHANNESBURG, RSA
Shelf-life:	24 months (provisional)
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: A40/20.1.2/0563

Name of medicine: AMYN S 250

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 250,0 mg

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

Applicant: DEZZO TRADING (PTY) LTD t/a INDO PHARMA

Manufacturer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Packer: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA

Laboratory:FPRC: KOPRAN LTD, KHALAPUR, RAIGAD, INDIA
CONSULTING CHEMICAL LABORATORIES,
ATLASVILLE, BOKSBURG, RSA
FPRR: DEZZO TRADING, LENASIA, JOHANNESBURG

Shelf-life: 24 months (provisional)

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number:	41/4/0063
Name of medicine:	LIGNOCAINE-HCl B BRAUN 1 % 10 ml
Dosage form:	INJECTION
Active ingredients:	EACH 1,0 ml SOLUTION CONTAINS: LIGNOCAINE HYDROCHLORIDE 10,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6
Applicant:	B BRAUN MEDICAL (PTY) LTD
Manufacturer:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Packer:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY
Laboratory:FPRC:	B BRAUN MELSUNGEN AG, BERLIN, GERMANY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
FPRR:	B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA
Shelf-life:	24 months
Date of registration:	6 OCTOBER 2006

MRF 15

Registration number: 41/4/0064

Name of medicine: LIGNOCAINE-HCl B BRAUN 1 % 20 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
LIGNOCAINE HYDROCHLORIDE 10,0 mg

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Packer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Laboratory:FPRC: B BRAUN MELSUNGEN AG, BERLIN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 41/4/0065

Name of medicine: LIGNOCAINE-HCl B BRAUN 2 % 10 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
LIGNOCAINE HYDROCHLORIDE 20,0 mg

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Packer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Laboratory:FPRC: B BRAUN MELSUNGEN AG, BERLIN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA

Shelf-life: 24 months

Date of registration: 6 OCTOBER 2006

MRF 15

Registration number: 41/4/0066

Name of medicine: LIGNOCAINE-HCl B BRAUN 2 % 20 ml

Dosage form: INJECTION

Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:
LIGNOCAINE HYDROCHLORIDE 20,0 mg

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

Applicant: B BRAUN MEDICAL (PTY) LTD

Manufacturer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Packer: B BRAUN MELSUNGEN AG, BERLIN, GERMANY

Laboratory:FPRC: B BRAUN MELSUNGEN AG, BERLIN, GERMANY
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA

FPRR: B BRAUN MEDICAL, HONEYDEW, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 6 OCTOBER 2006
