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REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1278 OF 2004

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 1278 VAN 2004

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 goedgedink 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. Bemarking 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.

MBR 15

Registration number/Registrasienommer: 34/10.1/0282 .

Name of medicine/Naam van medisyne: BENYLIN CHILDREN'S

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml LIQUID CONTAINS/ELKE 5,0 ml VLOEISTOF BEVAT:
AMMONIUM CHLORIDE 125,0 mg
DIPHENHYDRAMINE HYDROCHLORIDE 12,5 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: WARNER-LAMBERT SA (PTY) LTD

Manufacturer/Vervaardiger: WARNER-LAMBERT SA, RETREAT, RSA

Packer/Verpakker: WARNER-LAMBERT SA, RETREAT, RSA

Laboratory/Laboratorium: WARNER-LAMBERT SA, RETREAT, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 FEBRUARY 2004
Datum van registrasie 6 FEBRUARIE 2004

MBR 15

Registration number/Registrasienommer: 33/34/0201

Name of medicine/Naam van medisyne: CELLCEPT I.V.

Dosage form/Doseringsvorm: INFUSION (PARENTERAL)/
INFUSIE(PARENTERAAL)

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
MYCOPHENOLATE MOFETIL 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: PARKEDALE PHARMACEUTICALS,
ROCHESTER, M.I., USA

Packer/Verpakker: PARKEDALE PHARMACEUTICALS,
ROCHESTER, M.I., USA
F.HOFFMANN-LA ROCHE, KAISERGAUGST,
SWITZERLAND
ROCHE PRODUCTS, ISANDO, RSA

Laboratory/Laboratorium: PARKEDALE PHARMACEUTICALS,
ROCHESTER, M.I., USA
F.HOFFMANN-LA ROCHE, BASEL,
SWITZERLAND
ROCHE PRODUCTS, ISANDO, RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 2 APRIL 2004
Datum van registrasie 2 APRIL 2004

MBR 15

Registration number/Registrasienommer: 32/2.6.5/0584

Name of medicine/Naam van medisyne: GEODON 20 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ZIPRASIDONE HYDROCHLORIDE MONOHYDRATE EQUIVALENT TO ZIPRASIDONE 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY

Packer/Verpakker: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LTD, SANDWICH, KENT U.K.
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Laboratory/Laboratorium: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 2 APRIL 2004
Datum van registrasie 2 APRIL 2004

MBR 15

Registration number/Registrasienommer: 32/2.6.5/0585

Name of medicine/Naam van medisyne: GEODON 40 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ZIPRASIDONE HYDROCHLORIDE MONOHYDRATE EQUIVALENT TO
ZIPRASIDONE 40,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY

Packer/Verpakker: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LTD, SANDWICH, KENT U.K.
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Laboratory/Laboratorium: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 2 APRIL 2004
Datum van registrasie 2 APRIL 2004

MBR 15

Registration number/Registrasienommer: 32/2.6.5/0586

Name of medicine/Naam van medisyne: GEODON 60 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ZIPRASIDONE HYDROCHLORIDE MONOHYDRATE EQUIVALENT TO
ZIPRASIDONE 60,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY

Packer/Verpakker: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LTD, SANDWICH, KENT U.K.
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Laboratory/Laboratorium: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 2 APRIL 2004
Datum van registrasie 2 APRIL 2004

MBR 15

Registration number/Registrasienommer: 32/2.6.5/0587

Name of medicine/Naam van medisyne: GEODON 80 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ZIPRASIDONE HYDROCHLORIDE MONOHYDRATE EQUIVALENT TO
ZIPRASIDONE 80,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY

Packer/Verpakker: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LTD, SANDWICH, KENT U.K.
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Laboratory/Laboratorium: HEINRICH MACK NACHF.,ILLERTISSEN, GERMANY
PFIZER LABORATORIES, PIETERMARITZBURG, RSA
WARNER-LAMBERT, RETREAT, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 2 APRIL 2004
Datum van registrasie 2 APRIL 2004

MBR 15

Registration number/Registrasienommer: 34/30.1/0510

Name of medicine/Naam van medisyne: Td POLIO

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml DOSE CONTAINS/ELKE 0,5 ml DOSIS BEVAT:

DIPHTHERIA TOXOID	2,0 iu
INACTIVATED POLIOMYELITIS VACCINE	0,1 ml
TETANUS TOXOID	20,0 iu

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: RHONE-POULENC RORER SA (PTY) LTD

Manufacturer/Vervaardiger: PASTEUR MERIEUX SERUMS & VACCINES, MARCY L'ETOILE, FRANCE
PASTEUR MERIEUX SERUMS & VACCINES, VAL DE REUIL, FRANCE

Packer/Verpakker: PASTEUR MERIEUX SERUMS & VACCINES, MARCY L'ETOILE, FRANCE
PASTEUR MERIEUX SERUMS & VACCINES, VAL DE REUIL, FRANCE

Laboratory/Laboratorium: PASTEUR MERIEUX SERUMS & VACCINES, MARCY L'ETOILE, FRANCE
PASTEUR MERIEUX SERUMS & VACCINES, VAL DE REUIL, FRANCE
RHONE-POULENC RORER SA, HOLLARD PARK, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 2 APRIL 2004
Datum van registrasie 2 APRIL 2004

MBR 15

Registration number/Registrasienommer: 33/7.1/0113

Name of medicine/Naam van medisyne: ZANIDIP 10

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
LERCANIDIPINE HYDROCHLORIDE 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: RECORDATI INDUSTRIA CHEMICA E FARMACEUTICA SPA, MILAN, ITALY

Packer/Verpakker: RECORDATI INDUSTRIA CHEMICA E FARMACEUTICA SPA, MILAN, ITALY

Laboratory/Laboratorium: RECORDATI INDUSTRIA CHEMICA E FARMACEUTICA SPA, MILAN, ITALY
CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 2 APRIL 2004
Datum van registrasie 2 APRIL 2004

MBR 15

Registration number/Registrasienommer: 37/5.7.1/0034

Name of medicine/Naam van medisyne: ALLECET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CETIRIZINE DIHYDROCHLORIDE 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer/Vervaardiger:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Packer/Verpakker:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA
Laboratory/Laboratorium:	CIPLA LTD, PATALGANGA, MAHARASHTRA, INDIA CIPLA LIFE SCIENCES, ROSENPARK, RSA
Shelf-life/Rakleeftyd:	18 months/maande
Date of registration: Datum van registrasie	7 MAY 2004 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/5.7.1/0153

Name of medicine/Naam van medisyne: ALLECET SYRUP

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT:
CETIRIZINE DIHYDROCHLORIDE 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, SATARA, INDIA

Packer/Verpakker: CIPLA LTD, SATARA, INDIA

Laboratory/Laboratorium: CIPLA LTD, SATARA, INDIA
CIPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/26/0255

Name of medicine/Naam van medisyne: ANZATAX 30 MG/5 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
PACLITAXEL 6,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: F.H. FAULDING & CO LTD, VICTORIA, AUSTRALIA

Packer/Verpakker: F.H. FAULDING & CO LTD, VICTORIA, AUSTRALIA

Laboratory/Laboratorium: F.H. FAULDING & CO LTD, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG RSA
PHARMAPLAN, MIDRAND, JOHANNESBURG,RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/26/0256

Name of medicine/Naam van medisyne: ANZATAX 150 MG/25 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
PACLITAXEL 6,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: F.H. FAULDING & CO LTD, VICTORIA, AUSTRALIA

Packer/Verpakker: F.H. FAULDING & CO LTD, VICTORIA, AUSTRALIA

Laboratory/Laboratorium: F.H. FAULDING & CO LTD, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG RSA
PHARMAPLAN, MIDRAND, JOHANNESBURG,RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.2.8/0442

Name of medicine/Naam van medisyne: ASPEN DIDANOSINE 25 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DIDANOSINE 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, KORSTEN, PORT ELIZABETH

Packer/Verpakker: LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory/Laboratorium: LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA
PHARMACARE LTD, KORSTEN, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.2.8/0445

Name of medicine/Naam van medisyne: ASPEN DIDANOSINE 150 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DIDANOSINE 150,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, KORSTEN, PORT ELIZABETH

Packer/Verpakker: LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory/Laboratorium: LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA
PHARMACARE LTD, KORSTEN, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.2.8/0443

Name of medicine/Naam van medisyne: ASPEN DIDANOSINE 50 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DIDANOSINE 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, KORSTEN, PORT ELIZABETH

Packer/Verpakker: LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory/Laboratorium: LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA
PHARMACARE LTD, KORSTEN, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.2.8/0444

Name of medicine/Naam van medisyne: ASPEN DIDANOSINE 100 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DIDANOSINE 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, KORSTEN, PORT ELIZABETH

Packer/Verpakker: LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory/Laboratorium: LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, POTCHEFSTROOM, RSA
PHARMACARE LTD, KORSTEN, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/3.1/0452

Name of medicine/Naam van medisyne: BEXTRA 40

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
VALDECOXIB 40,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: SEARLE LTD, CAGUAS, PUERTO RICO

Packer/Verpakker: SEARLE, DIV. OF MONSANTO,
NORTHUMBERLAND, ENGLAND
HEINRICH MACK NACHF, ILLERTISSEN,GERMANY

Laboratory/Laboratorium: SEARLE LTD, CAGUAS, PUERTO RICO
SEARLE, DIV. OF MONSANTO,
NORTHUMBERLAND, ENGLAND
HEINRICH MACK NACHF, ILLERTISSEN,GERMANY
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA
PHARMACIA SA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/3.1/0450

Name of medicine/Naam van medisyne: BEXTRA 10

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
VALDECOXIB 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: SEARLE LTD, CAGUAS, PUERTO RICO

Packer/Verpakker: SEARLE, DIV. OF MONSANTO,
NORTHUMBERLAND, ENGLAND
HEINRICH MACK NACHF, ILLERTISSEN,GERMANY

Laboratory/Laboratorium: SEARLE LTD, CAGUAS, PUERTO RICO
SEARLE, DIV. OF MONSANTO,
NORTHUMBERLAND, ENGLAND
HEINRICH MACK NACHF, ILLERTISSEN,GERMANY
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA
PHARMACIA SA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/3.1/0451

Name of medicine/Naam van medisyne: BEXTRA 20

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
VALDECOXIB 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: SEARLE LTD, CAGUAS, PUERTO RICO

Packer/Verpakker: SEARLE, DIV. OF MONSANTO,
NORTHUMBERLAND, ENGLAND
HEINRICH MACK NACHF, ILLERTISSEN,GERMANY

Laboratory/Laboratorium: SEARLE LTD, CAGUAS, PUERTO RICO
SEARLE, DIV. OF MONSANTO,
NORTHUMBERLAND, ENGLAND
HEINRICH MACK NACHF, ILLERTISSEN,GERMANY
KHULULEKANI LABORATORY SERVICES,
MIDRAND, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA, RSA
PHARMACIA SA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/3/0455

Name of medicine/Naam van medisyne: CELOFTAL

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
HYPROMELLOSE 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: ALCON LABORATORIES (SA) (PTY) LTD

Manufacturer/Vervaardiger: ALCON COUVREUR, PUURS, BELGIUM

Packer/Verpakker: ALCON COUVREUR, PUURS, BELGIUM

Laboratory/Laboratorium: ALCON COUVREUR, PUURS, BELGIUM
ALCON LABORATORIES INC., FORT WORTH, TEXAS, USA
ALCON LABORATORIES, RANDBURG, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.2.8/0338

Name of medicine/Naam van medisyne: COMBIVIR POST-HIV EXPOSURE PROPHYLAXIS STARTER PACK

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:

LAMIVUDINE	150,0 mg
ZIDOVUDINE	300,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: GLAXOSMITHKLINE SOUTH AFRICA (PTY) LIMITED

Manufacturer/Vervaardiger:	GLAXO WELLCOME OPERATIONS, HERTFORDSHIRE, U.K.
Packer/Verpakker:	GLAXO WELLCOME OPERATIONS, HERTFORDSHIRE, U.K. GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN, RSA
Laboratory/Laboratorium:	GLAXO WELLCOME OPERATIONS, HERTFORDSHIRE, U.K. GLAXOSMITHKLINE S.A., EPPING, CAPE TOWN, RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	7 MAY 2004 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 35/7.1.3/0399

Name of medicine/Naam van medisyne: EQUI-MENOGLO DROPS

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 0,50 ml DROPS CONTAIN/ELKE 0,50 ml DRUPPELS BEVAT:
CLONIDINE HYDROCHLORIDE 25,0 ug

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: EQUITY PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: WRAPSA MANUFACTURING & PACKAGING, CENTURION, RSA

Packer/Verpakker: WRAPSA MANUFACTURING & PACKAGING, CENTURION, RSA

Laboratory/Laboratorium: WRAPSA MANUFACTURING & PACKAGING, CENTURION, RSA
EQUITY PHARMACEUTICALS, PRETORIA, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 35/8.2/0162

Name of medicine/Naam van medisyne: FRAGMIN 7 500 IU/0,3 ML

Dosage form/Doseringsvorm: INJECTIONINSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,3 ml SOLUTION CONTAINS/ELKE 0,3 ml OPLOSSING BEVAT:
DALTEPARIN SODIUM 7 500,00 iu

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger:	VETTER PHARMA-FERTIGUNG, SCHUTZEN-STRASSE, RAVENSBURG, GERMANY
Packer/Verpakker:	VETTER PHARMA-FERTIGUNG, HOLBEIN-STRASSE, RAVENSBURG, GERMANY
Laboratory/Laboratorium:	VETTER PHARMA-FERTIGUNG, SCHUTZEN-STRASSE, RAVENSBURG, GERMANY PHARMACIA & UPJOHN, STOCKHOLM, SWEDEN PHARMACIA & UPJOHN, PUURS, BELGIUM SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA KHULULEKANI LABORATORY SERVICES, MIDRAND, RSA PHARMACIA, MIDRAND, RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	7 MAY 2004 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 35/7.1/0231

Name of medicine/Naam van medisyne: HEXAL-FELODIPINE 10

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
FELODIPINE 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer/Vervaardiger: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer/Verpakker: DIVPHARM CC, LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA

Laboratory/Laboratorium: HEXAL AG, HOLZKIRCHEN, GERMANY
CONSULTING CHEMICAL LAB, STAR STREET, BOKSBURG, RSA
ANALYTICON CC, KEMPTON PARK, RSA
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/7.1/0303

Name of medicine/Naam van medisyne: HEXAL-FELODIPINE 5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
FELODIPINE 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: HEXAL PHARMA (SA) (PTY) LTD

Manufacturer/Vervaardiger: HEXAL AG, HOLZKIRCHEN, GERMANY

Packer/Verpakker: DIVPHARM CC, LONGDALE, RSA
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA

Laboratory/Laboratorium: HEXAL AG, HOLZKIRCHEN, GERMANY
CONSULTING CHEMICAL LAB, STAR STREET, BOKSBURG, RSA
ANALYTICON CC, KEMPTON PARK, RSA
PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG, RSA
HEXAL PHARMA, WESTMEAD, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/2.2/0540

Name of medicine/Naam van medisyne: IVEDAL

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ZOLPIDEM TARTRATE 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: SANOFI-SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger:	SANOFI WINTHROP INDUSTRIE, GUSTAVE EIFFEL, TOURS, FRANCE
Packer/Verpakker:	SANOFI WINTHROP INDUSTRIE, GUSTAVE EIFFFEL, TOURS, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA, RSA PHARMACEUTICAL CONTRACTORS, ISANDO,RSA
Laboratory/Laboratorium:	SANOFI WINTHROP INDUSTRIE, GUSTAVE EIFFEL, TOURS, FRANCE AVENTIS PHARMA, WALTLOO, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA SANOFI-SYNTHELABO, WOODMEAD, RSA
Shelf-life/Rakleeftyd:	48 months/maande
Date of registration: Datum van registrasie	7 MAY 2004 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 35/2.5/0143

Name of medicine/Naam van medisyne: LAMETEC

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LAMOTRIGINE 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, PUNA, MAHARASHTRA, INDIA

Packer/Verpakker: CIPLA LTD, PUNA, MAHARASHTRA, INDIA

Laboratory/Laboratorium: CIPLA LTD, PUNA, MAHARASHTRA, INDIA
CIPLA-MEDPRO, ROSENPARK, BELLVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/20.1.1/0331

Name of medicine/Naam van medisyne: LILLY-VANCOMYCIN CP 500 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
VANCOMYCIN HYDROCHLORIDE EQUIVALENT TO
VANCOMYCIN 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: ELI LILLY (SA) (PTY) LTD

Manufacturer/Vervaardiger: ELI LILLY & CO, INDIANAPOLIS, INDIANA,USA
ELI LILLY & CO, GREENFIELD, INDIANA,USA

Packer/Verpakker: ELI LILLY & CO, INDIANAPOLIS, INDIANA,USA
ELI LILLY & CO, GREENFIELD, INDIANA,USA

Laboratory/Laboratorium: ELI LILLY & CO, INDIANAPOLIS, INDIANA,USA
ELI LILLY & CO, GREENFIELD, INDIANA,USA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
CONSULTING CHEMICAL LAB, STAR STREET, BOKSBURG, RSA
CONSULTING MICHROBIOLOGICAL LAB, BLUEGUM CREEK, BENONI, RSA
ELI LILLY, BRYANSTON, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/20.1.1/0332

Name of medicine/Naam van medisyne: LILLY-VANCOMYCIN CP 1 G

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
VANCOMYCIN HYDROCHLORIDE EQUIVALENT TO
VANCOMYCIN 1,0 g

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: ELI LILLY (SA) (PTY) LTD

Manufacturer/Vervaardiger: ELI LILLY & CO, INDIANAPOLIS, INDIANA,USA
ELI LILLY & CO, GREENFIELD, INDIANA,USA

Packer/Verpakker: ELI LILLY & CO, INDIANAPOLIS, INDIANA,USA
ELI LILLY & CO, GREENFIELD, INDIANA,USA

Laboratory/Laboratorium: ELI LILLY & CO, INDIANAPOLIS, INDIANA,USA
ELI LILLY & CO, GREENFIELD, INDIANA,USA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
CONSULTING CHEMICAL LAB, STAR STREET, BOKSBURG, RSA
CONSULTING MICHROBIOLOGICAL LAB, BLUEGUM CREEK, BENONI, RSA
ELI LILLY, BRYANSTON, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.1.1/0384

Name of medicine/Naam van medisyne: MEDAXIME 250

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: SPECPHARM (PTY) LTD

Manufacturer/Vervaardiger: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer/Verpakker: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Laboratory/Laboratorium: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
SPECPHARM, RANDBURG, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.1.1/0385

Name of medicine/Naam van medisyne: MEDAXIME 750

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 750,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: SPECPHARM (PTY) LTD

Manufacturer/Vervaardiger: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer/Verpakker: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Laboratory/Laboratorium: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
SPECPHARM, RANDBURG, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.1.1/0386

Name of medicine/Naam van medisyne: MEDAXIME 1,5

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFUROXIME SODIUM EQUIVALENT TO CEFUROXIME 1,5 g

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: SPECPHARM (PTY) LTD

Manufacturer/Vervaardiger: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Packer/Verpakker: MEDOCHEMIE LTD, LIMASSOL, CYPRUS

Laboratory/Laboratorium: MEDOCHEMIE LTD, LIMASSOL, CYPRUS
SPECPHARM, RANDBURG, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/21.8.2/0541

Name of medicine/Naam van medisyne: MIRANOVA

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:

ETHINYLESTRADIOL	0,02 mg
LEVONORGESTREL	0,1 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: SCHERING GmbH & CO PRODUCTIONS, WEIMAR, GERMANY

Packer/Verpakker: SCHERING GmbH & CO PRODUCTIONS, WEIMAR, GERMANY
SCHERING AG, BERLIN, GERMANY

Laboratory/Laboratorium: SCHERING GmbH & CO PRODUCTIONS, WEIMAR, GERMANY
SCHERING AG, BERLIN, GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
SCHERING, MIDRAND, RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/21.8.2/0212

Name of medicine/Naam van medisyne: PLAN B

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LEVONORGESTREL 0,75 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: ELTTAB PHARMACEUTICALS CC

Manufacturer/Vervaardiger: CHEMICAL WORKS OF GEDEON RICHTER, BUDAPEST, HUNGARY

Packer/Verpakker: CHEMICAL WORKS OF GEDEON RICHTER, BUDAPEST, HUNGARY

Laboratory/Laboratorium: CHEMICAL WORKS OF GEDEON RICHTER, BUDAPEST, HUNGARY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA, RSA
ELTTAB PHARMACEUTICALS, SOMERSET WEST, RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/1.2/0040

Name of medicine/Naam van medisyne: RITAPHEN SR

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
METHYLPHENIDATE HYDROCHLORIDE 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: DANBURY PHARMACAL, CARMEL, NEW YORK, USA

Packer/Verpakker: DANBURY PHARMACAL, CARMEL, NEW YORK, USA
DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, JOHANNESBURG, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA

Laboratory/Laboratorium: DANBURY PHARMACAL, CARMEL, NEW YORK, USA
INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES BOKSBURG, RSA
TRIOMED, MONTAGUE GARDENS, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 37/20.2.8/0628

Name of medicine/Naam van medisyne: STOCRIN 600

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
EFAVIRENZ 600,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: MSD (PTY) LTD

Manufacturer/Vervaardiger: BRISTOL MYERS SQUIBB PHARMA, GARDEN CITY NEW YORK, USA

Packer/Verpakker: BRISTOL MYERS SQUIBB PHARMA, GARDEN CITY NEW YORK, USA
MSD, HALFWAY HOUSE, RSA

Laboratory/Laboratorium: BRISTOL MYERS SQUIBB PHARMA, GARDEN CITY NEW YORK, USA
MSD, HALFWAY HOUSE, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/26/0341

Name of medicine/Naam van medisyne: VINORELBINE PIERRE FABRE 10

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: TECHNIKON LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE

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

Laboratory/Laboratorium: PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
KQATSA, PRETORIA, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/26/0342

Name of medicine/Naam van medisyne: VINORELBINE PIERRE FABRE 50

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT:
VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: TECHNIKON LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE

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

Laboratory/Laboratorium: PIERRE FABRE MEDICAMENT PRODUCTION, IDRON, FRANCE
KQATSA, PRETORIA, RSA
TECHNIKON LABORATORIES, FLORIDA, RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 7 MAY 2004
Datum van registrasie 7 MEI 2004

MBR 15

Registration number/Registrasienommer: 36/3.1/0025

Name of medicine/Naam van medisyne: VOLTAREN ACTI-GO 12,5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
DICLOFENAC POTASSIUM 12,5 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger:	NOVARTIS FARMACEUTICA S.A., BARCELONA, SPAIN
Packer/Verpakker:	NOVARTIS FARMACEUTICA S.A., BARCELONA, SPAIN NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Laboratory/Laboratorium:	NOVARTIS FARMACEUTICA S.A., BARCELONA, SPAIN NOVARTIS, SPARTAN, KEMPTON PARK, RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	7 MAY 2004 7 MEI 2004


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