Government Gazette

REPUBLIC OF SOUTH AFRICA

Vol. 457 Pretoria 18 July 2003 No. 25200

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

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1893 OF 2003

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 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 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.

Registration number/Registrasienommer: 36/2.5/0409

Name of medicine/Naam van medisyne: TRILEPTAL ORAL SUSPENSION

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :
OXCARBAZEPINE 300,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, HUNINGUE FRANCE

Packer/Verpakker: NOVARTIS, HUNINGUE FRANCE

Laboratory/Laboratorium: NOVARTIS, HUNINGUE FRANCE
INSPECTORATE M & L, ORMONDE RSA
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/5.4/0448

Name of medicine/Naam van medisyne: DETRUSITOL SR 2 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
TOLTERODINE L-TARTRATE 2,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: INTERNATIONAL PROCES CORP, WINCHESTER KENTUCKY USA

Packer/Verpakker: ANDERSON PACKAGING, ILLINOIS, USA
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY
PHARMACIA & UPJOHN, MICHIGAN U.S.A

Laboratory/Laboratorium: KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY
PHARMACIA & UPJOHN, MICHIGAN U.S.A
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/5.4/0449

Name of medicine/Naam van medisyne: DETRUSITOL SR 4 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
TOLTERODINE L-TARTRATE 4,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7
Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: INTERNATIONAL PROCES CORP, WINCHESTER KENTUCKY USA

Packer/Verpakker: ANDERSON PACKAGING, ILLINOIS, USA
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY
PHARMACIA & UPJOHN, MICHIGAN U.S.A

Laboratory/Laboratorium: KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY
PHARMACIA & UPJOHN, MICHIGAN U.S.A
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/20.2.2/0453

Name of medicine/Naam van medisyne: AMBISOME

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

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
AMPHOTERICIN B 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7, 8

Applicant/Applikant: KEY ONCOLOGICS (PTY) LTD

Manufacturer/Vervaardiger: GENSIASICOR PHARMACEUTICALS, IRVINE, CALIFORNIA USA
GILEAD SCIENCES, SAN DIMAS, CALIFORNIA USA
MEDIMMUNE PHARMA BV, NIJMEGEN, NETHERLANDS

Packer/Verpakker: GENSIASICOR PHARMACEUTICALS, IRVINE, CALIFORNIA USA
GILEAD SCIENCES, SAN DIMAS, CALIFORNIA USA
GILEAD SCIENCES, BLACKROCK, DUBLIN IRELAND
MEDIMMUNE PHARMA BV, NIJMEGEN, NETHERLANDS

Laboratory/Laboratorium: GILEAD SCIENCES, SAN DIMAS, CALIFORNIA USA
GILEAD SCIENCES, BLACKROCK, DUBLIN IRELAND
KEY ONCOLOGICS, SANDTON RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/34/0484

Name of medicine/Naam van medisyne: COMBIBIC SH-EL 00

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1000,0 ml SOLUTION CONTAINS/ELKE 1000,0 ml OPLOSSING BEVAT:

CALCIUM CHLORIDE	1,98 g
GLUCOSE	9,0 g
MAGNESIUM CHLORIDE HEXAHYDRATE	0,91 g
SODIUM CHLORIDE	4,21 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: B BRAUN MEDICAL (PTY) LTD

Manufacturer/Vervaardiger: B BRAUN SCHIWA, GLANDORF GERMANY

Packer/Verpakker: B BRAUN SCHIWA, GLANDORF GERMANY

Laboratory/Laboratorium: B BRAUN SCHIWA, GLANDORF GERMANY
INSPECTORATE M & L, ORMONDE RSA
B BRAUN MEDICAL, RANDBURG RSA

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 37/7.1.3/0020

Name of medicine/Naam van medisyne: EGIS PERINDOPRIL 4 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
PERINDOPRIL 4,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: EGIS PHARMACEUTICALS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: LES LABORATOIRES SERVIER IND. FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND

Packer/Verpakker: LES LABORATOIRES SERVIER IND. FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND
TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: LES LABORATOIRES SERVIER IND. FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND
INSPECTORATE M & L, ORMONDE RSA
EGIS PHARMACEUTICALS, ROBERTVILLE, RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 37/7.1.3/0021

Name of medicine/Naam van medisyne: BIOGARAN PERINDOPRIL 4 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
PERINDOPRIL 4,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: LES LABORATOIRES SERVIER IND. FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND

Packer/Verpakker: LES LABORATOIRES SERVIER IND. FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND
TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: LES LABORATOIRES SERVIER IND. FLEURY-LES-AUBRAIS FRANCE
SERVIER, WICKLOW, IRELAND
INSPECTORATE M & L, ORMONDE RSA
BIOGARAN SA, RIVONIA RSA

Shelf-life/Rakleeftyd: 48 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 37/21.5.1/0022

Name of medicine/Naam van medisyne: CIPLA-PREDNISOLONE 15 MG/5 ML

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT :
PREDNISOLONE 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger:	MEDIORALS LABORATORIES, MAHARASHTRA INDIA
Packer/Verpakker:	MEDIORALS LABORATORIES, MAHARASHTRA INDIA
Laboratory/Laboratorium:	MEDIORALS LABORATORIES, MAHARASHTRA INDIA CIPLA-MEDPRO, ROSENPARK RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 37/2.7/0104

Name of medicine/Naam van medisyne: DAS-FENTANYL 0,1 MG/2 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml AMPOULE CONTAINS/ELKE 2,0 ml AMPULE BEVAT :
FENTANYL CITRATE EQUIVALENT TO FENTANYL 0,1 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: EDUAN STOLTZ

Manufacturer/Vervaardiger: BODENE, PORT ELIZABETH, RSA

Packer/Verpakker:	BODENE, PORT ELIZABETH, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA NATURA, SANDTON RSA
Laboratory/Laboratorium:	BODENE, PORT ELIZABETH, RSA COLUMBIA PHARMACEUTICALS, BOKSBURG RSA INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA SYNTHON B.V.,THE NETHERLANDS EDUAN STOLTZ, PRETORIA RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 37/2.7/0105

Name of medicine/Naam van medisyne: DAS-FENTANYL 0,5 MG/10 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml AMPOULE CONTAINS/ELKE 10,0 ml AMPULE BEVAT :
FENTANYL CITRATE EQUIVALENT TO FENTANYL 0,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: EDUAN STOLTZ

Manufacturer/Vervaardiger: BODENE, PORT ELIZABETH, RSA

Packer/Verpakker:	BODENE, PORT ELIZABETH, RSA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA NATURA, SANDTON RSA WRAPSA, CENTURION RSA
Laboratory/Laboratorium:	BODENE, PORT ELIZABETH, RSA COLUMBIA PHARMACEUTICALS, BOKSBURG RSA INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA SYNTHON B.V.,THE NETHERLANDS EDUAN STOLTZ, PRETORIA RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 37/20.2.8/0110

Name of medicine/Naam van medisyne: AP STAVUDINE 15 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
STAVUDINE 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 37/20.2.8/0111

Name of medicine/Naam van medisyne: AP STAVUDINE 20 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
STAVUDINE 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 37/20.2.8/0112

Name of medicine/Naam van medisyne: AP STAVUDINE 30 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
STAVUDINE 30,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 37/20.2.8/0113

Name of medicine/Naam van medisyne: AP STAVUDINE 40 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
STAVUDINE 40,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/2.9/0119

Name of medicine/Naam van medisyne: RAYZON 20 MG IV/IM

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
PARECOXIB SODIUM EQUIVALENT TO
PARECOXIB 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY

Packer/Verpakker: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY
PHARMACIA LTD, NORTHUMERLAND UK

Laboratory/Laboratorium: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA LTD, NORTHUMERLAND UK
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/2.9/0120

Name of medicine/Naam van medisyne: RAYZON 40 MG IV/IM

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml VIAL CONTAINS/ELKE 5,0 ml FLESSIE BEVAT:
PARECOXIB SODIUM EQUIVALENT TO PARECOXIB 40,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger:	BEN VENUE LABORATORIES, OHIO USA SEARLE, CARR, BARCELONETA, PUERTO RICO WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY
Packer/Verpakker:	BEN VENUE LABORATORIES, OHIO USA SEARLE, CARR, BARCELONETA, PUERTO RICO WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY PHARMACIA LTD, NORTHUMERLAND UK
Laboratory/Laboratorium:	BEN VENUE LABORATORIES, OHIO USA SEARLE, CARR, BARCELONETA, PUERTO RICO WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY KHULULEKANI LABORATORY SERVICES, MIDRAND RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA PHARMACIA LTD NORTHUMERLAND UK PHARMACIA SOUTH AFRICA, MIDRAND RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/34/0122

Name of medicine/Naam van medisyne: RAYZON 2 ML SOLVENT

Dosage form/Doseringsvorm: DILUENT FOR INJECTION/
OPLOSMIDDEL VIR INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH AMPOULE CONTAINS/ELKE AMPULE BEVAT:
SODIUM CHLORIDE 18,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: DOPPEL FARMACEUTICI, ROZZANO, ITALY

Packer/Verpakker: DOPPEL FARMACEUTICI, ROZZANO, ITALY

Laboratory/Laboratorium: DOPPEL FARMACEUTICI, ROZZANO, ITALY
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/20.1.1/0036

Name of medicine/Naam van medisyne: LILLY-CYCLOSERINE

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
CYCLOSERINE 250,0 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, BASINGSTOKE, HAMPSHIRE UK

Packer/Verpakker: ELI LILLY, BASINGSTOKE, HAMPSHIRE UK

Laboratory/Laboratorium: ELI LILLY, BASINGSTOKE, HAMPSHIRE UK
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/7.1.5/0384

Name of medicine/Naam van medisyne: CIALIS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
TADALAFIL 20,0 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, BASINGSTOKE, HAMPSHIRE UK
ELI LILLY, LILLY TECHNOLOGY CENTRE, INDIANAPOLIS, INDIANA USA

Packer/Verpakker: ELI LILLY, BASINGSTOKE, HAMPSHIRE UK
LILLY SA, MADRID SPAIN

Laboratory/Laboratorium: ELI LILLY, BASINGSTOKE, HAMPSHIRE UK
ELI LILLY, LILLY TECHNOLOGY CENTRE, INDIANAPOLIS, INDIANA USA
ELI LILLY, CORPORATE CENTRE INDIANAPOLIS INDIANA USA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 37/2.7/0104

Name of medicine/Naam van medisyne: DAS-FENTANYL 0,1 MG/2 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml SOLUTION CONTAINS/ELKE 2,0 ml OPLOSSING BEVAT:
FENTANYL CITRATE EQUIVALENT TO FENTANYL 0,1 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: EDUAN STOLTZ

Manufacturer/Vervaardiger: BODENE, PORT ELIZABETH, RSA

Packer/Verpakker: BODENE, PORT ELIZABETH, RSA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
PHARMA NATURA, SANDTON RSA
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: BODENE, PORT ELIZABETH, RSA
COLUMBIA PHARMACEUTICALS, BOKSBURG RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,BOKSBURG RSA
SYNTHON B.V.,THE NETHERLANDS
EDUAN STOLTZ, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 00/21.9/5

Name of medicine/Naam van medisyne: ADVOCIN 180

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
DANOFLOXACIN 180,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, AMBOISE FRANCE

Packer/Verpakker: PFIZER, AMBOISE FRANCE

Laboratory/Laboratorium: PFIZER, AMBOISE FRANCE
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 00/21.1/7

Name of medicine/Naam van medisyne: NOROCLAV INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 140,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID 35,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: NORBROOK LABORATORIES, ARMAGH ROAD
NEWRY NORTHERN IRELAND

Packer/Verpakker: NORBROOK LABORATORIES, ARMAGH ROAD
NEWRY NORTHERN IRELAND

Laboratory/Laboratorium: NORBROOK LABORATORIES, ARMAGH ROAD
NEWRY NORTHERN IRELAND
NORBROOK LABORATORIES, CENTURION, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/1.2/0129

Name of medicine/Naam van medisyne: RANFLOCS 20 CAPSULES

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakk er: RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/20.1.1/0348

Name of medicine/Naam van medisyne: CEROXIM 125 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 125,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/20.1.1/0349

Name of medicine/Naam van medisyne: CEROXIM 250 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA,
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/20.1.1/0350

Name of medicine/Naam van medisyne: CEROXIM 500 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
RANBAXY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/20.1.1/0351

Name of medicine/Naam van medisyne: MAGNASFOR 125 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 125,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/20.1.1/0352

Name of medicine/Naam van medisyne: MAGNASFOR 250 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/20.1.1/0353

Name of medicine/Naam van medisyne: MAGNASPOR 500 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFUROXIME AXETIL EQUIVALENT TO CEFUROXIME 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/7.1.3/0433

Name of medicine/Naam van medisyne: CARLOC 12.5

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, VIKHROLI INDIA

Packer/Verpakker: CIPLA LTD, VIKHROLI INDIA

Laboratory/Laboratorium: CIPLA LTD, VIKHROLI INDIA
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 34/34/0482

Name of medicine/Naam van medisyne: PLATELET ADDITIVE SOLUTION (T-SOL)

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1000,0 ml SOLUTION CONTAINS/ELKE 1000,0 ml OPLOSSING BEVAT:

SODIUM ACETATE	4,080 g
SODIUM CHLORIDE	6,750 g
SODIUM CITRATE	2,940 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD (CRITICAL CARE)

Manufacturer/Vervaardiger: BAXTER, LESSINES BELGIUM

Packer/Verpakker: BAXTER, LESSINES BELGIUM
ADCOCK INGRAM CRITICAL CARE,
JOHANNESBURG, RSA

Laboratory/Laboratorium: BAXTER, LESSINES BELGIUM
ADCOCK INGRAM CRITICAL CARE,
JOHANNESBURG, RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/16/0015

Name of medicine/Naam van medisyne: STREFEN

Dosage form/Doseringsvorm: LOZENGES/SUIGTABLETTE

Active ingredients/Aktiewe bestanddele:
EACH LOZENGE CONTAINS/ELKE SUIGTABLET BEVAT:
FLURBIPROFEN 8,75 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BOOTS HEALTHCARE (SOUTH AFRICA) (PTY) LTD

Manufacturer/Vervaardiger: BOOTS, NOTTINGHAM UK

Packer/Verpakker: BOOTS, NOTTINGHAM UK

Laboratory/Laboratorium: BOOTS, NOTTINGHAM UK
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
RECKITT BENCKISER PHARMACEUTICALS,
MOBENI RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/30.1/0030

Name of medicine/Naam van medisyne: FLUSONE-PASTEUR

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT :
INFLUENZA VIRUS A/BEIJING/535/95 (H1N1) 15,0 ug
INFLUENZA VIRUS A/SYDNEY/5/97-LIKE (H3N2) 15,0 ug
INFLUENZA VIRUS B/YAMANASHI/166/98

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PASTEUR, SWIFTWATER USA

Packer/Verpakker : AVENTIS PASTEUR, SWIFTWATER USA

Laboratory/Laboratorium: AVENTIS PASTEUR, SWIFTWATER USA
AVENTIS PHARMA, PORT ELIZABETH RSA
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/15.4/0089

Name of medicine/Naam van medisyne: MINIMS PROXYMETACAINE & FLUORESCEIN

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT:

FLUORESCEIN SODIUM	0.00125 g
PROXYMETACAINE HYDROCHLORIDE	0,0025 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SMITH & NEPHEW PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: CHAUVIN PHARMACEUTICALS, UK

Packer/Verpakker: CHAUVIN PHARMACEUTICALS, UK
SMITH & NEPHEW, PINETOWN RSA

Laboratory/Laboratorium: CHAUVIN PHARMACEUTICALS, UK
SMITH & NEPHEW, PINETOWN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/2.5/0099

Name of medicine/Naam van medisyne: NEURONTIN 600

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PARKE-DAVIS, VEGA BAJA, PUERTO RICO

Packer/Verpakker: PARKE-DAVIS, VEGA BAJA, PUERTO RICO
GOEDECKE, FREIBURG GERMANY
WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: PARKE-DAVIS, VEGA BAJA, PUERTO RICO
GOEDECKE, FREIBURG GERMANY
WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/2.5/0100

Name of medicine/Naam van medisyne: NEURONTIN 800

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
GABAPENTIN 800,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PARKE-DAVIS, VEGA BAJA, PUERTO RICO

Packer/Verpakker: PARKE-DAVIS, VEGA BAJA, PUERTO RICO
GOEDECKE, FREIBURG GERMANY
WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: PARKE-DAVIS, VEGA BAJA, PUERTO RICO
GOEDECKE, FREIBURG GERMANY
WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/21.10/0135

Name of medicine/Naam van medisyne: PUREGON 50 IU/0,5 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT :
FOLLITROPIN BETA 50,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: DONMED PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND

Packer/Verpakker: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Laboratory/Laboratorium: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/21.10/0136

Name of medicine/Naam van medisyne: PUREGON 100 IU/0,5 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT:
FOLLITROPIN BETA 100,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: DONMED PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND

Packer/Verpakker: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Laboratory/Laboratorium: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/21.10/0137

Name of medicine/Naam van medisyne: PUREGON 150 IU/0,5 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT:
FOLLITROPIN BETA 150,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: DONMED PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND

Packer/Verpakker: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Laboratory/Laboratorium: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/21.10/0138

Name of medicine/Naam van medisyne: PUREGON 200 IU/0,5 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT :
FOLLITROPIN BETA 200,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: DONMED PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND

Packer/Verpakker: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Laboratory/Laboratorium: NV ORGANON, OSS NETHERLANDS
ORGANON LTD, DUBLIN IRELAND
ADCOCK INGRAM LTD, WADEVILLE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/1.2/0145

Name of medicine/Naam van medisyne: ADCO-MOCLOBEMIDE 150 MG

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: DRAGENOPHARM, TITTMONING, GERMANY

Packer/Verpakker: DRAGENOPHARM, TITTMONING, GERMANY
MANUFACTURING PACKAGING FARMACA ,
HEERENVEEN THE NETHERLANDS

Laboratory/Laboratorium: SYNTHON B.V.,THE NETHERLANDS
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/1.2/0146

Name of medicine/Naam van medisyne: ADCO-MOCLOBEMIDE 300 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MOCLOBEMIDE 300,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: DRAGENOPHARM, TITTMONING, GERMANY

Packer/Verpakker: DRAGENOPHARM, TITTMONING, GERMANY
MANUFACTURING PACKAGING FARMACA ,
HEERENVEEN THE NETHERLANDS

Laboratory/Laboratorium: SYNTHON B.V.,THE NETHERLANDS
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/2.8/0167

Name of medicine/Naam van medisyne: GRAND-PA EFFERVESCENT HEADACHE POWDERS

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH SACHET CONTAINS/ELKE SAKKIE BEVAT:

ASPIRIN	453,60 mg
CAFFEINE	64,80 mg
PARACETAMOL	324,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM PHARMACEUTICALS, EPPING RSA

Packer/Verpakker: SMITHKLINE BEECHAM PHARMACEUTICALS, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM PHARMACEUTICALS, EPPING RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/7.1.3/0209

Name of medicine/Naam van medisyne: SINOPREN 5 TABLETS

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker : RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/7.1.3/0210

Name of medicine/Naam van medisyne: SINOPREN 10 TABLETS

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/7.1.3/0211

Name of medicine/Naam van medisyne: SINOPREN 20 TABLETS

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/13.4.2/0375

Name of medicine/Naam van medisyne: ORATANE 10 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ISOTRETINOIN 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: SCA LOHNHERSTELLUNGS, KITCHBERG ZWITZERLAND

Packer/Verpakker: DOUGLAS PHARMACEUTICALS, AUCKLAND, NEW ZEALAND

Laboratory/Laboratorium: SCA LOHNHERSTELLUNGS, KITCHBERG ZWITZERLAND
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/13.4.2/0376

Name of medicine/Naam van medisyne: ORATANE 20 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ISOTRETINOIN 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: SCA LOHNHERSTELLUNGS, KITCHBERG ZWITZERLAND

Packer/Verpakker: DOUGLAS PHARMACEUTICALS, AUCKLAND, NEW ZEALAND

Laboratory/Laboratorium: SCA LOHNHERSTELLUNGS, KITCHBERG ZWITZERLAND
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/10.2.2/0397

Name of medicine/Naam van medisyne: SINGULAIR 4 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
MONTELUKAST SODIUM EQUIVALENT TO MONTELUKAST 4,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MSD (PTY) LTD

Manufacturer/Vervaardiger: MERCK SHARP & DOHME, NORTHUMBERLAND UK

Packer/Verpakker: MMD HAARLEM, NETHERLANDS
MSD, HALFWAY HOUSE RSA

Laboratory/Laboratorium: MERCK SHARP & DOHME, NORTHUMBERLAND UK
MMD HAARLEM, NETHERLANDS
MSD, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/30.1/0401

Name of medicine/Naam van medisyne: AVAXIM 80

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SUSPENSION CONTAINS/ELKE 0,5 ml SUSPENSIE BEVAT:
HEPATITIS A VIRUS 80,0 antigen units

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PASTEUR, VAL DE REUIL, FRANCE
AVENTIS PASTEUR, L'ETOILE, FRANCE

Packer/Verpakker: AVENTIS PASTEUR, VAL DE REUIL, FRANCE
AVENTIS PASTEUR, L'ETOILE, FRANCE

Laboratory/Laboratorium: AVENTIS PASTEUR, VAL DE REUIL, FRANCE
AVENTIS PASTEUR, L'ETOILE, FRANCE
AVENTIS PHARMA, MIDRAND RSA
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/21.5.1/0404

Name of medicine/Naam van medisyne: SYMBICORD TURBUHALER 80:4,5 ug/DOSE

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH DELIVERED DOSE CONTAINS/ELKE AFGEMETE DOSIS BEVAT :
BUDESONIDE 80,0 ug
FORMOTEROL FUMARATE DIHYDRATE 4,5 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN

Packer/Verpakker: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN
ASTRAZENECA, CHESHIRE UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
ASTRAZENECA, ALRODE, ALBERTON RSA

Laboratory/Laboratorium: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 35/21.5.1/0405

Name of medicine/Naam van medisyne: SYMBICORD TURBUHALER
160:4,5 ug/DOSE

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH DELIVERED DOSE CONTAINS/ELKE AFGEMETE DOSIS BEVAT :
BUDESONIDE 160,0 ug
FORMOTEROL FUMARATE DIHYDRATE 4,5 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN

Packer/Verpakker: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN
ASTRAZENECA, CHESHIRE UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
ASTRAZENECA, ALRODE, ALBERTON RSA

Laboratory/Laboratorium: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE SWEDEN
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/5.7.1/0005

Name of medicine/Naam van medisyne: ROLOR

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SPARTAN KEMPTON PARK RSA

Packer/Verpakker: NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/26/0012

Name of medicine/Naam van medisyne: NAVELBINE ORAL 20 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TEMA MEDICAL (PTY) LTD

Manufacturer/Vervaardiger: R P SCHERER GmbH, BADEN,GERMANY

Packer/Verpakker: PIERRE FABRE, IDRON FRANCE

Laboratory/Laboratorium: PIERRE FABRE, IDRON FRANCE
BIOCON RESEARCH LAB, PRETORIA,RSA
INSPECTORATE M & L, ORMONDE RSA
TECHNIKON LABORATORIES, FLORIDA RSA
TEMA MEDICAL, SANDTON, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/26/0013

Name of medicine/Naam van medisyne: NAVELBINE ORAL 30 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 30,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TEMA MEDICAL (PTY) LTD

Manufacturer/Vervaardiger: R P SCHERER GmbH, BADEN,GERMANY

Packer/Verpakker: PIERRE FABRE, IDRON FRANCE

Laboratory/Laboratorium: PIERRE FABRE, IDRON FRANCE
BIOCON RESEARCH LAB, PRETORIA,RSA
INSPECTORATE M & L, ORMONDE RSA
TECHNIKON LABORATORIES, FLORIDA RSA
TEMA MEDICAL, SANDTON, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/26/0014

Name of medicine/Naam van medisyne: NAVELBINE ORAL 40 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 40,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TEMA MEDICAL (PTY) LTD

Manufacturer/Vervaardiger: R P SCHERER GmbH, BADEN,GERMANY

Packer/Verpakker: PIERRE FABRE, IDRON FRANCE

Laboratory/Laboratorium: PIERRE FABRE, IDRON FRANCE
BIOCON RESEARCH LAB, PRETORIA,RSA
INSPECTORATE M & L, ORMONDE RSA
TECHNIKON LABORATORIES, FLORIDA RSA
TEMA MEDICAL, SANDTON, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/26/0015

Name of medicine/Naam van medisyne: NAVELBINE ORAL 80 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
VINORELBINE TARTRATE EQUIVALENT TO VINORELBINE 80,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TEMA MEDICAL (PTY) LTD

Manufacturer/Vervaardiger: R P SCHERER GmbH, BADEN,GERMANY

Packer/Verpakker: PIERRE FABRE, IDRON FRANCE

Laboratory/Laboratorium: PIERRE FABRE, IDRON FRANCE
BIOCON RESEARCH LAB, PRETORIA,RSA
INSPECTORATE M & L, ORMONDE RSA
TECHNIKON LABORATORIES, FLORIDA RSA
TEMA MEDICAL, SANDTON, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/20.1.1/0036

Name of medicine/Naam van medisyne: LILLY-CYCLOSERINE

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
CYCLOSERINE 250,0 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, HANTS, HAMPSHIRE UK

Packer/Verpakker: ELI LILLY, HANTS, HAMPSHIRE UK

Laboratory/Laboratorium: ELI LILLY, HANTS, HAMPSHIRE UK
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG RSA
CONSULTING MICROBIOL LAB,
BLUEGUMCREEK,BENONI RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/1.2/0048

Name of medicine/Naam van medisyne: MOCLOBEMIDE-HEXAL 150 mg

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: SALUTAS PHARMA, BARLEBEN GERMANY
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/1.2/0049

Name of medicine/Naam van medisyne: MOCLOBEMIDE-HEXAL 300 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MOCLOBEMIDE 300,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker:	DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA-Q, INDUSTRIA RSA
Laboratory/Laboratorium:	SALUTAS PHARMA, BARLEBEN GERMANY ANALYTICON, KEMPTON PARK RSA CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/7.1.3/0067

Name of medicine/Naam van medisyne: TAREG 80 TABLET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
VALSARTAN 80,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS PHARMA STEIN AG, SWITZERLAND

Packer/Verpakker: NOVARTIS PHARMA STEIN AG, SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS PHARMA STEIN AG, SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA
INSPECTORATE M & L, ORMONDE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/7.1.3/0068

Name of medicine/Naam van medisyne: TAREG 160 TABLET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
VALSARTAN 160,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS PHARMA STEIN AG, SWITZERLAND

Packer/Verpakker: NOVARTIS PHARMA STEIN AG, SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS PHARMA STEIN AG, SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA
INSPECTORATE M & L, ORMONDE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0074

Name of medicine/Naam van medisyne: INSUMAN RAPID (300 IU/3 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 3,0 ml SOLUTION CONTAINS/ELKE 3,0 ml OPLOSSING BEVAT :
INSULIN HUMAN 300,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0075

Name of medicine/Naam van medisyne: INSUMAN RAPID (500 IU/5 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT:
INSULIN HUMAN 500,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0077

Name of medicine/Naam van medisyne: INSUMAN BASAL (300 IU/3 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 3,0 ml SOLUTION CONTAINS/ELKE 3,0 ml OPLOSSING BEVAT:
INSULIN HUMAN 300,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0078

Name of medicine/Naam van medisyne: INSUMAN BASAL (500 IU/5 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :
INSULIN HUMAN 500,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0079

Name of medicine/Naam van medisyne: INSUMAN BASAL (1000 IU/10 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml SOLUTION CONTAINS/ELKE 10,0 ml OPLOSSING BEVAT:
INSULIN HUMAN 1000,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0080

Name of medicine/Naam van medisyne: INSUMAN COMB 30/70 (300 IU/3 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 3,0 ml SOLUTION CONTAINS/ELKE 3,0 ml OPLOSSING BEVAT :
INSULIN HUMAN 300,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0081

Name of medicine/Naam van medisyne: INSUMAN COMB 30/70 (500 IU/5 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :
INSULIN HUMAN 500,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.1/0082

Name of medicine/Naam van medisyne: INSUMAN COMB 30/70 (1000 IU/10 ML)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml SOLUTION CONTAINS/ELKE 10,0 ml OPLOSSING BEVAT:
INSULIN HUMAN 1000,0 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Packer/Verpakker: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT

Laboratory/Laboratorium: AVENTIS PHARMA DEUTSCHLAND GmbH, FRANKFURT
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/1.2/0096

Name of medicine/Naam van medisyne: ADCO-PAROXETINE 20 MG

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6, 7
Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: HEUMANN PHARMA AND CO, NURNBERG GERMANY
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN

Packer/Verpakker: SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN
HEUMANN PHARMA AND CO, NURNBERG GERMANY
MANUFACTURING PACKAGING FARMACA , HEERENVEEN
THE NETHERLANDS

Laboratory/Laboratorium: HEUMANN PHARMA AND CO, NURNBERG GERMANY
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN
SYNTHON B.V.,THE NETHERLANDS
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/11.5/0104

Name of medicine/Naam van medisyne: BROOKLAX BISACODYL LAXATIVE PILLS

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM PHARMACEUTICALS, EPPING RSA

Packer/Verpakker: SMITHKLINE BEECHAM PHARMACEUTICALS, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM PHARMACEUTICALS, EPPING RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/7.1.3/0112

Name of medicine/Naam van medisyne: RENOTENS 5 TABLETS

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker : RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/7.1.3/0113

Name of medicine/Naam van medisyne: RENOTENS 10 TABLETS

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/7.1.3/0114

Name of medicine/Naam van medisyne: RENOTENS 20 TABLETS

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/2.9/0119

Name of medicine/Naam van medisyne: RAYZON 20 MG IV/IM

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
PARECOXIB SODIUM EQUIVALENT TO PARECOXIB 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: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK,
WASSERBURG GERMANY

Packer/Verpakker: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK,
WASSERBURG GERMANY
G D SEARLE, MORPETH NORTHUMERLAND UK

Laboratory/Laboratorium: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK,
WASSERBURG GERMANY
G D SEARLE, MORPETH NORTHUMERLAND UK
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/2.9/0120

Name of medicine/Naam van medisyne: RAYZON 40 MG IV/IM

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml VIAL CONTAINS/ELKE 5,0 ml FLESSIE BEVAT:
PARECOXIB SODIUM EQUIVALENT TO PARECOXIB 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: BEN VENUE LABORATORIES, OHIO USA
SEARLE, CARR, BARCELONETA, PUERTO RICO
WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY

Packer/Verpakker: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY
SEARLE, CARR, BARCELONETA, PUERTO RICO
G D SEARLE, MORPETH NORTHUMERLAND UK

Laboratory/Laboratorium: BEN VENUE LABORATORIES, OHIO USA
WASSERBURGER ARZNEIMITTELWERK, WASSERBURG GERMANY
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SEARLE, CARR, BARCELONETA, PUERTO RICO
G D SEARLE, MORPETH NORTHUMERLAND UK
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/34/0121

Name of medicine/Naam van medisyne: RAYZON 1 ML SOLVENT

Dosage form/Doseringsvorm: DILUENT FOR INJECTION/
OPLOSMIDDEL VIR INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH AMPOULE CONTAINS/ELKE AMPULE BEVAT :
SODIUM CHLORIDE 9,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMA HAMELN, HAMELN, WEST GERMANY
SEARLE FARMACEUTICI, ROZZANO, ITALY

Packer/Verpakker: PHARMA HAMELN, HAMELN, WEST GERMANY
SEARLE FARMACEUTICI, ROZZANO, ITALY

Laboratory/Laboratorium: PHARMA HAMELN, HAMELN, WEST GERMANY
SEARLE FARMACEUTICI, ROZZANO, ITALY
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/34/0122

Name of medicine/Naam van medisyne: RAYZON 2 ML SOLVENT

Dosage form/Doseringsvorm: DILUENT FOR INJECTION/
OPLOSMIDDEL VIR INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH AMPOULE CONTAINS/ELKE AMPULE BEVAT:
SODIUM CHLORIDE 18,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMA HAMELN, HAMELN, WEST GERMANY
SEARLE FARMACEUTICI, ROZZANO, ITALY

Packer/Verpakker: PHARMA HAMELN, HAMELN, WEST GERMANY
SEARLE FARMACEUTICI, ROZZANO, ITALY

Laboratory/Laboratorium: PHARMA HAMELN, HAMELN, WEST GERMANY
SEARLE FARMACEUTICI, ROZZANO, ITALY
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.8.2/0169

Name of medicine/Naam van medisyne: LEVONOR

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: MEDI-CHALLENGE (PTY) LTD

Manufacturer/Vervaardiger: LCO SANTE, OSNY FRANCE

Packer/Verpakker: LCO SANTE, OSNY FRANCE

Laboratory/Laboratorium: LCO SANTE, OSNY FRANCE
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
MEDI-CHALLENGE, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/20.1.1/0170

Name of medicine/Naam van medisyne: CIPRO-HEXAL 250

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN 250,0 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 MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA-Q, INDUSTRIA RSA
Laboratory/Laboratorium:	HEXAL AG, HOLZKIRCHEN GERMANY ANALYTICON, KEMPTON PARK RSA CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/20.1.1/0171

Name of medicine/Naam van medisyne: CIPRO-HEXAL 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN 500,0 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 MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA-Q, INDUSTRIA RSA
Laboratory/Laboratorium:	HEXAL AG, HOLZKIRCHEN GERMANY ANALYTICON, KEMPTON PARK RSA CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/20.1.1/0172

Name of medicine/Naam van medisyne: CIPRO-HEXAL 750

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN 750,0 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 MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA-Q, INDUSTRIA RSA
Laboratory/Laboratorium:	HEXAL AG, HOLZKIRCHEN GERMANY ANALYTICON, KEMPTON PARK RSA CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA HEXAL PHARMA , WESTMEAD RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/20.1.1/0190

Name of medicine/Naam van medisyne: ZITHROMAX IV

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

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: BEN VENUE LABORATORIES, OHIO USA

Packer/Verpakker: BEN VENUE LABORATORIES, OHIO USA
PFIZER, AMBOISE FRANCE
PFIZER LABS, PIETERMARITZBURG RSA
WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: PFIZER, AMBOISE FRANCE
PFIZER, TERRE HAUTE , INDIANA USA
PFIZER LABS, PIETERMARITZBURG RSA
WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/21.5.1/0191

Name of medicine/Naam van medisyne: PREFLAM

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT:
PREDNISOLONE 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer/Vervaardiger: MEDIORALS LABORATORIES, MAHARASHTRA INDIA

Packer/Verpakker: MEDIORALS LABORATORIES, MAHARASHTRA INDIA

Laboratory/Laboratorium: MEDIORALS LABORATORIES, MAHARASHTRA INDIA
CIPLA LIFE SCIENCES, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/2.9/0199

Name of medicine/Naam van medisyne: NOCTAGESIC TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
DIPHENHYDRAMINE HYDROCHLORIDE 25,0 mg
PARACETAMOL 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: PHARMA-Q, INDUSTRIA RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Packer/Verpakker: PHARMA-Q, INDUSTRIA RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Laboratory/Laboratorium: PHARMA-Q, INDUSTRIA RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/11.5/0239

Name of medicine/Naam van medisyne: LAXETTE DRY - LEMON

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH SACHET CONTAINS/ELKE SAKKIE BEVAT:
LACTULOSE A10,0 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MEDPRO PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: INFRA, PISTOIA ITALY

Packer/Verpakker: PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: INFRA, PISTOIA ITALY
MEDPRO PHARMACEUTICA, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/11.5/0240

Name of medicine/Naam van medisyne: LAXETTE DRY

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH SACHET CONTAINS/ELKE SAKKIE BEVAT:
LACTULOSE 10,0 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MEDPRO PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: INFRA, PISTOIA ITALY

Packer/Verpakker: PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: INFRA, PISTOIA ITALY
MEDPRO PHARMACEUTICA, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/10.2.2/0287

Name of medicine/Naam van medisyne: ADCO-SALBUTAMOL CLICKHALER

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH INHALED DOSE CONTAINS/ELKE DOSIS BEVAT:
SALBUTAMOL SULPHATE EQUIVALENT TO
SALBUTAMOL 90,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: MIZA PHARMACEUTICALS, CHESHIRE UK

Packer/Verpakker: MIZA PHARMACEUTICALS, CHESHIRE UK

Laboratory/Laboratorium: MIZA PHARMACEUTICALS, CHESHIRE UK
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 36/30.1/0358

Name of medicine/Naam van medisyne: HEBERBIOVAC HB 10 UG/0,5 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml SUSPENSION CONTAINS/ELKE 0,5 ml SUSPENSIE BEVAT:
HEPATITIS B ANTIGEN DNA RECOMBINANT VACCINE 10,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BIOVAC SA (PTY) LTD

Manufacturer/Vervaardiger:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, HAVANA CITY, CUBA
Packer/Verpakker:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, HAVANA CITY, CUBA
Laboratory/Laboratorium:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA NATIONAL CONTROL LAB(NCL) BLOEMFONTEIN, RSA BIOVAC SA, WADEVILLE RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/30.1/0359

Name of medicine/Naam van medisyne: HEBERBIOVAC HB 20 UG/1,0 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT:
HEPATITIS B ANTIGEN DNA RECOMBINANT VACCINE 20,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BIOVAC SA (PTY) LTD

Manufacturer/Vervaardiger:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, HAVANA CITY, CUBA
Packer/Verpakker:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, HAVANA CITY, CUBA
Laboratory/Laboratorium:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA NATIONAL CONTROL LAB(NCL) BLOEMFONTEIN RSA BIOVAC SA, WADEVILLE RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/30.1/0360

Name of medicine/Naam van medisyne: HEBERBIOVAC HB 100 UG/5,0 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
HEPATITIS B ANTIGEN DNA-RECOMBINANT VACCINE 100,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BIOVAC SA (PTY) LTD

Manufacturer/Vervaardiger:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, HAVANA CITY, CUBA
Packer/Verpakker:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY, HAVANA CITY, CUBA
Laboratory/Laboratorium:	BIOLOGICAL PREPARATIONS CENTER, BEJUCAL, CUBA NATIONAL CONTROL LAB (NCL) BLOEMFONTEIN, RSA BIOVAC SA, WADEVILLE RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	25 APRIL 2003 25 APRIL 2003

Registration number/Registrasienommer: 36/7.1.5/0384

Name of medicine/Naam van medisyne: CIALIS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT
TADALAFIL 20,0 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, LILLY TECHNOLOGY CENTRE, INDIANAPOLIS, INDIANA USA

Packer/Verpakker: ELI LILLY, HANTS, HAMPSHIRE UK
LILLY SA, MADRID SPAIN

Laboratory/Laboratorium: ELI LILLY, HANTS, HAMPSHIRE UK
ELI LILLY, CORPORATE CENTRE INDIANAPOLIS INDIANA USA
ELI LILLY, LILLY TECHNOLOGY CENTRE, INDIANAPOLIS, INDIANA USA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 APRIL 2003
Datum van registrasie 25 APRIL 2003

Registration number/Registrasienommer: 32/20.1.1/0118

Name of medicine/Naam van medisyne: CPL ALLIANCE CIPROFLOXACIN 250

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN ... 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6

Applicant/Applikant: ALLIANCE PHARMA (PTY) LTD

Manufacturer/Vervaardiger: CADILA PHARMACEUTICALS, AHMEDABAD INDIA

Packer/Verpakker: CADILA PHARMACEUTICALS, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA PHARMACEUTICALS, AHMEDABAD INDIA
ANALYTICON, KEMPTON PARK RSA
ALLIANCE PHARMA, VILLAGE MAIN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 APRIL 2003
Datum van registrasie 01 APRIL 2003

Registration number/Registrasienommer: 32/20.1.1/0119

Name of medicine/Naam van medisyne: CPL ALLIANCE CIPROFLOXACIN 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO
CIPROFLOXACIN ... 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6

Applicant/Applikant: ALLIANCE PHARMA (PTY) LTD

Manufacturer/Vervaardiger: CADILA PHARMACEUTICALS, AHMEDABAD INDIA

Packer/Verpakker: CADILA PHARMACEUTICALS, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA PHARMACEUTICALS, AHMEDABAD INDIA
ANALYTICON, KEMPTON PARK RSA
ALLIANCE PHARMA, VILLAGE MAIN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 01 APRIL 2003
Datum van registrasie 01 APRIL 2003