Government Gazette

REPUBLIC OF SOUTH AFRICA

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

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 1892 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: 34/2.8/0089

Name of medicine/Naam van medisyne: IBUMOL

Dosage form/Doseringsvorm: TABLET

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

IBUPROFEN	200,0 mg
PARACETAMOL	350,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: COLUMBIA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: COLUMBIA PHARMACEUTICALS, BOKSBURG RSA

Packer/Verpakker: COLUMBIA PHARMACEUTICALS, BOKSBURG RSA

Laboratory/Laboratorium: COLUMBIA PHARMACEUTICALS, BOKSBURG RSA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 34/34/0388

Name of medicine/Naam van medisyne: OTRISALINE SOLUTION

Dosage form/Doseringsvorm: SPRAY/SPROEI

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
SODIUM CHLORIDE 7,40 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, NYON SWITZERLAND

Packer/Verpakker: NOVARTIS, NYON SWITZERLAND

Laboratory/Laboratorium: NOVARTIS, NYON SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 34/13.6/0389

Name of medicine/Naam van medisyne: MC RUB

Dosage form/Doseringsvorm: OINTMENT/SALF

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g OINTMENT CONTAINS/ELKE 100,0 g SALF BEVAT:
METHYL SALICYLATE 10,0 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MC PHARMA CC

Manufacturer/Vervaardiger: IMPILO DRUGS (1966), ISITHEBE RSA

Packer/Verpakker: IMPILO DRUGS (1966), ISITHEBE RSA

Laboratory/Laboratorium: IMPILO DRUGS (1966), ISITHEBE RSA
MC PHARMA CC, MEYERSPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 34/24/0392

Name of medicine/Naam van medisyne: CALCICHEW

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CALCIUM CARBONATE EQUIVALENT TO ELEMENTAL CALCIUM 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, ASKER NORWAY

Packer/Verpakker: NYCOMED, ASKER NORWAY

Laboratory/Laboratorium: NYCOMED, ASKER NORWAY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 34/2.5/0442

Name of medicine/Naam van medisyne: TRILEPTAL 150

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SCHAFFHAUSERSTRASSE, SWITZERLAND

Packer/Verpakker: NOVARTIS, SCHAFFHAUSERSTRASSE, SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 34/5.7.1/0507

Name of medicine/Naam van medisyne: POLLENTYME TABLETS

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: PHARMA DYNAMICS (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
PHARMA DYNAMICS SILVERWOOD, WESTLAKE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/21.2/0042

Name of medicine/Naam van medisyne: PRIMAPEX 60 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
NATEGLINIDE 60,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SCHAFFHAUSERSTRASSE, SWITZERLAND

Packer/Verpakker: NOVARTIS, SCHAFFHAUSERSTRASSE, SWITZERLAND
ALLPACK AG, MUTTENZ, SWITZERLAND
IVERS-LEE LTD, BURGDORF SWITZERLAND
KONAPHARMA AG, PRATTELN, SWITZERLAND
PROMLOG AG, PRATTELN, SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/21.2/0043

Name of medicine/Naam van medisyne: PRIMAPEX 120 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
NATEGLINIDE 120,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, SCHAFFHAUSERSTRASSE, SWITZERLAND

Packer/Verpakker: NOVARTIS, SCHAFFHAUSERSTRASSE, SWITZERLAND
ALLPACK AG, MUTTENZ, SWITZERLAND
IVERS-LEE LTD, BURGDORF SWITZERLAND
KONAPHARMA AG. PRATTELN, SWITZERLAND
PROMLOG AG, PRATTELN, SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/15.4/0076

Name of medicine/Naam van medisyne: ZADITEN EYE DROPS

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSNG BEVAT :
KETOTIFEN FUMARATE EQUIVALENT TO KETOTIFEN 0,25 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: LABORATOIRES CIBA VISION,CEDEX,FRANCE

Packer/Verpakker: LABORATOIRES CIBA VISION,CEDEX,FRANCE
NOVO NORDISK, JOHANNESBURG RSA

Laboratory/Laboratorium: LABORATOIRES CIBA VISION,CEDEX,FRANCE
ADCOCK INGRAM LTD, WADEVILLE RSA
NOVO NORDISK, JOHANNESBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/21.2/0091

Name of medicine/Naam van medisyne: HEXAFORMIN 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
METFORMIN HYDROCHLORIDE 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: GEA FARMACEUTISK , FREDERIKSBERG, DENMARK

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: GEA FARMACEUTISK , FREDERIKSBERG, DENMARK
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/21.2/0092

Name of medicine/Naam van medisyne: HEXAFORMIN 850

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
METFORMIN HYDROCHLORIDE 850,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: GEA FARMACEUTISK , FREDERIKSBERG, DENMARK

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: GEA FARMACEUTISK , FREDERIKSBERG, DENMARK
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/21.2/0093

Name of medicine/Naam van medisyne: GLUCOFORMIN 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
METFORMIN HYDROCHLORIDE 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: GEA FARMACEUTISK., FREDERIKSBERG, DENMARK

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
GEA FARMACEUTISK., FREDERIKSBERG, DENMARK
HEXAL PHARMA, WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/21.2/0094

Name of medicine/Naam van medisyne: GLUCOFORMIN 850

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
METFORMIN HYDROCHLORIDE 850,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: GEA FARMACEUTISK , FREDERIKSBERG, DENMARK

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: GEA FARMACEUTISK , FREDERIKSBERG, DENMARK
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/21.12/0155

Name of medicine/Naam van medisyne: CYPROPLEX 50 MG

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACHEMIE (PTY) LTD

Manufacturer/Vervaardiger: PHARMACHEMIE B.V. HAARLEM NETHERLANDS

Packer/Verpakker: PHARMACHEMIE B.V. HAARLEM NETHERLANDS
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: PHARMACHEMIE B.V. HAARLEM NETHERLANDS
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
PHARMACHEMIE, MIDRAND RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 6 JUNE2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/20.1.2/0212

Name of medicine/Naam van medisyne: RANMOXY SUSPENSION 125 MG/5 ML

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT :
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 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
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/20.1.2/0213

Name of medicine/Naam van medisyne: RANMOXY SUSPENSION 250 MG/5 ML

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 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
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNIE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/13.3/0217

Name of medicine/Naam van medisyne: MEDICATED INGRAM'S HERBAL OINTMENT

Dosage form/Doseringsvorm: OINTMENT/SALF

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g OINTMENT CONTAINSELKE 100.0 g SALF BEVAT :

CAMPHOR	1,81 g
EUCALYPTUS OIL	5,03 g
THYME OIL	0,50 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, WADEVILLE RSA

Packer/Verpakker: ADCOCK INGRAM LTD, WADEVILLE RSA

Laboratory/Laboratorium: ADCOCK INGRAM LTD, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/2.1/0228

Name of medicine/Naam van medisyne: RECOFOL 1 % 20 ML AMPOULE

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml EMULSION CONTAINS/ELKE 1,0 ml EMULSIE BEVAT:
PROPOFOL 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: SANTEN OY, TAMPERE FINLAND

Packer/Verpakker: SANTEN OY, TAMPERE FINLAND
MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE RSA

Laboratory/Laboratorium: SANTEN OY, TAMPERE FINLAND
MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE RSA
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
MERCK GENERICS RSA, MODDERFONTEIN, RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/2.1/0229

Name of medicine/Naam van medisyne: RECOFOL 1 % 50 ML VIAL

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml EMULSION CONTAINS/ELKE 1,0 ml EMULSIE BEVAT:
PROPOFOL 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: SANTEN OY, TAMPERE FINLAND

Packer/Verpakker: SANTEN OY, TAMPERE FINLAND
MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE RSA

Laboratory/Laboratorium: SANTEN OY, TAMPERE FINLAND
MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE RSA
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
MERCK GENERICS RSA, MODDERFONTEIN RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 35/2.1/0230

Name of medicine/Naam van medisyne: RECOFOL 1 % 100 ML VIAL

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml EMULSION CONTAINS/ELKE 1,0 ml EMULSIE BEVAT:
PROPOFOL 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MERCK GENERICS RSA (PTY) LTD

Manufacturer/Vervaardiger: SANTEN OY, TAMPERE FINLAND

Packer/Verpakker:	SANTEN OY, TAMPERE FINLAND MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE RSA
Laboratory/Laboratorium:	SANTEN OY, TAMPERE FINLAND MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE RSA RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA MERCK GENERICS RSA, MODDERFONTEIN RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	6 JUNE 2003 6 JUNIE 2003

Registration number/Registrasienommer: 35/7.3/0400

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

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 0,50 ml DROPS CONTAIN/ELKE 0,50 ml DRUPPELS BEVAT:
CLONIDINE HYDROCHLORIDE 5,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: EQUITY PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: WRAPSA, CENTURION RSA

Packer/Verpakker: WRAPSA, CENTURION RSA

Laboratory/Laboratorium: WRAPSA, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 20903

Registration number/Registrasienommer: 35/11.9.2/0407

Name of medicine/Naam van medisyne: SANTAX-S CAPSULES

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
DRIED YEAST 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: ASCHE AG, HAMBURG GERMANY

Packer/Verpakker: ASCHE AG, HAMBURG GERMANY

Laboratory/Laboratorium: ASCHE AG, HAMBURG GERMANY
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/26/0024

Name of medicine/Naam van medisyne: BIOLYSE PACLITAXEL FOR INJECTION 5ML

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: KEY ONCOLOGICS (PTY) LTD

Manufacturer/Vervaardiger: OMEGA LABORATORIES, QUEBEC, CANADA

Packer/Verpakker: OMEGA LABORATORIES, QUEBEC, CANADA

Laboratory/Laboratorium: OMEGA LABORATORIES, QUEBEC, CANADA
BIOLYSE PHARMA CORP, ONTARIO CANADA
BIOLYSE PHARMA CORP, QUEBEC CANADA
LABORATOIRES NEO PHARM, QUEBEC CANADA
KEY ONCOLOGICS, SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/13.1/0093

Name of medicine/Naam van medisyne: PROTEX CREAM BAR

Dosage form/Doseringsvorm: SOAP/SEEP

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g SOAP CONTAINS/ELKE 100,0 g SEEP BEVAT :
TRICLOCARBAN 0,100 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: COLGATE-PALMOLIVE (PTY) LTD

Manufacturer/Vervaardiger: COLGATE-PALMOLIVE, CANELANDS RSA

Packer/Verpakker: COLGATE-PALMOLIVE, CANELANDS RSA

Laboratory/Laboratorium: COLGATE-PALMOLIVE, CANELANDS RSA
COLGATE-PALMOLIVE, BOKSBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/13.1/0094

Name of medicine/Naam van medisyne: PROTEX FRESH

Dosage form/Doseringsvorm: SOAP/SEEP

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g SOAP CONTAINS/ELKE 100,0 g SEEP BEVAT:
TRICLOCARBAN 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: COLGATE-PALMOLIVE (PTY) LTD

Manufacturer/Vervaardiger: COLGATE-PALMOLIVE, CANELANDS RSA

Packer/Verpakker: COLGATE-PALMOLIVE, CANELANDS RSA

Laboratory/Laboratorium: COLGATE-PALMOLIVE, CANELANDS RSA
COLGATE-PALMOLIVE, BOKSBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/2.7/0103

Name of medicine/Naam van medisyne: PARAMED EXTEND

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
PARACETAMOL 665,0 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, DUNGARVAN IRELAND

Packer/Verpakker: SMITHKLINE BEECHAM, DUNGARVAN IRELAND
GLAXOSMITHKLINE, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM, DUNGARVAN IRELAND
GLAXOSMITHKLINE, EPPING RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNE 2003

Registration number/Registrasienommer: 36/20.1.2/0115

Name of medicine/Naam van medisyne: ZALOXY SUSPENSION 125 MG/5 ML

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT :
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 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
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.1.2/0116

Name of medicine/Naam van medisyne: ZALOXY SUSPENSION 250 MG/5 ML

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT :
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 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
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.1.2/0117

Name of medicine/Naam van medisyne: TRIOMAXCIL P 125 MG/5 ML

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT :
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 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
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.1.2/0118

Name of medicine/Naam van medisyne: TRIOMAXCIL PF 250

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT :
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN 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
CENTRE FOR QUALITY ASSURANCE,
POTCHEFSTROOM RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/18.6/0130

Name of medicine/Naam van medisyne: VARI-ECONAZOLE NITRATE 1 % M/M VAGINAL CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g CREAM CONTAINS/ELKE 1,0 g ROOM BEVAT :
ECONAZOLE NITRATE 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: DANENE PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: VARICHEM LABORATORIES,HARARE, ZIMBABWE

Packer/Verpakker: VARICHEM LABORATORIES,HARARE, ZIMBABWE

Laboratory/Laboratorium: VARICHEM LABORATORIES,HARARE, ZIMBABWE
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
DANENE PHARMACEUTICALS, PTA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.1.1/0246

Name of medicine/Naam van medisyne: ADCO-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, 5, 6, 7

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.1.1/0247

Name of medicine/Naam van medisyne: ADCO-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, 5, 6, 7

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.1.1/0248

Name of medicine/Naam van medisyne: ADCO-CIPROFLOXACIN 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: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker:	DELTA LIMITED,HAFNARFJOROUR,ICELAND ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA
Laboratory/Laboratorium:	DELTA LIMITED,HAFNARFJOROUR,ICELAND ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA
Shelf-life/Rakleeftyd:	24 months/maande
Date of registration: Datum van registrasie	6 JUNE 2003 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.2.2/0261

Name of medicine/Naam van medisyne: FLUZOL 50

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
FLUCONAZOLE 50,0 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: PHARMA-Q, INDUSTRIA RSA
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: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.2.2/0262

Name of medicine/Naam van medisyne: FLUZOL 150

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
FLUCONAZOLE 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
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.2.2/0263

Name of medicine/Naam van medisyne: FLUZOL 200

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
FLUCONAZOLE 200,0 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
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.2.2/0264

Name of medicine/Naam van medisyne: HEXAL-FLUCONAZOLE 50

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
FLUCONAZOLE 50,0 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 PHARMA-Q, INDUSTRIA RSA 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	6 JUNE 2003 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.2.2/0265

Name of medicine/Naam van medisyne: HEXAL-FLUCONAZOLE 150

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
FLUCONAZOLE 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
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/20.2.2/0266

Name of medicine/Naam van medisyne: HEXAL-FLUCONAZOLE 200

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
FLUCONAZOLE 200,0 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
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA, WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/7.1/0302

Name of medicine/Naam van medisyne: FELODIPINE-HEXAL 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 MANUFACTURING AND PACKAGING, LONGDALE RSA
PHARMA-Q, INDUSTRIA RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/21.8.2/0330

Name of medicine/Naam van medisyne: FEMOSTON-CONTI

Dosage form/Doseringsvorm: TABLET

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

DYDROGESTERONE	5,0 mg
ESTRADIOL	1,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SOLVAY PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SOLVAY PHARM BV, OLST, NETHERLANDS

Packer/Verpakker: SOLVAY PHARM BV, OLST, NETHERLANDS

Laboratory/Laboratorium: SOLVAY PHARM BV, OLST, NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/18.9/0335

Name of medicine/Naam van medisyne: TRACTOCILE SOLUTION FOR INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
ATOSIBAN 7,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: FERRING (PTY) LTD

Manufacturer/Vervaardiger: FERRING AB, MALMO SWEDEN

Packer/Verpakker: FERRING AB, MALMO SWEDEN

Laboratory/Laboratorium: FERRING AB, MALMO SWEDEN
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
M-SCAN LTD, BERKSHIRE, UK
SANGTEC-INTERLAB, BROMMA SWEDEN
FERRING, KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/18.9/0336

Name of medicine/Naam van medisyne: TRACTOCILE CONCENTRATE FOR SOLUTION FOR INFUSION

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
ATOSIBAN 7,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: FERRING (PTY) LTD

Manufacturer/Vervaardiger: FERRING AB, MALMO SWEDEN

Packer/Verpakker: FERRING AB, MALMO SWEDEN

Laboratory/Laboratorium: FERRING AB, MALMO SWEDEN
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
M-SCAN LTD, BERKSHIRE, UK
SANGTEC-INTERLAB, BROMMA SWEDEN
FERRING, KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/22.1.4/0362

Name of medicine/Naam van medisyne: VITA FORCE A 1000 000 IU

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
VITAMIN A PALMITATE 100 000 IU

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMA NATURA (PTY) LTD

Manufacturer/Vervaardiger: PHARMA NATURA, SANDTON RSA

Packer/Verpakker: PHARMA NATURA, SANDTON RSA

Laboratory/Laboratorium: PHARMA NATURA. SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/22.1.4/0363

Name of medicine/Naam van medisyne: VITA FORCE A 200 000 IU

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
VITAMIN A PALMITATE 200 000 iu

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMA NATURA (PTY) LTD

Manufacturer/Vervaardiger: PHARMA NATURA, SANDTON RSA

Packer/Verpakker: PHARMA NATURA, SANDTON RSA

Laboratory/Laboratorium: PHARMA NATURA, SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/7.1.5/0515

Name of medicine/Naam van medisyne: LEVITRA 5

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: BAYER AG, LEVERKUSEN GERMANY

Packer/Verpakker: BAYER AG, LEVERKUSEN GERMANY
GLAXOSMITHKLINE SA, HALFWAY HOUSE, MIDRAND RSA
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: BAYER AG, LEVERKUSEN GERMANY
GLAXOSMITHKLINE SA, HALFWAY HOUSE, MIDRAND RSA
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
BAYER, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/7.1.5/0516

Name of medicine/Naam van medisyne: LEVITRA 10

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: BAYER AG, LEVERKUSEN GERMANY

Packer/Verpakker: BAYER AG, LEVERKUSEN GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
GLAXOSMITHKLINE SA, HALFWAY HOUSE, MIDRAND RSA
PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Laboratory/Laboratorium: BAYER AG, LEVERKUSEN GERMANY
GLAXOSMITHKLINE SA, HALFWAY HOUSE, MIDRAND RSA
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
BAYER, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 36/7.1.5/0517

Name of medicine/Naam van medisyne: LEVITRA 20

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: BAYER AG, LEVERKUSEN GERMANY

Packer/Verpakker: BAYER AG, LEVERKUSEN GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
GLAXOSMITHKLINE SA, HALFWAY HOUSE, MIDRAND RSA
PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Laboratory/Laboratorium: BAYER AG, LEVERKUSEN GERMANY
GLAXOSMITHKLINE SA, HALFWAY HOUSE, MIDRAND RSA
RESEARCH INSTITUTE FOR IND. PHARMACY, POTCHEFSTROOM RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
BAYER, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/2.2/0023

Name of medicine/Naam van medisyne: MIDANIUM 5 MG/5 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
MIDAZOLAM 1.0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND

Packer/Verpakker: WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND

Laboratory/Laboratorium: WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/2.2/0024

Name of medicine/Naam van medisyne: MIDANIUM 15 MG/3 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
MIDAZOLAM 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND

Packer/Verpakker: WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND

Laboratory/Laboratorium: WARSAW PHARMACEUTICAL WORKS, WARSAW, POLAND
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/11.4.1/0027

Name of medicine/Naam van medisyne: ACIBAN

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT: :
DRIED ALUMINIUM HYDROXIDE 250,0 mg
MAGNESIUM TRISILICATE 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Packer/Verpakker: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/26/0028

Name of medicine/Naam van medisyne: DOXORUBICIN-HEXAL 10 MG/ 5 ML

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

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT:
DOXORUBICIN HYDROCHLORIDE 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: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA

Packer/Verpakker: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/26/0029

Name of medicine/Naam van medisyne: DOXORUBICIN-HEXAL 50 MG/ 25 ML

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

Active ingredients/Aktiewe bestanddele:
EACH 25,0 ml SOLUTION CONTAINS/ELKE 25,0 ml OPLOSSING BEVAT :
DOXORUBICIN HYDROCHLORIDE 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA

Packer/Verpakker: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/26/0030

Name of medicine/Naam van medisyne: HX-DOXORUBICIN 10 MG/ 5ML

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

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :
DOXORUBICIN HYDROCHLORIDE 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: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA

Packer/Verpakker:	EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA PHARMA-Q, INDUSTRIA RSA
Laboratory/Laboratorium:	EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA PHARMA-Q, INDUSTRIA RSA 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	6 JUNE 2003 6 JUNIE 2003

Registration number/Registrasienommer: 37/26/0031

Name of medicine/Naam van medisyne: HX-DOXORUBICIN 50 MG/ 25 ML

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

Active ingredients/Aktiewe bestanddele:
EACH 25,0 ml SOLUTION CONTAINS/ELKE 25,0 ml OPLOSSING BEVAT :
DOXORUBICIN HYDROCHLORIDE 50.0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA

Packer/Verpakker: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: EBEWE ARZNEIMITTEL, UNTERLACH AUSTRIA
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/20.2.2/0032

Name of medicine/Naam van medisyne: HEXAL-FLUCONAZOLE 2MG/ 1ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
FLUCONAZOLE 2,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: SOLUPHARM, MELSUNGEN, GERMANY

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

Laboratory/Laboratorium: SOLUPHARM, MELSUNGEN, GERMANY
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/20.2.2/0033

Name of medicine/Naam van medisyne: FLUZOL 2 MG/ 1ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
FLUCONAZOLE 2,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: SOLUPHARM, MELSUNGEN, GERMANY

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

Laboratory/Laboratorium: SOLUPHARM, MELSUNGEN, GERMANY
PHARMA-Q, INDUSTRIA RSA
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003

Registration number/Registrasienommer: 37/3.2/0129

Name of medicine/Naam van medisyne: ACTONEL ONCE-A-WEEK

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
RISEDRONATE SODIUM 35,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5, 6

Applicant/Applikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: OSG NORWICH PHARMACEUTICALS,
NORTH NORWICH NY USA

Packer/Verpakker: AVENTIS PHARMA, SCOPPITO, ITALY
PROCTER & GAMBLE. WEITERSTADT, GERMANY
AVENTIS PHARMA, WALTLOO RSA

Laboratory/Laboratorium: OSG NORWICH PHARMACEUTICALS,
NORTH NORWICH NY USA
AVENTIS PHARMA, SCOPPITO, ITALY
PROCTER & GAMBLE. WEITERSTADT, GERMANY
AVENTIS PHARMA, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 6 JUNE 2003
Datum van registrasie 6 JUNIE 2003