



# Government Gazette

**REPUBLIC OF SOUTH AFRICA**

Vol. 457    Pretoria    18    July    2003    **No. 25201**



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

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## GENERAL NOTICE ALGEMENE KENNISGEWING

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### NOTICE 1894 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.

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Registration number/Registrasienuommer: 34/10.2.2/0198

Name of medicine/Naam van medisyne: MUCOLATOR 200 MG

Dosage form/Doseringsvorm: GRANULES

Active ingredients/Aktiewe bestanddele:

EACH 3,0 g SACHET CONTAINS/ELKE SAKKIE BEVAT :

ACETYLCYSTEINE ... 200,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, ST-REMY-SUR-AVRE FRANCE

Packer/Verpakker: ABBOTT, ST-REMY-SUR-AVRE FRANCE

Laboratory/Laboratorium: ABBOTT, ST-REMY-SUR-AVRE FRANCE  
ABBOTT, AEROTON RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/30.1/0317

Name of medicine/Naam van medisyne: RUDI-ROUVAX

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:

MEASLES VACCINE(LIVE ATTENUATED) ... 1 000 ccid50

RUBELLA VACCINE (LIVE ATTENUATED) ... 1 000 ccid50

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: AVENTIS PHARMA (PTY) LTD

Manufacturer/Vervaardiger: AVENTIS PASTEUR, L'ETOILE, FRANCE

Packer/Verpakker: AVENTIS PASTEUR, L'ETOILE, FRANCE

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

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 35/30.1/0239

Name of medicine/Naam van medisyne: PREVENAR

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH-0,5 ml DOSE CONTAINS/ELKE 0,5 ml DOSIS BEVAT:

STREPTOCOCCUS PNEUMONIAE

SEROTYPES:	4	2,0 ug
	6B	2,0 ug
	9V	2,0 ug
	14	2,0 ug
	18C	2,0 ug
	19F	2,0 ug
	23F	2,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: WYETH S.A. (PTY) LTD

Manufacturer/Vervaardiger: WYETH LEDERLE, PEARL RIVER, NY USA

Packer/Verpakker: WYETH LEDERLE, PEARL RIVER, NY USA  
WYETH, HAMPSHIRE UK

Laboratory/Laboratorium: WYETH, HAMPSHIRE UK  
NATIONAL CONTROL LAB (NCL) BLOEMFONTEIN  
WYETH S.A., MIDRAND, RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 7 MARCH 2003

Datum van registrasie: 7 MAART 2003

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Registration number/Registrasiënommer: 36/21.2/0411

Name of medicine/Naam van medisyne: GLUCOVANCE 250 MG/1,25 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :

GLIBENCLAMIDE ... 1,25 mg

METFORMIN HYDROCHLORIDE ... 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: MERCK (PTY) LTD

Manufacturer/Vervaardiger: LIPHA S.A., SEMOY CEDEX, FRANCE

Packer/Verpakker: LIPHA S.A., SEMOY CEDEX, FRANCE  
LIPHA S.A., LYON, FRANCE

Laboratory/Laboratorium: LIPHA S.A., SEMOY CEDEX, FRANCE  
LIPHA S.A., LYON, FRANCE  
MERCK PHARMACEUTICALS MANUFACTURING,  
WADEVILLE RSA  
MERCK, MIDRAND RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënómmer: 36/21.2/0412

Name of medicine/Naam van medisyne: GLUCOVANCE 500 MG/2,5 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :

GLIBENCLAMIDE ... 2,5 mg

METFORMIN HYDROCHLORIDE ... 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MERCK (PTY) LTD

Manufacturer/Vervaardiger: LIPHA S.A., SEMOY CEDEX, FRANCE

Packer/Verpakker: LIPHA S.A., SEMOY CEDEX, FRANCE  
LIPHA S.A., LYON, FRANCE

Laboratory/Laboratorium: LIPHA S.A., SEMOY CEDEX, FRANCE  
LIPHA S.A., LYON, FRANCE  
MERCK PHARMACEUTICALS MANUFACTURING,  
WADEVILLE RSA  
MERCK, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/21.2/0413

Name of medicine/Naam van medisyne: GLUCOVANCE 500 MG/5 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

GLIBENCLAMIDE ... 5,0 mg

METFORMIN HYDROCHLORIDE ... 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MERCK (PTY) LTD

Manufacturer/Vervaardiger: LIPHA S.A., SEMOY CEDEX, FRANCE

Packer/Verpakker: LIPHA S.A., SEMOY CEDEX, FRANCE  
LIPHA S.A., LYON, FRANCE

Laboratory/Laboratorium: LIPHA S.A., SEMOY CEDEX, FRANCE  
LIPHA S.A., LYON, FRANCE  
MERCK, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienuommer: 36/21.4/0334

Name of medicine/Naam van medisyne: FORTEO

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml SOLUTION CONTAINS/  
ELKE 1,0 ml OPLOSSING BEVAT:  
TERIPARATIDE ... 250,0 ug

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

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

Manufacturer/Vervaardiger: LILLY FRANCE SA, FEGERSHEIM FRANCE

Packer/Verpakker: LILLY FRANCE SA, FEGERSHEIM FRANCE

Laboratory/Laboratorium: LILLY FRANCE SA, FEGERSHEIM FRANCE  
CONSULTING CHEMICAL LAB, STAR STREET  
BOKSBURG RSA  
CONSULTING MICROBIOL LAB,  
BLUEGUMCREEK, BENONI RSA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/7.1/0372

Name of medicine/Naam van medisyne: TEVETEN 600

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
EPROSARTAN MESYLATE EQUIVALENT TO  
EPROSARTAN ... 600,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: SOLVAY PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK  
SOLVAY PHARM BV, OLST, NETHERLANDS

Packer/Verpakker: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK  
SOLVAY PHARM BV, OLST, NETHERLANDS

Laboratory/Laboratorium: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK  
SOLVAY PHARM BV, OLST, NETHERLANDS  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
SCHERING, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 00/2.2/8

Name of medicine/Naam van medisyne: XYLAVET 2 %

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/

ELKE 1,0 ml OPLOSSING BEVAT :

XYLAZINE ... 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: INTERVET SA (PTY) LTD

Manufacturer/Vervaardiger: VERICORE, DUNDEE, SCOTLAND UNK

Packer/Verpakker: CHANELLE, GALWAY IRELAND

Laboratory/Laboratorium: VERICORE, DUNDEE, SCOTLAND UNK

CHANELLE, GALWAY IRELAND

INTERVET S.A., EDENVALE RSA

Shelf-life/Rakleefyd: 36 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 00/2.2/9

Name of medicine/Naam van medisyne: XYLAVET 10 % FOR HORSES

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml SOLUTION CONTAINS/  
ELKE 1,0 ml OPLOSSING BEVAT:  
XYLAZINE ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: INTERVET SA (PTY) LTD

Manufacturer/Vervaardiger: VERICORE, DUNDEE, SCOTLAND UNK

Packer/Verpakker: CHANELLE, GALWAY IRELAND

Laboratory/Laboratorium: VERICORE, DUNDEE, SCOTLAND UNK  
CHANELLE, GALWAY IRELAND  
INTERVET S.A., EDENVALE RSA

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienuommer: 35/28/0086

Name of medicine/Naam van medisyne: MULTIHANCE

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/

ELKE 1,0 ml OPLOSSING BEVAT:

GADOBENIC ACID ... 334,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: BRACCO spa, MILAN ITALY

Packer/Verpakker: BRACCO spa, MILAN ITALY

Laboratory/Laboratorium: BRACCO spa, MILAN ITALY  
CONSULTING CHEMICAL LAB, STAR STREET  
BOKSBURG RSA  
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 35/8.1/0236

Name of medicine/Naam van medisyne: BENEFIX 1000 IU

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :  
FACTOR IX ... 1000,0 iu

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: WYETH S.A. (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, KANSAS USA

Packer/Verpakker: ABBOTT, KANSAS USA  
PHARMA-Q, INDUSTRIA

Laboratory/Laboratorium: ABBOTT, KANSAS USA  
GENETICS INSTITUTE, ANDOVER, USA  
PHARMA-Q, INDUSTRIA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
WYETH S.A., MIDRAND, RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 34/2.9/0239

Name of medicine/Naam van medisyne: PreceDEX

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

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:  
DEXMEDETOMIDINE ... 100,0 ug

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant:                    ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, NORTH CAROLINA USA  
  ORION PHARMACEUTICA, ESPOO FINLAND

Packer/Verpakker:                    ABBOTT, NORTH CAROLINA USA

Laboratory/Laboratorium: ABBOTT, NORTH CAROLINA USA  
  ORION PHARMACEUTICA, ESPOO FINLAND  
  ABBOTT, AEROTON RSA

Shelf-life/Rakleef tyd:               36 months/maande

Date of registration:                 07 MARCH 2003  
Datum van registrasie                07 MAART 2003

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Registration number/Registrasiennommer: 35/20.1.1/0170

Name of medicine/Naam van medisyne: ROLAB-CIPROFLOXACIN 100

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :  
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO  
CIPROFLOXACIN ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/20.1.1/0171

Name of medicine/Naam van medisyne: ROLAB-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, 7

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie 07 MAART 2003

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Registration number/Registrasienommer: 35/20.1.1/0172

Name of medicine/Naam van medisyne: ROLAB-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, 7

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie 07 MAART 2003

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Registration number/Registrasiënommer: 35/20.1.1/0173

Name of medicine/Naam van medisyne: ROLAB-CIPROFLOXACIN 750

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO  
CIPROFLOXACIN ... 750,0

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: DELTA LIMITED,HAFNARFJOROUR,ICELAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/2.9/0010

Name of medicine/Naam van medisyne: TRAMACET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

PARACETAMOL ... 325,0 mg

TRAMADOL HYDROCHLORIDE ... 37,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN ORTHO LLC, GURABO PUERTO RICO

Packer/Verpakker: JANSSEN ORTHO LLC, GURABO PUERTO RICO  
ORTHO McNEIL PHARMACEUTICAL INC, NEW JERSEY  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: JANSSEN ORTHO LLC, GURABO PUERTO RICO  
ORTHO McNEIL PHARMACEUTICAL INC, NEW JERSEY  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/15.1/0410

Name of medicine/Naam van medisyne: CILOXAN EYE OINTMENT

Dosage form/Doseringsvorm: OINTMENT/SALF

Active ingredients/Aktiewe bestanddele:

EACH 1,0 g OINTMENT CONTAINS/ELKE 1,0 g SALF BEVAT:  
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT TO  
CIPROFLOXACIN ... 3,0 mg .

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: SA ALCON-COUVREUR NV PUURS, BELGIUM

Packer/Verpakker: SA ALCON-COUVREUR NV PUURS, BELGIUM

Laboratory/Laboratorium: SA ALCON-COUVREUR NV PUURS, BELGIUM  
RESEARCH INSTITUTE FOR IND. PHARMACY,  
POTCHEFSTROOM RSA  
ALCON, RANDBURG RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/10.2.1/0449

Name of medicine/Naam van medisyne: BROVENT 250 UG/1 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :  
IPRATROPIUM BROMIDE ... 250,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Packer/Verpakker: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Laboratory/Laboratorium: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA  
KHULULEKANI LABORATORY SERVICES, MIDRAND  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie 07 MAART 2003

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Registration number/Registrasienommer: 34/10.2.1/0450

Name of medicine/Naam van medisyne: BROVENT 500 UG/2 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:  
IPRATROPIUM BROMIDE ... 250,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Packer/Verpakker: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Laboratory/Laboratorium: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
KHULULEKANI LABORATORY SERVICES, MIDRAND  
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiensnommer: 34/10.2.1/0451

Name of medicine/Naam van medisyne: BROVENT 500 UG/1 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:

IPRATROPIUM BROMIDE ... 500,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: PHARMACIA SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Packer/Verpakker: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Laboratory/Laboratorium: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA  
KHULULEKANI LABORATORY SERVICES, MIDRAND  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
PHARMACIA SOUTH AFRICA, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/34/0374

Name of medicine/Naam van medisyne: ZYBAN

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
BUPROPION HYDROCHLORIDE ... 150,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, ZEBULON,NORTH  
CAROLINA,USA

Packer/Verpakker: GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, ZEBULON,NORTH  
CAROLINA,USA  
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie 07 MAART 2003

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Registration number/Registrasiënommer: 34/11.5/0333

Name of medicine/Naam van medisyne: PLANTABEN

Dosage form/Doseringsvorm: GRANULES

Active ingredients/Aktiewe bestanddele:

EACH SACHET CONTAINS/

ELKE SAKKIE BEVAT:

ISPAGHULA HUSK ... 3,5 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BYK MADAUS (PTY) LTD

Manufacturer/Vervaardiger: LABORATORIOS MADAUS CERAFARM,  
BARCELONA, SPAIN

Packer/Verpakker: LABORATORIOS MADAUS CERAFARM,  
BARCELONA, SPAIN

Laboratory/Laboratorium: LABORATORIOS MADAUS CERAFARM,  
BARCELONA, SPAIN  
BYK MADAUS, MIDRAND RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 35/34/0057

Name of medicine/Naam van medisyne: CELLCEPT OS

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT:  
MYCOPHENOLATE MOFETIL ... 200,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: HOFFMANN-LA ROCHE INC, NEW JERSEY USA

Packer/Verpakker: HOFFMANN-LA ROCHE INC, NEW JERSEY USA  
ALLPACK AG, MUTTENZ, SWITZERLAND  
ROCHE, ISANDO RSA

Laboratory/Laboratorium: HOFFMANN-LA ROCHE INC, NEW JERSEY USA  
F HOFFMANN-LA ROCHE, GREN, BASLE SWITZERLAND  
ROCHE, ISANDO RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/34/0132

Name of medicine/Naam van medisyne: SANDIMMUN NEORAL 10 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:

EACH CAPSULE CONTAINS/

ELKE KAPSULE BEVAT:

CICLOSPORIN ... 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

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

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

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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MARCH 2003

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Registration number/Registrasienuommer: 34/2.7/0315

Name of medicine/Naam van medisyne: BAYER ASPIRIN 500 T

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

ASPIRIN ... 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: ROCHE, ISANDO RSA

Packer/Verpakker: ROCHE, ISANDO RSA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA

Laboratory/Laboratorium: ROCHE, ISANDO RSA  
BAYER, ISANDO RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 35/34/0292

Name of medicine/Naam van medisyne: VISICARE

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:  
POLIHEXANIDE ... 0,001 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: CIBA VISION, ONTARIO CANADA  
CIBA VISION, MUNICH GERMANY  
LABORATOIRES CIBA VISION,CEDEX,FRANCE

Packer/Verpakker: CIBA VISION, ONTARIO CANADA  
CIBA VISION, MUNICH GERMANY  
LABORATOIRES CIBA VISION,CEDEX,FRANCE  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: CIBA VISION, ONTARIO CANADA  
CIBA VISION, MUNICH GERMANY  
LABORATOIRES CIBA VISION,CEDEX,FRANCE  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 35/10.1/0266

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

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:

EACH 10,0 ml LIQUID CONTAINS/ELKE 10,0 ml VOEISTOF BEVAT:

GUAIFENESIN ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: WARNER-LAMBERT, RETREAT RSA

Packer/Verpakker: WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/2.6.5/0373

Name of medicine/Naam van medisyne: CLOMENT 25

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: DOUGLAS PHARMACEUTICALS, AUCKLAND,  
NEW ZEALAND

Packer/Verpakker: DOUGLAS PHARMACEUTICALS, AUCKLAND,  
NEW ZEALAND

Laboratory/Laboratorium: DOUGLAS PHARMACEUTICALS, AUCKLAND,  
NEW ZEALAND  
CONSULTING CHEMICAL LAB, STAR STREET  
BOKSBURG RSA  
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienuommer: 34/2.7/0166

Name of medicine/Naam van medisyne: CHILDREN'S MOTRIN SUSPENSION

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:  
EACH 5,0 ml SUSPENSION CONTAINS/  
ELKE 5,0 ml SUSPENSIE BEVAT:  
IBUPROFEN ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: MC NEIL CONSUMER HEALTHCARE,  
FORT WASHINGTON USA

Packer/Verpakker: MC NEIL CONSUMER HEALTHCARE,  
FORT WASHINGTON USA

Laboratory/Laboratorium: MC NEIL CONSUMER HEALTHCARE,  
FORT WASHINGTON USA  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleefyd: 36 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie 07 MAART 2003

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Registration number/Registrasiënommer: 34/20.1.1/0130

Name of medicine/Naam van medisyne: MICRO GENTAMICIN  
INJECTION 10 mg/ml (2ml C/V)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

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

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 34/20.1.1/0131

Name of medicine/Naam van medisyne: MICRO GENTAMICIN  
INJECTION 40 mg/ml (2 ml C/V)

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :  
GENTAMICIN SULPHATE EQUIVALENT TO GENTAMICIN ... 40,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/2.6.5/0374

Name of medicine/Naam van medisyne: CLOMENT 100

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

CLOZAPINE ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: DOUGLAS PHARMACEUTICALS, AUCKLAND,  
NEW ZEALAND

Packer/Verpakker: DOUGLAS PHARMACEUTICALS, AUCKLAND,  
NEW ZEALAND

Laboratory/Laboratorium: DOUGLAS PHARMACEUTICALS, AUCKLAND,  
NEW ZEALAND  
CONSULTING CHEMICAL LAB, STAR STREET  
BOKSBURG RSA  
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/1.2/0092

Name of medicine/Naam van medisyne: CILIFT 20 MG TABLET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :

CITALOPRAM HYDROBROMIDE EQUIVALENT TO CITALOPRAM ... 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON LTD, PORT ELIZABETH RSA  
SAD SELF MEDICATION, EAST LONDON RSA

Packer/Verpakker: LENNON LTD, PORT ELIZABETH RSA  
SAD SELF MEDICATION, EAST LONDON

Laboratory/Laboratorium: LENNON LTD, PORT ELIZABETH RSA  
SAD SELF MEDICATION, EAST LONDON  
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienuommer: 35/2.6.5/0385

Name of medicine/Naam van medisyne: SEROQUEL Starter Pack

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH PEACH TABLET CONTAINS:

QUETIAPINE ... 25,0 mg

EACH YELLOW TABLET CONTAINS:

QUETIAPINE ... 100,0 mg

EACH WHITE TABLET CONTAINS:

QUETIAPINE ... 200,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA, CHESHIRE UK  
ASTRAZENECA, NEWARK, DELAWARE, USA

Packer/Verpakker: ASTRAZENECA, CHESHIRE UK  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA  
PCI SERVICES, LANCASTER WAY, BOLTON UK  
PCI SERVICES, NORTHAMPTONSHIRE, UK  
ASTRAZENECA, ALRODE, ALBERTON RSA

Laboratory/Laboratorium: ASTRAZENECA, CHESHIRE UK  
ASTRAZENECA, NEWARK, DELAWARE, USA  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA  
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleefyd: 36 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 36/2.2/0131

Name of medicine/Naam van medisyne: ADCO-ZOLPIDEM HEMITARTRATE 5 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
ZOLPIDEM HEMITARTRATE ... 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: JANSSEN-CILAG, QUELUZ DE BAIXO PORTUGAL  
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT,  
SPAIN

Packer/Verpakker: JANSSEN-CILAG, QUELUZ DE BAIXO PORTUGAL  
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN  
MANUFACTURING PACKAGING FARMACA ,  
HEERENVEEN THE NETHERLANDS

Laboratory/Laboratorium: SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN  
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA  
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleefyd: 36 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienuommer: 36/2.2/0132

Name of medicine/Naam van medisyne: ADCO-ZOLPIDEM HEMITARTRATE 10 MG

Dosage form/Doseringsvorm: TABLET

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

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: JANSSEN-CILAG, QUELUZ DE BAIXO PORTUGAL  
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN

Packer/Verpakker: JANSSEN-CILAG, QUELUZ DE BAIXO PORTUGAL  
MANUFACTURING PACKAGING FARMACA,  
HEERENVEEN THE NETHERLANDS  
SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN

Laboratory/Laboratorium: SYNTHON HISPANIA, SANT BOI DE LLOBREGAT, SPAIN  
ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA  
ADCOCK INGRAM HEALTHCARE, WADEVILLE RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/15.4/0157

Name of medicine/Naam van medisyne: LUMIGAN

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml SOLUTION CONTAINS/  
ELKE 1,0 ml OPLOSSING BEVAT :  
BIMATOPROST ... 0,3 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: ALLERGAN PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ALLERGAN, WACO TEXAS USA  
ALLERGAN, COUNTY MAYO IRELAND

Packer/Verpakker: ALLERGAN, WACO TEXAS USA  
ALLERGAN, COUNTY MAYO IRELAND

Laboratory/Laboratorium: ALLERGAN, WACO TEXAS USA  
ALLERGAN, COUNTY MAYO IRELAND  
INSTITUTE FOR PHARMACEUTICAL  
SERVICES, BOKSBURG RSA  
ALLERGAN, MIDRAND RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/31/0178

Name of medicine/Naam van medisyne: CEREZYME 200

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 5,0 ml LIQUID CONTAINS/

ELKE 5,0 ml VLOEISTOF BEVAT:

IMIGLUCERASE ... 200,0 units

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: GENZYME CORPORATION, ALLSTON, MA USA

Packer/Verpakker: GENZYME CORPORATION, ALLSTON, MA USA

Laboratory/Laboratorium: GENZYME CORPORATION, ALLSTON, MA USA  
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/31/0179

Name of medicine/Naam van medisyne: CEREZYME 400

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 10,0 ml LIQUID CONTAINS/

ELKE 10,0 ml VOEISTOF BEVAT :

IMIGLUCERASE ... 400,0 units

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger: GENZYME CORPORATION, ALLSTON, MA USA

Packer/Verpakker: GENZYME CORPORATION, ALLSTON, MA USA

Laboratory/Laboratorium : GENZYME CORPORATION, ALLSTON, MA USA  
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie 07 MAART 2003

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Registration number/Registrasiënommer: 36/16.4/0195

Name of medicine/Naam van medisyne: ANDOLEX-C LOZENGES ORANGE

Dosage form/Doseringsvorm: LOZENGES/SUIGTABLETTE

Active ingredients/Aktiewe bestanddele:

EACH LOZENGE CONTAINS/ELKE SUIGTABLET BEVAT:

BENZYDAMINE HYDROCHLORIDE ... 3,0 mg

CETYLPYRIDINIUM CHLORIDE ... 1,33 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: 3M PHARMACEUTICALS SA (PTY) LTD

Manufacturer/Vervaardiger: 3M, CHILVERS RD, THORNLEIGH, AUSTRALIA  
NESTLE, BLACKTOWN, AUSTRALIA

Packer/Verpakker: 3M, CHILVERS RD, THORNLEIGH, AUSTRALIA

Laboratory/Laboratorium: 3M, CHILVERS RD, THORNLEIGH, AUSTRALIA  
ANALYTICON, KEMPTON PARK RSA  
3M, ISANDO RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/18.2/0402

Name of medicine/Naam van medisyne: DDAVP TABLET 0,2 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
DESMOPRESSIN ACETATE ... 0,2 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: 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  
INSTITUTE FOR SCIENTIFIC BIOCHEMISTRY,  
UPSALLA SWEDEN  
SANGTEC-INTERLAB, BROMMA SWEDEN  
FERRING, KEMPTON PARK RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 34/5.10/0379

Name of medicine/Naam van medisyne: ZOFTRAN MULTIDOSE 2 MG/ML VIAL

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml LIQUID CONTAINS/ELKE 1,0 ml VLOEISTOF BEVAT:  
ONDANSETRON HYDROCHLORIDE EQUIVALENT TO  
ONDANSETRON ... 2,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, DURHAM UK

Packer/Verpakker: GLAXO WELLCOME, DURHAM UK  
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, DURHAM UK  
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/20.1.1/0405

Name of medicine/Naam van medisyne: DYNAFLOC 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, 7

Applicant/Applikant: PHARMA DYNAMICS (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED, HAFNARFJOROUR, ICELAND

Packer/Verpakker: DELTA LIMITED, HAFNARFJOROUR, ICELAND

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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/20.1.1/0406

Name of medicine/Naam van medisyne: DYNAFLOC 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, 5a, 6, 7

Applicant/Applikant: PHARMA DYNAMICS (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED, HAFNARFJOROUR, ICELAND

Packer/Verpakker: DELTA LIMITED, HAFNARFJOROUR, ICELAND

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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2002

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Registration number/Registrasienuommer: 34/20.1.1/0404

Name of medicine/Naam van medisyne: DYNAFLOC 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: PHARMA DYNAMICS (PTY) LTD

Manufacturer/Vervaardiger: DELTA LIMITED,HAFNARFJOROUR,ICELAND

Packer/Verpakker: DELTA LIMITED,HAFNARFJOROUR,ICELAND

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie 07 MAART 2003

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Registration number/Registrasiënommer: 36/16.4/0208

Name of medicine/Naam van medisyne: L.C.C. THROAT LOZENGES –  
HONEY AND LEMON

Dosage form/Doseringvorm: LOZENGES/SUIGTABLETTE

Active ingredients/Aktiewe bestanddele:  
EACH LOZENGE CONTAINS/ELKE SUIGTABLET BEVAT:  
BENZYL ALCOHOL ... 6,5 mg  
CETYLPYRIDINIUM CHLORIDE ... 1,47 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA

Packer/Verpakker: ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA

Laboratory/Laboratorium: ADCOCK INGRAM HEALTHCARE, CLAYVILLE RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 36/20.1.1/0322

Name of medicine/Naam van medisyne: SABAX CEFOTAXIME 500 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:

CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME ... 500,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer/Vervaardiger: ACS DOBFAR SpA, MILAN ITALY  
ANFARM-HELLAS S.A., ATHENS GREECE

Packer/Verpakker: ANFARM-HELLAS S.A., ATHENS GREECE

Laboratory/Laboratorium: ACS DOBFAR SpA, MILAN ITALY  
ANFARM-HELLAS S.A., ATHENS GREECE  
ADCOCK INGRAM CRITICAL CARE, JOHANNESBURG

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/20.1.1/0323

Name of medicine/Naam van medisyne: SABAX CEFOTAXIME 1 G

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:

CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME ... 1000,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer/Vervaardiger: ACS DOBFAR SpA, MILAN ITALY  
ANFARM-HELLAS S.A., ATHENS GREECE

Packer/Verpakker: ANFARM-HELLAS S.A., ATHENS GREECE

Laboratory/Laboratorium: ACS DOBFAR SpA, MILAN ITALY  
ANFARM-HELLAS S.A., ATHENS GREECE  
ADCOCK INGRAM CRITICAL CARE,  
JOHANNESBURG, RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 36/20.1.1/0324

Name of medicine/Naam van medisyne: SABAX CEFOTAXIME 2 G

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH VIAL CONTAINS/

ELKE FLESSIE BEVAT:

CEFOTAXIME SODIUM EQUIVALENT TO

CEFOTAXIME ... 2000,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer/Vervaardiger: ACS DOBFAR SpA, MILAN ITALY  
ANFARM-HELLAS S.A., ATHENS GREECE

Packer/Verpakker: ANFARM-HELLAS S.A., ATHENS GREECE

Laboratory/Laboratorium: ACS DOBFAR SpA, MILAN ITALY  
ANFARM-HELLAS S.A., ATHENS GREECE  
ADCOCK INGRAM CRITICAL CARE, JOHANNESBURG

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/20.1.1/0325

Name of medicine/Naam van medisyne: SABAX CEFOXITIN 1 G

Dosage form/Doseringsvorm: INJECTION/INSPIUTING

Active ingredients/Aktiewe bestanddele:  
EACH VIAL CONTAINS/  
ELKE FLESSIE BEVAT:  
CEFOXITIN SODIUM EQUIVALENT TO  
CEFOXITIN ... 1000,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer/Vervaardiger: ACS DOBFAR SpA, MILAN ITALY

Packer/Verpakker: MITIM s.r.l. VIA CACCIAMALI, BRESCIA, ITALY

Laboratory/Laboratorium: ACS DOBFAR SpA, MILAN ITALY  
MITIM s.r.l. VIA CACCIAMALI, BRESCIA, ITALY  
ADCOCK INGRAM CRITICAL CARE, JOHANNESBURG

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/20.1.1/0326

Name of medicine/Naam van medisyne: SABAX CEFOXITIN 2 G

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:

CEFOXITIN SODIUM EQUIVALENT TO CEFOXITIN ... 2000,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer/Vervaardiger: ACS DOBFAR SpA, MILAN ITALY

Packer/Verpakker: MITIM s.r.l. VIA CACCIAMALI, BRESCIA, ITALY

Laboratory/Laboratorium: ACS DOBFAR SpA, MILAN ITALY  
MITIM s.r.l. VIA CACCIAMALI, BRESCIA, ITALY  
ADCOCK INGRAM CRITICAL CARE, JOHANNESBURG

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 32/20.1.1/0667

Name of medicine/Naam van medisyne: ZITHROMAX 600 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

AZITHROMYCIN DIHYDRATE EQUIVALENT TO AZITHROMYCIN ... 600,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, LATINA ITALY

Packer/Verpakker: PFIZER, LATINA ITALY  
PFIZER LABS, PIETERMARITZBURG RSA  
WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: PFIZER, LATINA ITALY  
PFIZER LABS, PIETERMARITZBURG RSA  
WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 83/2.6/654

Name of medicine/Naam van medisyne: ARTHRIDINE NF

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 100,0 ml SOLUTION CONTAINS/  
ELKE 100,0 ml OPLOSSING BEVAT:  
PHENYLBUTAZONE ... 20,0 g

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: LOGOS AGVET (PTY) LTD

Manufacturer/Vervaardiger: VIRBAC SA , CARROS FRANCE

Packer/Verpakker: VIRBAC SA , CARROS FRANCE

Laboratory/Laboratorium: VIRBAC SA , CARROS FRANCE  
LOGOS AGVET, HALFWAY HOUSE RSA

Shelf-life/Rakleef tyd: 12 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 32/1.2/0002

Name of medicine/Naam van medisyne: TEVA-TRAZODONE HYDROCHLORIDE 100 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :  
TRAZODONE HYDROCHLORIDE .... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL

Packer/Verpakker: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL

Laboratory/Laboratorium: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL  
INSTITUTE FOR INDUSTRIAL PHARMACY,  
POTCHEFSTROOM UNIVERSITY RSA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
TEVA, INDUSTRIA RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 32/1.2/0001

Name of medicine/Naam van medisyne: TEVA-TRAZODONE HYDROCHLORIDE 50 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

TRAZODONE HYDROCHLORIDE ... 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL

Packer/Verpakker: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL

Laboratory/Laboratorium: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL  
INSTITUTE FOR INDUSTRIAL PHARMACY,  
POTCHEFSTROOM UNIVERSITY RSA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
TEVA, INDUSTRIA RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/11.5/0333

Name of medicine/Naam van medisyne: PLANTABEN

Dosage form/Doseringsvorm: GRANULES

Active ingredients/Aktiewe bestanddele:

EACH SACHET CONTAINS/

ELKE SAKKIE BEVAT:

ISPAGHULA HUSK ... 3,5 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: BYK MADAUS (PTY) LTD

Manufacturer/Vervaardiger: LABORATORIOS MADAUS CERAFARM,  
BARCELONA, SPAIN

Packer/Verpakker: LABORATORIOS MADAUS CERAFARM,  
BARCELONA, SPAIN

Laboratory/Laboratorium: LABORATORIOS MADAUS CERAFARM,  
BARCELONA, SPAIN  
BYK MADAUS, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 34/5.10/0379

Name of medicine/Naam van medisyne: ZOFTRAN MULTIDOSE 2 MG/ML VIAL

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml LIQUID CONTAINS/ELKE 1,0 ml VLOEISTOF BEVAT:  
ONDANSETRON HYDROCHLORIDE EQUIVALENT TO  
ONDANSETRON ... 2,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, DURHAM UK

Packer/Verpakker: GLAXO WELLCOME, DURHAM UK  
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, DURHAM UK  
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 32/11.2/0242

Name of medicine/Naam van medisyne: MICRO HYOSCINE BUTYLBROMIDE  
INJECTION 20 MG/1 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ML SOLUTION CONTAINS/  
ELKE 1,0 ml OPLOSSING BEVAT:  
HYOSCINE-N-BUTYL BROMIDE ... 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienuommer: 28/5.2/0661

Name of medicine/Naam van medisyne: TEVA - ATENOLOL 25 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

ATENOLOL ... 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BIOGAL PHARMACEUTICAL WORKS, DEBRECEN  
HUNGARY

Packer/Verpakker: APS-BERK PHARMACEUTICALS, EAST SUSSEX UK

Laboratory/Laboratorium: APS-BERK PHARMACEUTICALS, EAST SUSSEX UK  
RESEARCH INSTITUTE FOR IND. PHARMACY,  
POTCHEFSTROOM RSA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
TEVA, INDUSTRIA RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 33/15.4/0063

Name of medicine/Naam van medisyne: CIBALLERGE

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:

ANTAZOLINE HYDROCHLORIDE ... 0,50 mg

TETRAHYDROZOLINE HYDROCHLORIDE ... 0,40 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: CIBA VISION, HETTLINGEN SWITZERLAND  
NOVO NORDISK, JOHANNESBURG RSA

Packer/Verpakker: CIBA VISION, HETTLINGEN SWITZERLAND  
NOVO NORDISK, JOHANNESBURG RSA

Laboratory/Laboratorium: CIBA VISION, HETTLINGEN SWITZERLAND  
NOVO NORDISK, JOHANNESBURG RSA

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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**B6H****REGISTRATION OF MEDICINES:****B6/SEPTEMBER 2002**

The following applications refers:

6.1	340089	A2.8	IBUMOL
6.2	340388	A32	OTRISALINE SOLUTION
6.3	340389	A13.6	MC RUB
6.4	340392	A24	CALCICHEW
6.5	340442	A2.5	TRILEPTAL 150
6.6	340507	A5.7.1	POLLENTYME TABLETS
6.7	350042	A21.2	PRIMAPEX 60MG TABLETS
6.8	350043	A21.2	PRIMAPEX 120MG TABLETS
6.9	350076	A15.4	ZADITEN
6.10	350091	A21.2	HEXAFORMIN 500
6.11	350092	A21.2	HEXAFORMIN 850
6.12	350093	A21.2	GLUCOFORMIN 500
6.13	350094	A21.2	GLUCOFORMIN 850
6.14	350155	A21.12	CYPROPLEX 50MG
6.15	350212	A20.1.2	RANMOXY SUSPENSION 125MG
6.16	350213	A20.1.2	RANMOXY SUSPENSION 250MG
6.17	350217	A13	MEDICATED INGRAM'S
6.18	350228	A2.1	RECOFOL 1% 20ML
6.19	350229	A2.1	RECOFOL 1% 50ML
6.20	350230	A2.1	RECOFOL 1% 100ML

Registration number/Registrasienommer: 32/11.4.3/0703

Name of medicine/Naam van medisyne: ALTOSEC 10

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:

EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:

OMEPRAZOLE ... 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE  
SWEDEN

Packer/Verpakker: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE  
SWEDEN  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA  
LENNON LTD, PORT ELIZABETH RSA  
SAD SELF MEDICATION, EAST LONDON RSA

Laboratory/Laboratorium: ASTRAZENECA AB, GARTUNAVAGEN, SODERTALJE  
SWEDEN  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA  
LENNON LTD, PORT ELIZABETH RSA  
SAD SELF MEDICATION, EAST LONDON RSA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
PHARMACARE LTD, PORT ELIZABETH RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 03 MARCH 2003

Datum van registrasie: 03 MAART 2003

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Registration number/Registrasiënommer: 28/5.2/0661

Name of medicine/Naam van medisyne: TEVA - ATENOLOL 25 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

ATENOLOL ... 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BIOGAL PHARMACEUTICAL WORKS, DEBRECEN  
HUNGARY

Packer/Verpakker: APS-BERK PHARMACEUTICALS, EAST SUSSEX UK

Laboratory/Laboratorium: APS-BERK PHARMACEUTICALS, EAST SUSSEX UK  
RESEARCH INSTITUTE FOR IND. PHARMACY,  
POTCHEFSTROOM RSA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
TEVA, INDUSTRIA RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 32/11.2/0242

Name of medicine/Naam van medisyne: MICRO HYOSCINE BUTYLBROMIDE  
INJECTION 20 MG/1 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ML SOLUTION CONTAINS/  
ELKE 1,0 ml OPLOSSING BEVAT:  
HYOSCINE-N-BUTYL BROMIDE ... 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: MICRO HEALTHCARE (PTY) LTD

Manufacturer/Vervaardiger: MICRO HEALTHCARE, BETHLEHEM RSA

Packer/Verpakker: MICRO HEALTHCARE, BETHLEHEM RSA

Laboratory/Laboratorium: MICRO HEALTHCARE, BETHLEHEM RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 33/15.4/0063

Name of medicine/Naam van medisyne: CIBALLERGE

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:

ANTAZOLINE HYDROCHLORIDE ... 0,50 mg

TETRAHYDROZOLINE HYDROCHLORIDE ... 0,40 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: CIBA VISION, HETTLINGEN SWITZERLAND  
NOVO NORDISK, JOHANNESBURG RSA

Packer/Verpakker: CIBA VISION, HETTLINGEN SWITZERLAND  
NOVO NORDISK, JOHANNESBURG RSA

Laboratory/Laboratorium: CIBA VISION, HETTLINGEN SWITZERLAND  
NOVO NORDISK, JOHANNESBURG RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasienommer: 32/1.2/0002

Name of medicine/Naam van medisyne: TEVA-TRAZODONE HYDROCHLORIDE 100 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :

TRAZODONE HYDROCHLORIDE .... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL

Packer/Verpakker: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL

Laboratory/Laboratorium: TEVA PHARMACEUTICAL IND, KFAR SAVA ISRAEL  
INSTITUTE FOR INDUSTRIAL PHARMACY,  
POTCHEFSTROOM UNIVERSITY RSA  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
TEVA, INDUSTRIA RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/7.1.3/0021

Name of medicine/Naam van medisyne: TECHNIKON PERINDOPRIL

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. 5a, 6, 7

Applicant/Aplikant: TECHNIKON LABORATORIES (PTY) LTD

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

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

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

Shelf-life/Rakleefyd: 48 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie 07 MAART 2003

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Registration number/Registrasiennommer: 34/1.2/0094

Name of medicine/Naam van medisyne: CIPLA-MEDPRO FLUOXETINE

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, 5a, 6, 7

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA, MUMBAI INDIA

Packer/Verpakker: CIPLA, MUMBAI INDIA

Laboratory/Laboratorium: CIPLA, MUMBAI INDIA  
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 35/11.9.2/0185

Name of medicine/Naam van medisyne: ZELNORM

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

TEGASEROD ... 6,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5a, 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  
PROMOLOG 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/Rakleef tyd: 24 months/maande

Date of registration: 07 MARCH 2003

Datum van registrasie: 07 MAART 2003

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Registration number/Registrasiënommer: 36/7.3/0133

Name of medicine/Naam van medisyne: ZOMIG NASAL SPRAY

Dosage form/Doseringsvorm: NASAL SPRAY/NEUSSPROEI

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml SOLUTION CONTAINS/  
ELKE 1,0 ml OPLOSSING BEVAT:  
ZOLMITRIPTAN ... 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:  
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: ASTRAZENECA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRAZENECA, CHESHIRE UK

Packer/Verpakker: ASTRAZENECA, CHESHIRE UK  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA  
ASTRAZENECA, ALRODE, ALBERTON RSA

Laboratory/Laboratorium: ASTRAZENECA, CHESHIRE UK  
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA  
ANALYTICON, KEMPTON PARK RSA  
CONSULTING CHEMICAL LAB, STAR STREET  
BOKSBURG RSA  
ASTRAZENECA, ALRODE, ALBERTON RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MARCH 2003  
Datum van registrasie: 07 MAART 2003

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