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

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GENERAL NOTICE • ALGEMENE KENNISGEWING

NOTICE 1411 OF 2001**DEPARTMENT OF HEALTH****MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT No. 101 OF 1965)****REGISTRATION OF MEDICINES**

It is hereby notified in terms of section 17 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), that the Registrar of Medicines, with the approval of the Medicines Control Council established by section 2 of the said Act, has registered the following medicines described in the Schedule hereto:

The undermentioned Conditions of Registration of Medicines applies to the medicines following:

Conditions of registration:

- 1a. An acceptable standard of Good Manufacturing Practice must be maintained in the place of manufacture.
- 1b. An applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practice as determined by the Medicines Control Council.
2. The applicant must comply with all the legal requirements of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965).
3. The registration of this product shall be subject to review every three years.
4. The information in the package insert shall be updated on a regular basis to conform to a package insert recently approved by the Council.
- 5a. The first two production lots must be fully validated and the full details of the proposed process-validation program to be followed by the applicant and/or manufacturer be submitted.
- 5b. The first two production lots of the locally manufactured products must be validated.
- 5c. The first two production lots after registration must be validated, unless this documentation is available.
- 5d. The first two production lots must be validated.
- 5e. The first two production lots manufactured by each local manufacturer must be validated.
6. The manufacture of this medicine is subject to regular investigation and inspection by inspectors to assess compliance with current Good Manufacturing Practice.
7. The registration dossier is subject to review at intervals as determined by Council.
- 8a. A post-registration inspection must be conducted on the first production lot of the locally manufactured product.
- 8b. A post-registration inspection must be conducted on the first production lot manufactured by each local manufacturer.
- 8c. A post-registration inspection must be conducted on the first production lot.
9. Marketing of the product may only commence following a satisfactory post-registration inspection report.
10. The product may be advertised to the professions only.
11. One sample of every lot, together with four copies of the protocols for testing of the bulk lot and filling lot, be submitted to Council for lot releasing purposes.
12. One sample of every lot, together with six copies of the protocols for testing of the bulk lot and filling lot and six copies of the certificate of release issued by the competent authority in the country in which the product was manufactured, be submitted to Council for lot releasing purposes.
13. The expiry date allocated shall be modified by adding to a statement that the virus strains are currently recommended for South African usage in the specified year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

**KENNISGEWING 1411 VAN 2001
DEPARTEMENT VAN GESONDHEID**

**WET OP BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965 (WET No. 101 VAN 1965)
REGISTRASIE VAN MEDISYNE**

Hierby word ingevolge artikel 17 van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965), bekendgemaak dat die Registrateur van Medisyne, met die goedkeuring van die Medisynebeheerraad ingestel by artikel 2 van genoemde Wet, die volgende medisyne soos in die Bylae hiervan omskryf, geregistreer het:

Die onderstaande Voorwaardes vir Registrasie van Medisyne is van toepassing op die hiernagemelde medisyne:

Voorwaardes vir registrasie:

- 1a. 'n Aanvaarbare standaard van Goeie Vervaardigingspraktyk moet by die plek van vervaardiging gehandhaaf word.
- 1b. Die applikant sal verseker dat die medisyne vervaardig en beheer word in terme van huidige Goeie Vervaardigingspraktyk soos bepaal deur die Medisynebeheerraad.
2. Die applikant moet voldoen aan al die wetlike vereistes van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
3. Die registrasie van die produk is onderhewig aan hersiening elke drie jaar.
4. Die inligting in die voubiljet moet op 'n gereelde basis opgedateer word in ooreenstemming met 'n voubiljet onlangs deur die Raad goedgekeur.
- 5a. Die eerste twee produksielotte moet ten volle gevalideer word en die volle besonderhede van die voorgestelde prosesvalidasieprogram wat gevolg gaan word deur die Applikant en/of die vervaardiger moet ingedien word.
- 5b. Die eerste twee produksielotte van die plaaslik vervaardigde produk moet gevalideer word.
- 5c. Die eerste twee produksielotte na registrasie moet gevalideer word, tensy die dokumentasie beskikbaar is.
- 5d. Die eerste twee produksielotte moet gevalideer word.
- 5e. Die eerste twee produksielotte van elke plaaslike vervaardiger moet gevalideer word.
6. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs om die nakoming van Goeie Vervaardigingspraktyke te bepaal.
7. Die registrasie-aansoek is onderhewig aan hersiening met tussenpose soos deur die Raad bepaal.
- 8a. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslik vervaardigde produk uitgevoer word.
- 8b. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
- 8c. 'n Na-registrasie-inspeksie moet op die eerste produksielot uitgevoer word.
9. Bemaking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
10. Die produk mag slegs aan die professies geadverteer word.
11. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die finale lot en die vullot ingedien word by die Raad vir lotvrystellingsdoeleindes.
12. Een monster van elke lot moet tesame met ses kopieë van die protokolle vir die toets van die finale lot en die vullot sowel as ses kopieë van die vrystellingstifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken moet verander word deur 'n toegevoegde stelling dat die virusstamme wat tans aanbeveel word vir Suid-Afrikaanse gebruik is vir die gespesifiseerde jaar.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

SCHEDULE • BYLAE

MBR 15

Registration number/Registrasienommer: E/11.10/1484

Name of medicine/Naam van medisyne: ALVERCOL

Dosage form/Doseringsvorm: GRANULES

Active ingredients/Aktiewe bestanddele:
EACH 10,0 g GRANULES CONTAINS/ELKE 10,0 g GRANULES BEVAT:
ALVERINE CITRATE ... 0,05 g
STERCULIA ... 6,2 g

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

Applicant/Applikant: NORGINE (PTY) LTD

Manufacturer/Vervaardiger: NORGINE LTD,HENGOED, WALES UK

Packer/Verpakker: NORGINE LTD,HENGOED, WALES UK

Laboratory/Laboratorium: NORGINE LTD,HENGOED, WALES UK
NORGINE (PTY) LTD RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 08 FEBRUARY 2001
Datum van registrasie 08 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 29/8.1/0348

Name of medicine/Naam van medisyne: TACHOCOMB ABSORBABLE
WOUND COVER

Dosage form/Doseringsvorm: DRESSING/WONDDEKKING

Active ingredients/Aktiewe bestanddele:
ONE CM2 OF FLEECE CONTAINS/ELKE CM² DEKKING BEVAT :
APROTININ BOVINE ... 0,071 ph eur u
COLLAGEN EQUINE ... 1,65 mg
HUMAN FIBRINOGEN ... 5,50 mg
THROMBIN, BOVINE ... 2,0 iu

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: NYCOMED, LINZ AUSTRIA
NYCOMED, MUNCHEN, GERMANY

Packer/Verpakker: NYCOMED, LINZ AUSTRIA
LIEBENZELLER VERPACKUNGS, BAD LIEBENZEL,
GERMANY

Laboratory/Laboratorium: NYCOMED, LINZ AUSTRIA
ROCHE, ISANDO RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 08 FEBRUARY 2001
Datum van registrasie 08 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 29/13.6/0223

Name of medicine/Naam van medisyne: PERSKINDOL CLASSIC GEL

Dosage form/Doseringsvorm: GEL/JEL

Active ingredients/Aktiewe bestanddele:

EACH 1,0 g GEL CONTAINS/ELKE 1,0 g JEL BEVAT:

MENTHOL ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MC PHARMA CC

Manufacturer/Vervaardiger: TRICHEMA, BAAR SWITZERLAND

Packer/Verpakker: TRICHEMA, BAAR SWITZERLAND

Laboratory/Laboratorium: CONSULTING CHEMICAL LAB, STAR STREET,
BOKSBURG, RSA
PHARMA-SINGER, NIEDERURNEN,
SWITZERLAND
MC PHARMA CC, MEYERSPARK RSA

Shelf-life/Rakleef tyd: 60 months/maande

Date of registration: 08 FEBRUARY 2001

Datum van registrasie: 08 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: H/12/881

Name of medicine/Naam van medisyne: IMPILO YEZIKELEMU WORM SYRUP

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:

EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT:

PIPERAZINE HYDRATE ... 625,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: IMPILO DRUGS (1966) (PTY) LTD

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

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

Laboratory/Laboratorium: IMPILO DRUGS (1966), ISITHEBE RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 08 FEBRUARY 2001

Datum van registrasie: 08 FEBRUARIE 2001

MBR 15

Registration number/Registrasiënommer: 34/20.1.1/0043

Name of medicine/Naam van medisyne: PHARMACARE-CEFTRIAXONE 0,5 g
INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE ... 500,0 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 02 MARCH 2001
Datum van registrasie 02 MAART 2001

MBR 15

Registration number/Registrasiënommer: 34/20.1.1/0044

Name of medicine/Naam van medisyne: PHARMACARE-CEFTRIAXONE 1 g
INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE ... 1,0 g

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 02 MARCH 2001
Datum van registrasie 02 MAART 2001

MBR 15

Registration number/Registrasiensnommer: 34/20.1.1/0045

Name of medicine/Naam van medisyne: PHARMACARE-CEFTRIAXONE 2 g
INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPIITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE ... 2,0 g

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 02 MARCH 2001
Datum van registrasie: 02 MAART 2001

MBR 15

Registration number/Registrasiensnommer: 34/20.1.1/0046

Name of medicine/Naam van medisyne: PHARMACARE-CEFTRIAXONE 2 g
INFUSION

Dosage form/Doseringsvorm: INFUSION(PARENTERAL)

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :
CEFTRIAXONE SODIUM EQUIVALENT TO CEFTRIAXONE ... 2,0 g

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY

Packer/Verpakker: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Laboratory/Laboratorium: ECZACIBASI PHARMACEUTICALS, LULEBURGAZ,
TURKEY
INTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 02 MARCH 2001
Datum van registrasie: 02 MAART 2001

MBR 15

Registration number/Registrasienommer: 29/21.5.1/0366

Name of medicine/Naam van medisyne: CYCLOSON 100 CYCLOCAPS

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE FOR INHALATION CONTAINS/ELKE INHALASIE KAPSULE BEVAT:
BECLOMETHASONE DIPROPIONATE ... 100,0 mcg

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

Applicant/Applikant: PHARMACHEMIE (PTY) LTD

Manufacturer/Vervaardiger: PHARMACHEMIE BV, HAARLEM NETHERLANDS

Packer/Verpakker: PHARMACHEMIE BV, HAARLEM NETHERLANDS
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

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

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 08 MARCH 2001
Datum van registrasie: 08 MAART 2001

MBR 15

Registration number/Registrasienommer: 29/21.5.1/0367

Name of medicine/Naam van medisyne: CYCLOSON 200 CYCLOCAPS

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE FOR INHALATION CONTAINS/ELKE INHALASIE KAPSULE BEVAT:
BECLOMETHASONE DIPROPIONATE ... 200,0 mcg

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

Applicant/Applikant: PHARMACHEMIE (PTY) LTD

Manufacturer/Vervaardiger: PHARMACHEMIE BV, HAARLEM NETHERLANDS

Packer/Verpakker: PHARMACHEMIE BV, HAARLEM NETHERLANDS
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

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

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 08 MARCH 2001
Datum van registrasie: 08 MAART 2001

MBR 15

Registration number/Registrasiënommer: 29/21.5.1/0368

Name of medicine/Naam van medisyne: CYCLOSON 400 CYCLOCAPS

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:

EACH CAPSULE FOR INHALATION CONTAINS/ELKE INHALASIEKAPSULE BEVAT:

BECLOMETHASONE DIPROPIONATE ... 400,0 mcg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACHEMIE (PTY) LTD

Manufacturer/Vervaardiger: PHARMACHEMIE BV, HAARLEM NETHERLANDS

Packer/Verpakker: PHARMACHEMIE BV, HAARLEM NETHERLANDS
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

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

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 08 MARCH 2001

Datum van registrasie: 08 MAART 2001

MBR 15

Registration number/Registrasiënommer: 31/20.1.7/0288

Name of medicine/Naam van medisyne: BE-TABS NYSTATIN SUSPENSION

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT:
NYSTATIN ... 100 000 u

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 08 MARCH 2001

Datum van registrasie: 08 MAART 2001

Registration number/Registrasiënommer: 32/20.2.8/0204

Name of medicine/Naam van medisyne: RETROVIR 300

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

ZIDOVUDINE ... 300,0 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, HERTFORDSHIRE UK
GLAXO WELLCOME, KENT UK

Packer/Verpakker: GLAXO WELLCOME, HERTFORDSHIRE UK
GLAXO WELLCOME, KENT UK
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, HERTFORDSHIRE UK
GLAXO WELLCOME, KENT UK
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 13 MARCH 2001

Datum van registrasie 13 MAART 2001

Registration number/Registrasiënommer: 32/7.1/0410

Name of medicine/Naam van medisyne: TOPACE 25 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

CAPTOPRIL ... 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 6, 7

Applicant/Applikant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer/Vervaardiger: BRISTOL-MYERS SQUIBB, VICTORIA AUSTRALIA

Packer/Verpakker: BRISTOL-MYERS SQUIBB, VICTORIA AUSTRALIA

Laboratory/Laboratorium: BRISTOL-MYERS SQUIBB, VICTORIA AUSTRALIA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RS RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 13 MARCH 2001

Datum van registrasie 13 MAART 2001

MBR 15

Registration number/Registrasiensnommer: 32/7.1/0411

Name of medicine/Naam van medisyne: TOPACE 50 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :

CAPTOPRIL ... 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 6, 7

Applicant/Applikant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer/Vervaardiger BRISTOL-MYERS SQUIBB, VICTORIA AUSTRALIA

Packer/Verpakker: BRISTOL-MYERS SQUIBB, VICTORIA AUSTRALIA

Laboratory/Laboratorium: BRISTOL-MYERS SQUIBB, VICTORIA AUSTRALIA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 13 MARCH 2001

Datum van registrasie: 13 MAART 2001

MBR 15

Registration number/Registrasiensnommer: 33/16.1/0339

Name of medicine/Naam van medisyne: VICKS SINEX DECONGESTANT NASAL
SPRAY

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 15,0 ml SOLUTION CONTAINS/ELKE 15,0 ml OPLOSSING BEVAT :

OXYMETAZOLINE HYDROCHLORIDE ... 7,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PROCTER & GAMBLE SA (PTY) LTD

Manufacturer/Vervaardiger: PROCTER & GAMBLE, GROSS-GERAU GERMANY

Packer/Verpakker: PROCTER & GAMBLE, GROSS-GERAU GERMANY

Laboratory/Laboratorium: PROCTER & GAMBLE, GROSS-GERAU GERMANY
CONSULTING LABORATORY SERVICES, BENONI RSA
PROCTER & GAMBLE SA, KEMPTON PARK RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 14 MARCH 2001

Datum van registrasie: 14 MAART 2001

MBR 15

Registration number/Registrasienommer: 34/11.4.3/0004

Name of medicine/Naam van medisyne: TRIO-RANITIDINE 75

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

RANITIDINE ... 75,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Packer/Verpakker: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA

Laboratory/Laboratorium: CHEMINOR DRUGS LTD, BACHEPALLI, INDIA
INSTITUTE FOR PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 14 MARCH 2001

Datum van registrasie: 14 MAART 2001

MBR 15

Registration number/Registrasienommer: 32/21.2/0407

Name of medicine/Naam van medisyne: GLAMIDE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

GLIBENCLAMIDE ... 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 6, 7

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

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 14 MARCH 2001

Datum van registrasie: 14 MAART 2001

MBR 15

Registration number/Registrasienommer: 32/10.2.2/0620

Name of medicine/Naam van medisyne: PARKE-MED KETOTIFEN

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT:
KETOTIFEN FUMARATE EQUIVALENT TO KETOTIFEN ... 1,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 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: 14 MARCH 2001
Datum van registrasie: 14 MAART 2001

MBR 15

Registration number/Registrasienommer: 30/20.1.2/0430

Name of medicine/Naam van medisyne: COMBICIN 375

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN ... 250,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID ... 125,0 mg

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, VICTORIA AUSTRALIA

Packer/Verpakker: SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM, VICTORIA AUSTRALIA
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 15 MARCH 2001
Datum van registrasie: 15 MAART 2001

Registration number/Registrasienommer: 33/2.2/0552

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

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 0,5 ml SOLUTION CONTAINS/ELKE 0,5 ml OPLOSSING BEVAT :
DOXYLAMINE SUCCINATE ... 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5a, 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/Rakleefityd: 24 months/maande

Date of registration: 16 MARCH 2001

Datum van registrasie 16 MAART 2001

Registration number/Registrasienommer: 33/10.2.2/0528

Name of medicine/Naam van medisyne: CUROSURF

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT :
PORACTANT ALFA ... 80,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SAFELINE PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: CHIESI FARMACEUTICI SPA, PARMA ITALY
OPOCRIN SpA, MODENA, ITALY

Packer/Verpakker: CHIESI FARMACEUTICI SPA, PARMA ITALY

Laboratory/Laboratorium: CHIESI FARMACEUTICI SPA, PARMA ITALY
INSPECTORATE M & L, ORMONDE RSA
SAFELINE PHARMACEUTICALS (PTY) LTD

Shelf-life/Rakleefityd: 15 months/maande

Date of registration: 19 MARCH 2001

Datum van registrasie 19 MAART 2001

Registration number/Registrasiënommer: 32/11.9/0359

Name of medicine/Naam van medisyne: IMPILO DIARRHOEA MIXTURE

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:

LIGHT KAOLIN ... 1,875 g

PECTIN ... 65,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: IMPILO DRUGS (1966) (PTY) LTD

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

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

Laboratory/Laboratorium: IMPILO DRUGS (1966), ISITHEBE RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 14 MARCH 2001

Datum van registrasie: 14 MAART 2001

Registration number/Registrasiënommer: 32/2.6/0153

Name of medicine/Naam van medisyne: PARKE-MED ALPRAZOLAM 0,25 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

ALPRAZOLAM ... 0,25 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/Rakleefityd: 24 months/maande

Date of registration: 28 MARCH 2001

Datum van registrasie: 28 MAART 2001

MBR 15

Registration number/Registrasiënommer: 32/2.6/0154

Name of medicine/Naam van medisyne: PARKE-MED ALPRAZOLAM 0,5 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ALPRAZOLAM ... 0,5 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: 28 MARCH 2001
Datum van registrasie: 28 MAART 2001

MBR 15

Registration number/Registrasiënommer: 32/2.6/0155

Name of medicine/Naam van medisyne: PARKE-MED ALPRAZOLAM 1,0 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ALPRAZOLAM ... 1,0 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: 28 MARCH 2001
Datum van registrasie: 28 MAART 2001

Registration number/Registrasienommer: 30/5.7.2/0004

Name of medicine/Naam van medisyne: GASTRONORM 10 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN PHARMACEUTICA NV, BEERSE BELGIUM

Packer/Verpakker: JANSSEN PHARMACEUTICA NV, BEERSE BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: JANSSEN PHARMACEUTICA NV, BEERSE BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleef tyd: 60 months/maande

Date of registration: 28 MARCH 2001
Datum van registrasie: 28 MAART 2001

Registration number/Registrasienommer: 32/20.2.8/0379

Name of medicine/Naam van medisyne: VYROHEXAL 400

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ACICLOVIR ... 400,0 mg

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: KLOCKE VERPACKINGS-SERVICE GMBH, BADEN
GERMANY
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 28 MARCH 2001
Datum van registrasie: 28 MAART 2001

MBR 15

Registration number/Registrasiënommer: 32/20.2.8/0394

Name of medicine/Naam van medisyne: HEXAL ACICLOVIR 400 MG TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ACICLOVIR ... 400,0 mg

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

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

Manufacturer/Vervaardiger: SALUTAS PHARMA, BARLEBEN GERMANY

Packer/Verpakker: KLOCKE VERPACKINGS-SERVICE GMBH, BADEN
GERMANY
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 29 MARCH 2001
Datum van registrasie: 29 MAART 2001

MBR 15

Registration number/Registrasiënommer: 32/2.5/0085

Name of medicine/Naam van medisyne: NEUROTOP RETARD 600

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: BYK MADAUS (PTY) LTD

Manufacturer/Vervaardiger: GEROT PHARMAZEUTIKA GMBH, VIENNA AUSTRIA

Packer/Verpakker: GEROT PHARMAZEUTIKA GMBH, VIENNA AUSTRIA

Laboratory/Laboratorium: GEROT PHARMAZEUTIKA GMBH, VIENNA AUSTRIA
BYK MADAUS, MIDRAND RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 29 MARCH 2001
Datum van registrasie: 29 MAART 2001

Registration number/Registrasiënommer: 33/34/0484

Name of medicine/Naam van medisyne: BAUSCH & LOMB RENU
MULTIPLUS SOLUTION

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
POLYHEXAMETHYLENE BIGUANIDE ... 0,0010 mg
HYDROXYALKYL PHOSPHONATE ... 0,30 mg

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

Applicant/Applikant: SOFLENS (PTY) LTD

Manufacturer/Vervaardiger: BAUSCH & LOMB PHARMACEUTICALS, MILAN ITALY

Packer/Verpakker: BAUSCH & LOMB PHARMACEUTICALS, MILAN ITALY

Laboratory/Laboratorium: BAUSCH & LOMB PHARMACEUTICALS, MILAN ITALY
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
SOFLENS, RANDBURG RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 29 MARCH 2001
Datum van registrasie: 29 MAART 2001

Registration number/Registrasiënommer: 32/11.4.3/0655

Name of medicine/Naam van medisyne: ROLAB-RANITIDINE 150

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE ... 150,0 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
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA
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: 29 MARCH 2001
Datum van registrasie: 29 MAART 2001

MBR 15

Registration number/Registrasiënommer: 29/13.6/0224

Name of medicine/Naam van medisyne: PERSKINDOL CLASSIC SPRAY

Dosage form/Doseringsvorm: TOPICAL SPRAY/TOPIKALE SPROEI

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g SPRAY CONTAINS/ELKE 1,0 g SPROEI BEVAT:
MENTHOL ... 15,0 mg

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

Applicant/Aplikant: MC PHARMA CC

Manufacturer/Vervaardiger: TRICHEMA, BAAR SWITZERLAND

Packer/Verpakker: TRICHEMA, BAAR SWITZERLAND

Laboratory/Laboratorium: PHARMA-SINGER, NIEDERURNEN SWITZERLAND
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
MC PHARMA CC, MEYERSPARK RSA

Shelf-life/Rakleefyd: 60 months/maande

Date of registration: 30 MARCH 2001
Datum van registrasie: 30 MAART 2001

MBR 15

Registration number/Registrasiënommer: 32/21.5.1/0501

Name of medicine/Naam van medisyne: BEZAINE SYRUP

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT:
BETAMETHASONE ... 0,6 mg

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

Applicant/Aplikant: BRAINWARE COMPU (PTY) LTD

Manufacturer/Vervaardiger: WRAPSA, CENTURION RSA

Packer/Verpakker: WRAPSA, CENTURION RSA

Laboratory/Laboratorium: WRAPSA, CENTURION RSA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
PHARMA-Q, INDUSTRIA RSA
SEDEK AGRIKEM, KAMEELDRIFT RSA
BRAINWARE COMPU, LYNWOOD RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 30 MARCH 2001
Datum van registrasie: 30 MAART 2001

MBR 15

Registration number/Registrasienommer: 32/20.1.1/0574

Name of medicine/Naam van medisyne: CIPROBAY IV FLEXIBAG

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

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :
CIPROFLOXACIN LACTATE EQUIVALENT TO CIPROFLOXACIN ... 2,0 mg

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, NORTH CHICAGO, ILLINOIS USA

Packer/Verpakker: ABBOTT, NORTH CHICAGO, ILLINOIS USA

Laboratory/Laboratorium: ABBOTT, NORTH CHICAGO, ILLINOIS USA
BAYER AG, LEVERKUSEN GERMANY
GLAXO WELLCOME, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
BAYER, ISANDO RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 30 MARCH 2001
Datum van registrasie: 30 MAART 2001

MBR 15

Registration number/Registrasienommer: H/19/1966

Name of medicine/Naam van medisyne: SYNTOMETRINE

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
ERGOMETRINE MALEATE ... 0,5 mg
OXYTOCIN (SYNTHETIC) ... 5,0 iu

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND

Packer/Verpakker: NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND
GLAXO WELLCOME, MIDRAND RSA
NOVARTIS, SPARTAN KEMPTON PARK RSA

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

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 30 MARCH 2001
Datum van registrasie: 30 MAART 2001

Registration number/Registrasienommer: 31/20.1.2/0138

Name of medicine/Naam van medisyne: CLAVICYL SF

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
POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID ... 62,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, WORTHING SUSSEX UK

Packer/Verpakker: SMITHKLINE BEECHAM, WORTHING SUSSEX UK
SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM, WORTHING SUSSEX UK
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 30 MARCH 2001

Datum van registrasie: 30 MAART 2001

Registration number/Registrasienommer: 31/11.4.3/0524

Name of medicine/Naam van medisyne: LO-ACID TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DRIED ALUMINIUM HYDROXIDE ... 200,0 mg
MAGNESIUM HYDROXIDE ... 200,0 mg
SIMETHICONE ... 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 30 MARCH 2001

Datum van registrasie: 30 MAART 2001

Registration number/Registrasienommer: 34/2.7/0193

Name of medicine/Naam van medisyne: ADVIL LIQUI-GELS

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
IBUPROFEN ... 200,0 mg

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

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

Manufacturer/Vervaardiger: R P SCHERER, SWINDON WILTSHIRE UK

Packer/Verpakker: WYETH, CATANIA, APRILLA ITALY

Laboratory/Laboratorium: R P SCHERER, SWINDON WILTSHIRE UK
WYETH, CATANIA, APRILLA ITALY
ANALYTICON, KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
RSA
WYETH S.A., MIDRAND, RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 05 APRIL 2001
Datum van registrasie: 05 APRIL 2001

Registration number/Registrasienommer: 33/7.1/0278

Name of medicine/Naam van medisyne: TENSIOMIN-COR 25 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: ELTTAB PHARMACEUTICALS CC

Manufacturer/Vervaardiger: EGIS PHARMACEUTICALS, BUDAPEST, HUNGARY

Packer/Verpakker: EGIS PHARMACEUTICALS, BUDAPEST, HUNGARY

Laboratory/Laboratorium: EGIS PHARMACEUTICALS, BUDAPEST, HUNGARY
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
ELTTAB PHARM, MOWBRAY, RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 05 APRIL 2001
Datum van registrasie: 05 APRIL 2001

MBR 15

Registration number/Registrasiënommer: 33/26/0470

Name of medicine/Naam van medisyne: SCHEIN ETOPOSIDE 20 MG/ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 1.0 ml SOLUTION CONTAINS/ELKE 1.0 ml OPLOSSING BEVAT:
ETOPOSIDE ... 20.0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Packer/Verpakker: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Laboratory/Laboratorium: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA
INSTITUTE FOR PHARM & CHEM SERVICE.
TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 05 APRIL 2001

Datum van registrasie: 05 APRIL 2001

MBR 15

Registration number/Registrasiënommer: 33/11.10/0046

Name of medicine/Naam van medisyne: GELACID

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

EACH 10.0 ml SUSPENSION CONTAINS/ELKE 10.0 ml SUSPENSIE BEVAT :
CALCIUM CARBONATE ... 160,0 mg
SODIUM ALGINATE ... 500,0 mg
SODIUM BICARBONATE ... 267,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: XERAGEN LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Packer/Verpakker: PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Laboratory/Laboratorium: PHARMACEUTICAL CONTRACTORS, ISANDO RSA
XERAGEN LABORATORIES (PTY) LTD RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 06 APRIL 2001

Datum van registrasie: 06 APRIL 2001

MBR 15

Registration number/Registrasiënommer: 34/26/0419

Name of medicine/Naam van medisyne: HERCEPTIN 440 MG

Dosage form/Doseringsvorm: INJECTION/INSPUTTING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
TRASTUZUMAB ... 25,0 mgConditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: GENENTECH INC, SAN FRANCISCO USA

Packer/Verpakker: GENENTECH INC, SAN FRANCISCO USA
F HOFFMANN-LA ROCHE, KAISERAUGST,
SWITZERLAND
ROCHE, ISANDO RSALaboratory/Laboratorium: GENENTECH INC, SAN FRANCISCO USA
F HOFFMANN-LA ROCHE, GREN, BASLE
SWITZERLAND
ROCHE, ISANDO RSA

Shelf-life/Rakleefyd: 36 months/maande

Date of registration: 06 APRIL 2001
Datum van registrasie: 06 APRIL 2001

MBR 15

Registration number/Registrasiënommer: 34/30.4/0261

Name of medicine/Naam van medisyne: HEMOPURE

Dosage form/Doseringsvorm: INFUSION/INFUUS

Active ingredients/Aktiewe bestanddele:
EACH INFUSION BAG CONTAINS/ELKE INFUUSSAK BEVAT:
HEMOGLOBIN GLUTAMER-250 ... 30,0 gConditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Aplikant: MC PHARMA CC

Manufacturer/Vervaardiger: BIOPURE, CAMBRIDGE, MA, USA

Packer/Verpakker: BIOPURE, CAMBRIDGE, MA, USA

Laboratory/Laboratorium: BIOPURE, CAMBRIDGE, MA, USA
MC PHARMA CC, MEYERSPARK RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 06 APRIL 2001
Datum van registrasie: 06 APRIL 2001

MBR 15

Registration number/Registrasienommer: 33/7.1/0279

Name of medicine/Naam van medisyne: TENSIO MIN-COR 50 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: ELTTAB PHARMACEUTICALS CC

Manufacturer/Vervaardiger: EGIS PHARMACEUTICALS, BUDAPEST, HUNGARY

Packer/Verpakker: EGIS PHARMACEUTICALS, BUDAPEST, HUNGARY

Laboratory/Laboratorium: EGIS PHARMACEUTICALS, BUDAPEST, HUNGARY
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
ELTTAB PHARM, MOWBRAY, RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 06 APRIL 2001
Datum van registrasie: 06 APRIL 2001

MBR 15

Registration number/Registrasienommer: 34/1.4/0143

Name of medicine/Naam van medisyne: REVIA

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
NALTREXONE HYDROCHLORIDE ... 50,0 mg

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: DU PONT, NEW YORK USA

Packer/Verpakker: DU PONT, NEW YORK USA
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA
PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Laboratory/Laboratorium: DU PONT, NEW YORK USA
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
INSPECTORATE M & L, ORMONDE RSA
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 05 APRIL 2001
Datum van registrasie: 05 APRIL 2001

Registration number/Registrasienommer: 98/15.4.1/11

Name of medicine/Naam van medisyne: OTOMAX EAR DROPS

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

EACH 1,0 g VISCOUS SUSPENSION CONTAINS:

BETAMETHASONE VALERATE EQUIVALENT TO

BETAMETHASONE ... 1,0 mg

CLOTRIMAZOLE ... 10,0 mg

GENTAMICIN SULPHATE EQUIVALENT TO

GENTAMICIN ... 3,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING CANADA, POINTE-CLAIRE QUEBEC
CANADA

Packer/Verpakker: SCHERING CANADA, POINTE-CLAIRE QUEBEC
CANADA
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING CANADA, POINTE-CLAIRE QUEBEC
CANADA
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 06 APRIL 2001

Datum van registrasie: 06 APRIL 2001

Registration number/Registrasienommer: 33/24/0539

Name of medicine/Naam van medisyne: EUROMED 0,9 % SODIUM CHLORIDE 1000 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:

EACH 100,0 ml SOLUTION CONTAINS/ELKE 100,0 ml OPLOSSING BEVAT:

SODIUM CHLORIDE ... 900,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: DANENE PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: EURO-MED LABORATORIES, CAVITE, PHILIPPINES

Packer/Verpakker: EURO-MED LABORATORIES, CAVITE, PHILIPPINES

Laboratory/Laboratorium: EURO-MED LABORATORIES, CAVITE, PHILIPPINES
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
DANENE PHARMACEUTICALS, PTA RSA

Shelf-life/Rakleef tyd: 48 months/maande

Date of registration: 18 APRIL 2001

Datum van registrasie: 18 APRIL 2001

MBR 15

Registration number/Registrasiensnommer: 99/21.1/1

Name of medicine/Naam van medisyne: ORBAX 6,25 MG TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS:

ORBIFLOXACIN ... 6,25 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, POINTE-CLAIRE QUEBEC CANADA

Packer/Verpakker: SCHERING, POINTE-CLAIRE QUEBEC CANADA

Laboratory/Laboratorium: SCHERING, POINTE-CLAIRE QUEBEC CANADA
SCHERING-PLOUGH (ANIMAL), FRANCE
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 19 APRIL 2001

Datum van registrasie: 19 APRIL 2001

MBR 15

Registration number/Registrasiensnommer: 99/21.1/2

Name of medicine/Naam van medisyne: ORBAX 25 MG TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS:

ORBIFLOXACIN ... 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, POINTE-CLAIRE QUEBEC CANADA

Packer/Verpakker: SCHERING, POINTE-CLAIRE QUEBEC CANADA

Laboratory/Laboratorium: SCHERING, POINTE-CLAIRE QUEBEC CANADA
SCHERING-PLOUGH (ANIMAL), FRANCE
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 19 APRIL 2001

Datum van registrasie: 19 APRIL 2001

MBR 15

Registration number/Registrasiensnommer: 99/21.1/3

Name of medicine/Naam van medisyne: ORBAX 75 MG TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS:

ORBIFLOXACIN ... 75,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, POINTE-CLAIRE QUEBEC CANADA

Packer/Verpakker: SCHERING, POINTE-CLAIRE QUEBEC CANADA

Laboratory/Laboratorium: SCHERING, POINTE-CLAIRE QUEBEC CANADA
SCHERING-PLOUGH (ANIMAL), FRANCE
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 19 APRIL 2001

Datum van registrasie: 19 APRIL 2001

MBR 15

Registration number/Registrasiensnommer: 34/7.1.3/0190

Name of medicine/Naam van medisyne: PHARMAPRESS CO

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

ENALAPRIL MALEATE ... 20,0 mg

HYDROCHLOROTHIAZIDE ... 12,5 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 6, 7

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON, PORT ELIZABETH RSA

Packer/Verpakker: LENNON, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON, PORT ELIZABETH RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 20 APRIL 2001

Datum van registrasie: 20 APRIL 2001

MBR 15

Registration number/Registrasiennommer: 31/3.1/0334

Name of medicine/Naam van medisyne: BE-TABS DICLOFENAC INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 3,0 ml AMPOULE CONTAINS/ELKE 3,0 ml AMPULE BEVAT:
DICLOFENAC SODIUM ... 75,0 mg

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

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

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker: CADILA, AHMEDABAD INDIA

Laboratory/Laboratorium: CADILA, AHMEDABAD INDIA
BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MAY 2001
Datum van registrasie: 07 MEI 2001

MBR 15

Registration number/Registrasiennommer: 32/20.1.1/0595

Name of medicine/Naam van medisyne: SUMADAX 400

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
CEFTIBUTEN ... 400,0 mg

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

Applicant/Aplikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, MIAMI FLORIDA USA

Packer/Verpakker: SCHERING-PLOUGH, MIAMI FLORIDA USA
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA
SCHERING-PLOUGH, SUFFOLK, U.K.

Laboratory/Laboratorium: SCHERING-PLOUGH, MIAMI FLORIDA USA
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 07 MAY 2001
Datum van registrasie: 07 MEI 2001

Registration number/Registrasienommer: 33/20.2.6/0243

Name of medicine/Naam van medisyne: METROGEL V

Dosage form/Doseringsvorm: GEL/JEL

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g GEL CONTAINS/ELKE 1,0 g JEL BEVAT:
METRONIDAZOLE ... 7,5 mg

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

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

Manufacturer/Vervaardiger DPT LABORATORIES, SAN ANTONIO, TEXAS, USA

Packer/Verpakker: DPT LABORATORIES, SAN ANTONIO, TEXAS, USA

Laboratory/Laboratorium: DPT LABORATORIES, SAN ANTONIO, TEXAS, USA
3M, LOUGHBOROUGH, LEICESTERSHIRE, UK
3M, CHILVERS RD, THORNLEIGH, AUSTRALIA AUS
3M, ISANDO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 11 MAY 2001
Datum van registrasie: 11 MEI 2001

Registration number/Registrasienommer: 33/1.2/0042

Name of medicine/Naam van medisyne: DEPREZAK

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: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: SIEGFRIED PHARMA, ZOFINGEN, SWITZERLAND

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

Laboratory/Laboratorium: SIEGFRIED PHARMA, ZOFINGEN, SWITZERLAND
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA
INSTITUTE FOR PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleefityd: 12 months/maande

Date of registration: 11 MAY 2001
Datum van registrasie: 11 MEI 2001

MBR 15

Registration number/Registrasienommer: 33/1.2/0043

Name of medicine/Naam van medisyne: REZAK

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: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: SIEGFRIED PHARMA, ZOFINGEN, SWITZERLAND

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA

Laboratory/Laboratorium: SIEGFRIED PHARMA, ZOFINGEN, SWITZERLAND
DIVPHARM MANUFACTURING AND PACKAGING,
LONGDALE RSA
INSTITUTE FOR PHARM & CHEM SERVICE,
TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleef tyd: 12 months/maande

Date of registration: 11 MAY 2001

Datum van registrasie: 11 MEI 2001

MBR 15

Registration number/Registrasienommer: 33/20.2.2/0267

Name of medicine/Naam van medisyne: PIN-CLOTRIMAZOLE VAGINAL CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:

EACH 1,0 g CREAM CONTAINS/ELKE 1,0 g ROOM BEVAT:

CLOTRIMAZOLE ... 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: MEDPRO PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
ZENECA, ALRODE RSA

Packer/Verpakker: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
ZENECA, ALRODE RSA

Laboratory/Laboratorium: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
ZENECA, ALRODE RSA
MEDPRO PHARMACEUTICA, ROSENPARK RSA

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 14 MAY 2001

Datum van registrasie: 14 MEI 2001

Registration number/Registrasienommer: 32/5.7.1/0742

Name of medicine/Naam van medisyne: POLARATYNE EFFERVESCENT

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, 5a, 6, 7

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: ASTA MEDICA ARZNEIMITTEL GmBH, WOLFSBERG
AUSTRIA

Packer/Verpakker: SCHERING-PLOUGH, COMAZZO ITALY
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: ASTA MEDICA ARZNEIMITTEL GmBH, WOLFSBERG
AUSTRIA
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 14 MAY 2001
Datum van registrasie: 14 MEI 2001

Registration number/Registrasienommer: 32/6.2/0514

Name of medicine/Naam van medisyne: ARYCOR 200

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
AMIODARONE HYDROCHLORIDE ... 200,0 mg

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK

Packer/Verpakker: SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK

Laboratory/Laboratorium: SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK
INSPECTORATE M & L, ORMONDE RSA
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 14 MAY 2001
Datum van registrasie: 14 MEI 2001

MBR 15

Registration number/Registrasienommer: 33/2.5/0543

Name of medicine/Naam van medisyne: GEBITRIL 5 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

TIAGABINE HYDROCHLORIDE EQUIVALENT TO TIAGABINE ... 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, KENT UK

Packer/Verpakker: UNIPAK LTD, ESSEX, UK
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK

Laboratory/Laboratorium: AAI, NORTH CAROLINA, USA
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK
ALFRED JORGENSEN LAB, FREDERIKSBERG, DENMARK
INSPECTORATE M & L, ORMONDE RSA
INTERNATIONAL LABORATORY
SERVICES, DERBYSHIRE UK
NOVO NORDISK A/S, BAGSVAERD DENMARK
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, POTCHEFSTROOM
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 14 MAY 2001

Datum van registrasie: 14 MEI 2001

MBR 15

Registration number/Registrasienommer: 33/2.5/0544

Name of medicine/Naam van medisyne: GEBITRIL 10 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

TIAGABINE HYDROCHLORIDE EQUIVALENT TO TIAGABINE ... 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, KENT UK

Packer/Verpakker: UNIPAK LTD, ESSEX, UK
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK

Laboratory/Laboratorium: AAI, NORTH CAROLINA, USA
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK
ALFRED JORGENSEN LAB, FREDERIKSBERG, DENMARK
INSPECTORATE M & L, ORMONDE RSA
INTERNATIONAL LABORATORY
SERVICES, DERBYSHIRE UK
NOVO NORDISK A/S, BAGSVAERD DENMARK
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, POTCHEFSTROOM
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 14 MAY 2001

Datum van registrasie: 14 MEI 2001

Registration number/Registrasiënommer: 33/2.5/0545

Name of medicine/Naam van medisyne: GEBITRIL 15 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

TIAGABINE HYDROCHLORIDE EQUIVALENT TO TIAGABINE ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, KENT UK

Packer/Verpakker: UNIPAK LTD, ESSEX, UK
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK

Laboratory/Laboratorium: AAI, NORTH CAROLINA, USA
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK
ALFRED JORGENSEN LAB, FREDERIKSBERG, DENMARK
INSPECTORATE M & L, ORMONDE RSA
INTERNATIONAL LABORATORY
SERVICES, DERBYSHIRE UK
NOVO NORDISK A/S, BAGSVAERD DENMARK
PHARMACEUTICAL CONTRACTORS, ISANDO RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, POTCHEFSTROOM
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 14 MAY 2001

Datum van registrasie: 14 MEI 2001

Registration number/Registrasiënommer: E/11.5/0752

Name of medicine/Naam van medisyne: FAMS MIST ALBA

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

EACH 10,0 ml SUSPENSION CONTAINS/ELKE 10,0 ml SUSPENSIE BEVAT:

LIGHT MAGNESIUM CARBONATE ... 0,5 g

MAGNESIUM SULPHATE ... 4,0 g

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ALLIANCE PHARMA, VILLAGE MAIN RSA
WRAPSA, CENTURION RSA

Packer/Verpakker: ALLIANCE PHARMA, VILLAGE MAIN RSA
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: ALLIANCE PHARMA, VILLAGE MAIN RSA
WRAPSA, CENTURION RSA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
PHARMA-Q, INDUSTRIA RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 15 MAY 2001

Datum van registrasie: 15 MEI 2001

Registration number/Registrasienommer: 33/2.2/0244

Name of medicine/Naam van medisyne: SOLUNA 5

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
ZALEPLON ... 5,0 mg

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

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

Manufacturer/Vervaardiger: WYETH PHARMACEUTICALS CO, GUAYAMA
PUERTO RICO

Packer/Verpakker: TECHNIKON LABORATORIES, FLORIDA RSA
WYETH MEDICA IRELAND, KILDARE IRELAND

Laboratory/Laboratorium: WYETH PHARMACEUTICALS CO, GUAYAMA
PUERTO RICO
TECHNIKON LABORATORIES, FLORIDA RSA
WYETH MEDICA IRELAND, KILDARE IRELAND
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 16 MAY 2001
Datum van registrasie: 16 MEI 2001

Registration number/Registrasienommer: 33/2.2/0245

Name of medicine/Naam van medisyne: SOLUNA 10

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

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

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

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

Manufacturer/Vervaardiger: WYETH PHARMACEUTICALS CO, GUAYAMA
PUERTO RICO

Packer/Verpakker: TECHNIKON LABORATORIES, FLORIDA RSA
WYETH MEDICA IRELAND, KILDARE IRELAND

Laboratory/Laboratorium: WYETH PHARMACEUTICALS CO, GUAYAMA
PUERTO RICO
TECHNIKON LABORATORIES, FLORIDA RSA
WYETH MEDICA IRELAND, KILDARE IRELAND
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 16 MAY 2001
Datum van registrasie: 16 MEI 2001

Registration number/Registrasienommer: 32/18.8/0470

Name of medicine/Naam van medisyne: HARMONET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

21 WHITE HORMONAL TABLETS CONTAINING:

ETHINYLESTRADIOL ... 0,02 mg

GESTODENE ... 0,075 mg

7 RED NON-HORMONAL PLACEBO TABLETS

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: WYETH MEDICA IRELAND, KILDARE IRELAND

Packer/Verpakker: TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: WYETH MEDICA IRELAND, KILDARE IRELAND
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
TECHNIKON LABORATORIES, FLORIDA RSA
WYETH S.A., MIDRAND, RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 16 MAY 2001

Datum van registrasie: 16 MEI 2001

Registration number/Registrasienommer: 33/4/0174

Name of medicine/Naam van medisyne: TOPLA

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:

EACH 1,0 g CREAM CONTAINS/ELKE 1,0 g ROOM BEVAT:

LIDOCAINE ... 25,0 mg

PRILOCAINE ... 25,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA

Packer/Verpakker: CIPLA LTD, PATALGANGA MAHARASHTRA INDIA

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

Shelf-life/Rakleefityd: 18 months/maande

Date of registration: 16 MAY 2001

Datum van registrasie: 16 MEI 2001

MBR 15

Registration number/Registrasienommer: 32/30.1/0415

Name of medicine/Naam van medisyne: TWINRIX JUNIOR

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

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

HEPATITIS A VIRAL ANTIGEN ... 360,0 elisa units

HEPATITIS B ANTIGEN ... 10,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SMITHKLINE BEECHAM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM

Packer/Verpakker: SMITHKLINE BEECHAM, (BIO MAN) RIXENSART BELGIUM
SMITHKLINE BEECHAM, (BIO MAN) WAVRE BELGIUM
SMITHKLINE BEECHAM, EPPING RSA
SACHSISCHE SERUMWERK GmbH,DRESDEN,GERMANY

Laboratory/Laboratorium: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 16 MAY 2001

Datum van registrasie 16 MEI 2001

MBR 15

Registration number/Registrasienommer: 32/30.1/0244

Name of medicine/Naam van medisyne: TWINRIX ADULT

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,0 ml DOSE CONTAINS/ELKE 1,0 ml DOSIS BEVAT:

HEPATITIS A VIRAL ANTIGEN ... 720,0 elisa units

HEPATITIS B ANTIGEN ... 20,0 ug

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: SMITHKLINE BEECHAM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM

Packer/Verpakker: SMITHKLINE BEECHAM, (BIO MAN) RIXENSART BELGIUM
SMITHKLINE BEECHAM, (BIO MAN) WAVRE BELGIUM
SMITHKLINE BEECHAM, EPPING RSA
SACHSISCHE SERUMWERK GmbH,DRESDEN,GERMANY

Laboratory/Laboratorium: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 17 MAY 2001

Datum van registrasie 17 MEI 2001

Registration number/Registrasiënnummer: 31/30.1/0294

Name of medicine/Naam van medisyne: HAVRIX JUNIOR

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml DOSE CONTAINS/ELKE 0,5 ml DOSIS BEVAT :
HEPATITIS A VIRUS ... 720,0 ELISA UNITS

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

Applicant/Applikant: SMITHKLINE BEECHAM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM

Packer/Verpakker: SMITHKLINE BEECHAM, (BIO MAN) WAVRE BELGIUM
SMITHKLINE BEECHAM, (BIO MAN) RIXENSART
BELGIUM
SMITHKLINE BEECHAM, EPPING RSA
SACHSISCHE SERUMWERK GmbH,DRESDEN,GERMANY

Laboratory/Laboratorium: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 17 MAY 2001
Datum van registrasie: 17 MEI 2001

Registration number/Registrasiënnummer: 30/30.1/0191

Name of medicine/Naam van medisyne: HAVRIX 360

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,5 ml DOSE CONTAINS/ELKE 0,5 ml DOSIS BEVAT:
HEPATITIS A VIRAL ANTIGEN ... 360,0 ELISA UNITS

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

Applicant/Applikant: SMITHKLINE BEECHAM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM

Packer/Verpakker: SMITHKLINE BEECHAM, (BIO MAN) WAVRE BELGIUM
SMITHKLINE BEECHAM, (BIO MAN) RIXENSART
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SACHSISCHE SERUMWERK GmbH,DRESDEN,GERMANY

Laboratory/Laboratorium: SMITHKLINE BEECHAM, (BIO) RIXENSART BELGIUM
SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 17 MAY 2001
Datum van registrasie: 17 MEI 2001

MBR 15

Registration number/Registrasiensnommer: 33/2.8/0380

Name of medicine/Naam van medisyne: LIBRA-EFFERGESIC

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

CAFFEINE ... 50,0 mg

CODEINE PHOSPHATE ... 10,0 mg

DOXYLAMINE SUCCINATE ... 5,0 mg

PARACETAMOL ... 450,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 5a, 6, 7, 8a, 9

Applicant/Applikant: LIBRA PHARMACEUTICALS LTD

Manufacturer/Vervaardiger: COLUMBIA PHARMACEUTICALS, BOKSBURG RSA

Packer/Verpakker: COLUMBIA PHARMACEUTICALS, BOKSBURG RSA

Laboratory/Laboratorium: COLUMBIA PHARMACEUTICALS, BOKSBURG RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 17 MAY 2001

Datum van registrasie 17 MEI 2001

MBR 15

Registration number/Registrasiensnommer: 33/21.10/0420

Name of medicine/Naam van medisyne: NORDITROPIN PLUS 5 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,5 ml SOLUTION CONTAINS/ELKE 1,5 ml OPLOSSING BEVAT:

SOMATROPIN ... 5,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVO NORDISK (PTY) LTD

Manufacturer/Vervaardiger: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK

Packer/Verpakker: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK

Laboratory/Laboratorium: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE, DENMARK
NOVO NORDISK A/S, GENTOFTE, DENMARK
NOVO NORDISK, JOHANNESBURG RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 17 MAY 2001

Datum van registrasie 17 MEI 2001

Registration number/Registrasienommer: 33/21.10/0421

Name of medicine/Naam van medisyne: NORDITROPIN PLUS 10 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,5 ml SOLUTION CONTAINS/ELKE 1,5 ml OPLOSSING BEVAT:
SOMATROPIN ... 10,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVO NORDISK (PTY) LTD

Manufacturer/Vervaardiger: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE
DENMARK

Packer/Verpakker: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE
DENMARK

Laboratory/Laboratorium: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE
DENMARK
NOVO NORDISK A/S, GENTOFTE, DENMARK
NOVO NORDISK, JOHANNESBURG RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 17 MAY 2001

Datum van registrasie: 17 MEI 2001

Registration number/Registrasienommer: 33/21.10/0422

Name of medicine/Naam van medisyne: NORDITROPIN PLUS 15 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 1,5 ml SOLUTION CONTAINS/ELKE 1,5 ml OPLOSSING BEVAT:
SOMATROPIN ... 15,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVO NORDISK (PTY) LTD

Manufacturer/Vervaardiger: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE
DENMARK

Packer/Verpakker: NOVO NORDISK A/S, HAGEDORNSVEJ, GENTOFTE
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DENMARK
NOVO NORDISK A/S, GENTOFTE, DENMARK
NOVO NORDISK, JOHANNESBURG RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 17 MAY 2001

Datum van registrasie: 17 MEI 2001

MBR 15

Registration number/Registrasienommer: 32/2.5/0084

Name of medicine/Naam van medisyne: NEUROTOP RETARD 300

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: BYK MADAUS (PTY) LTD

Manufacturer/Vervaardiger: GEROT PHARMAZEUTIKA GMBH, VIENNA AUSTRIA

Packer/Verpakker: GEROT PHARMAZEUTIKA GMBH, VIENNA AUSTRIA

Laboratory/Laboratorium: GEROT PHARMAZEUTIKA GMBH, VIENNA AUSTRIA
BYK MADAUS, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 17 MAY 2001

Datum van registrasie: 17 MEI 2001

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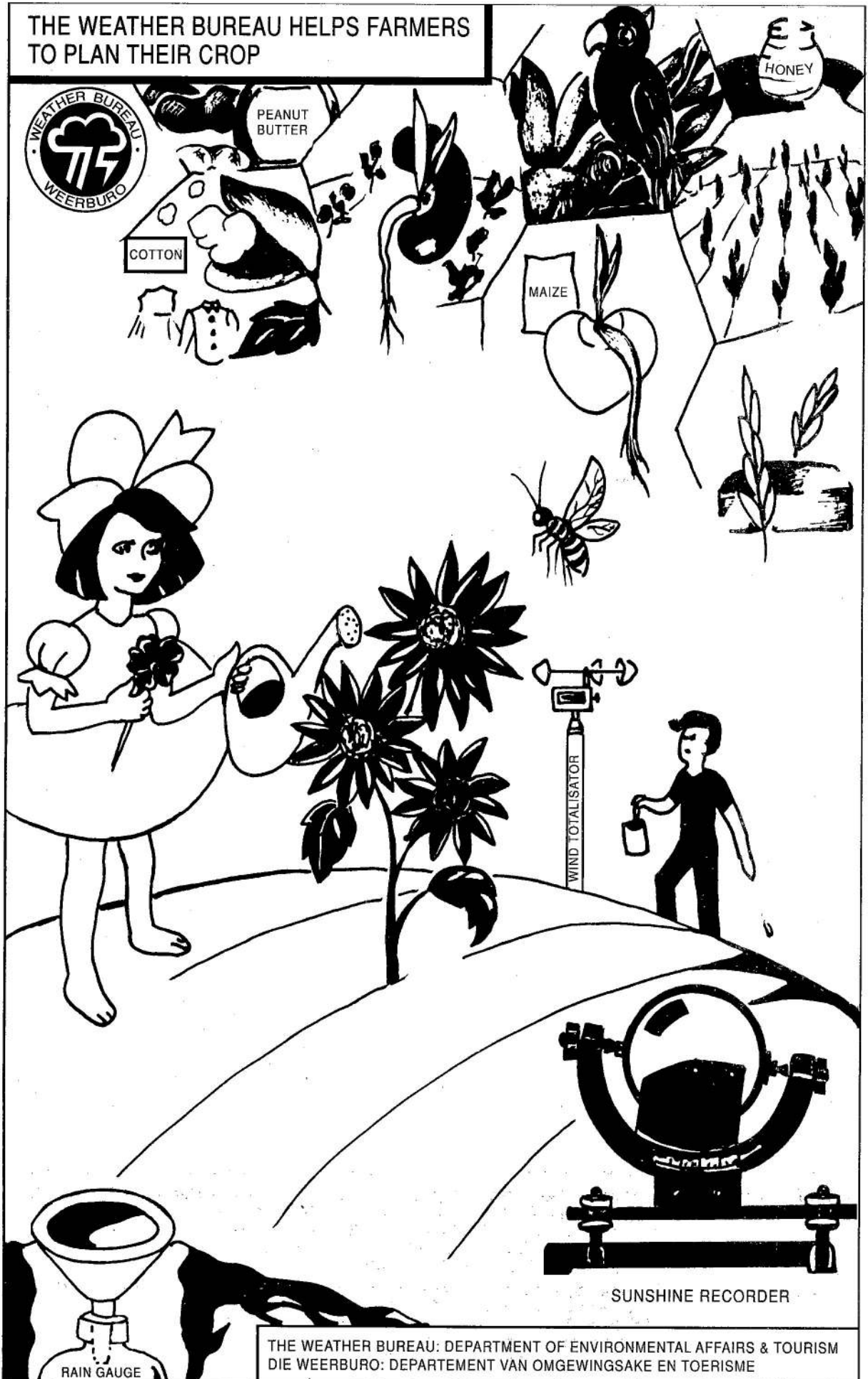
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