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GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 3230 OF 2000

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 iots 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 iots 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 iot, 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.

SCHEDULE • BYLAE

Registration number/Registrasienommer: 32/26/0426

Name of medicine/Naam van medisyne: ABIC-DOXORUBICIN HCL 50 mg

Dosage form/Doseringsvorm: INJECTION/INS PUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
DOXORUBICIN HYDROCHLORIDE/
DOKSORUBISIENHIDROCHLORIED 50,0 mg

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

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ABIC LTD, NETANYA ISRAEL

Packer/Verpakker: ABIC LTD, NETANYA ISRAEL

Laboratory/Laboratorium: ABIC LTD, NETANYA ISRAEL
INTRAMED, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JUNE 2000
Datum van registrasie 20 JUNIE 2000

Registration number/Registrasienommer: 34/20.2,8/0055

Name of medicine/Naam van medisyne: ABBOTT-ACYCLOVIR IV 250 mg

Dosage forrn/Doseringsvorm: INFUSION (PARENTERAL)/
INFUUS (PARENTERAAL)

Active ingredients/Aktiewe bestanddele.
EACH 5,0 ml VIAL" CONTAINS/ELKE 5,0 ml FLESSIE BEVAT:
ACICLOVIR/ASIKLOVIR . ..250.0 mg

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

Applicant/Applikant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, NORTH CHICAGO, ILLINOIS USA

Packer/Verpakker: ABBOTT, NORTH CHICAGO, ILLINOIS USA

Laboratory/Laboratoriu m: ABBOTT, NORTH CHICAGO, ILLINOIS USA
ABBOTT, AEROTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 JUNE 2000
Datum van registrasie 23 JUNIE 2000

Registration number/Registrasienommer: 34/20.2.8/0056

Name of medicine/Naam van medisyne: ABBOTT-ACYCLOVIR IV 500 mg

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

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml VLAL CONTAINS/ELKE 10,0 ml FLESSIE BEVAT:
ACICLOVIR/ASIKLOVIR . ..500.0 mg

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

Applicant/Applikant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: ABBOTT, NORTH CHICAGO, ILLINOIS USA

Packer /Verpakker: ABBOTT, NORTH CHICAGO, ILLINOIS USA

Laboratory/Laboratorium: ABBOTT, NORTH CHICAGO, ILLINOIS USA
ABBOTT, AEROTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 JUNE 2000
Datum van registrasie 23 JUNIE 2000

Registration number/Registrasienommer: 32/21.8.1/0209

Name of medicine/Naam van medisyne: LYRELLE 50

Dosage form/Doseringsvorm: TRANSDERMAL THERAPEUTIC SYSTEM/
TRANSDERMALE TERAPEUTIESE SISTEEM

Active ingredients/Aktiewe bestanddele:
EACH PATCH CONTAINS/ELKE PLAKKER BEVAT:
ESTRADIOL . ..24.22 mg

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

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

Manufacturer/Vervaardiger: LTS LOHMANN, ANDERNACHT GERMANY

Packer /Verpakker: LTS LOHMANN, ANDERNACHT GERMANY

Laboratory/Laboratoriu m: LTS LOHMANN, ANDERNACHT GERMANY
AKROMED PRODUCTS. OLIFANTSFONTEIN RSA
WYETH S, A., MIDRAND, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 JUNE 2000
Datum van registrasie 23 JUNIE 2000

Registration number/Registrasienommer: 32/21,8.1/0210

Name of medicine/Naam van medisyne: LYRELLE 80

Dosage form/Doseringsvorm: TRANSDERMAL THERAPEUTIC SYSTEM/ TRANSDERMALE TERAPEUTIESE SISTEEM

Active ingredients/Aktiewe bestanddele:
EACH PATCH CONTAINS/ELKE PLAKKER BEVAT:
ESTRADIOL . ..38.74 mg

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

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

Manufacturer/Vervaardiger: LTS LOHMANN, ANDERNACHT GERMANY

Packer/Verpakker: LTS LOHMANN, ANDERNACHT GERMANY

Laboratory/Laboratorium: LTS LOHMANN, ANDERNACHT GERMANY
AKROMED PRODUCTS, OLIFANTSFONTEIN RSA
WYETH S.A., MIDRAND, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 JUNE 2000
Datum van registrasie 23 JUNIE 2000

Registration number/Registrasienommer: 32/30.4/0527

Name of medicine/Naam van medisyne: REGRANEX 0,01 %

Dosage forrn/Doseringsvorm: GEL/JEL

Active ingredients/AMiewe bestanddele:
EACH 1,0 g GEL CONTAINS/ELKE 1,0 g JEL BEVAT:
BECAPLERMIN 0,100 mg

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

Applicant/Applikant:	JANSSEN PHARMACEUTICAL (PTY) LTD
Manufacturer/Vervaardiger:	OMJ PHARMACEUTICALS INC, SAN GERMAN PUERTO RICCO
Packer/Verpakker:	OMJ PHARMACEUTICALS INC, SAN GERMAN PUERTO RICCO
Laboratory/Laboratorium:	OMJ PHARMACEUTICALS INC, SAN GERMAN PUERTO RICCO JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA
Shelf-life/Rakleeftyd:	12 months/maande
Date of registration: Datum van registrasie	23 JUNE 2000 23 JUNIE 2000

Registration number/Registrasienommer: 32/1 1,4.3/0539

Name of medicine/Naam van medisyne: ULTAK- 150

Dosage orm/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE/
RANITIDIENHIDROCHLORIED
EQUIVALENT TO/EKWIVALENT AAN
RANITIDINE/RANITIDIEN ,.. 150,0 mg

Conditions of registrationNoorwaardes vir registrasie:
1,2, 3,4,6,7

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, BOMBAY INDIA
CIPLA LTD, PATALGANGA MAHARASHTRA INDIA

Packer/Verpakker: CIPLA LTD, BOMBAY INDIA
CIPLA LTD, PATALGANGA MAHARASHTRA INDIA

Laboratory/Laboratorium: CIPLA LTD, BOMBAY INDIA
CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
CIPLA-MEDPRO (PTY) LTD

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 JUNE 2000
Datum van registrasie 23 JUNIE 2000

Registration number/Registrasienommer: 32/1 1.43./0540

Name of medicine/Naam van medisyne: ULTAK-300

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE/
RANITIDIENHIDROCHLORIED
EQUIVALENT TO/EKWIVALENT AAN
RANITIDINE/RANITIDIEN 300,0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, BOMBAY INDIA
CIPLA LTD, PATALGANGA MAHARASHTRA INDIA

Packer/Verpakker: CIPLA LTD, BOMBAY INDIA
CIPLA LTD, PATALGANGA MAHARASHTRA INDIA

Laboratory/Laboratorium: CIPLA LTD, BOMBAY INDIA
CIPLA LTD, PATALGANGA MAHARASHTRA INDIA
CIPLA-MEDPRO (PTY) LTD

Shelf-i ife/Rakleeftyd: 24 months/maande

Date of registration: 23 JUNE 2000
Datum van registrasie 23 JUNIE 2000

Registration number/Registrasienommer: 29/2210492

Name of medicine/Naam van medisyne: KONAKION MM PEDIATRIC

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Akliewe bestanddele:
EACH 0,2 ml AMPOULE CONTAINS/ELKE 0,2 ml AMPUUL BEVAT :
VITAMIN K1 . . . 2,0 mg

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

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: F HOFFMANN-LA ROCHE, GREN, BASLE SWITZERLAND

Packer/Verpakker: F HOFFMANN-LA ROCHE, GREN, BASLE SWITZERLAND

Laboratory/Laboratorium: F HOFFMANN-LA ROCHE, GREN, BASLE SWITZERLAND
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 23 JUNE 2000
Datum van registrasie 23 JUNIE 2000

Registration number/Registrasienommer: 32/11.4.3/0512

Name of medicine/Naam van medisyne: ACI-MED OTC

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND

Packer/Verpakker: WRAPSA, CENTURION RSA

Laboratory/Laboratoriu m: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JUNE 2000
Datum van registrasie 26 JUNIE 2000

Registration number/Registrasienommer: 33/16.2/0024

Name of medicine/Naam van medisyne: CIPROBAY HC OTIC DROPS

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml BOTTLE CONTAINS/ELKE 10,0 ml BOTTEL BEVAT:
CIPROFLOXACIN HYDROCHLORIDE/
SIPROFLOKSASIENHJDROCHLOR3ED
EQUIVALENT TO/EKWIVALENT AAN
CIPROFLOXACIN/SIPROFLOKSASIEN . . . 20,0 mg
HYDROCORTISONE/HIDROKORTISOON . ..100.0 mg

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: BAYER, PENNSYLVANIA U.S.A

Packer/Verpakker: BAYER, PENNSYLVANIA U.S.A
BAYER, LEVERKUSEN WEST GERMANY
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratonum: BAYER, PENNSYLVANIA U.S.A
BAYER, LEVERKUSEN WEST GERMANY
GLAXO WELLCOME, MIDRAND RSA
BAYER, ISANDO RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JUNE 2000
Datum van registrasie 26 JUNIE 2000

Registration number/Registrasienommer: 33/20.1.1/0219

Name of medicine/Naam van medisyne: DISTA-CEFACLOR 250

Dosage form/Doseringsvorm: CAPSULES/KAPSULE

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSUUL BEVAT:
CEFACLOR . ..250.0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/20.1.1/0220

Name of medicine/Naam van medisyne: DISTA-CEFACLOR 500

Dosage form/Doseringsvorm: CAPSULEWKAPSUUL

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSUUL BEVAT:
CEFACLOR . ..500.0 mg

Conditions of registrationNoorwaardes vir registrasie:
1,2, 3, 4, 5a, 6, 7

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/20,1.1/0221

Name of medicine/Naam van medisyne: DISTA-CEFACLOR 125 P

Dosage form/Dosenngsvorrn: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 *ml* SUSPENSION CONTAINS/
ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR . ..125.0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratonum: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB,
STAR STREET BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/20. 1. 1/0222

Name of medicine/Naam van medisyne: DISTA-CEFACLOR 250P

Dosage forrn/Dosenngsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR . ..250.0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/20.I 1/0223

Name of medicine/Naam van medisyne: DISTA-CEFACLOR BD 187

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/
ELKE 5,0 ml SUSPENSIE BEVAT :
CEFACLOR . ..187.5 mg

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

Applicant/Applikant:	ELI LILLY (SA) (PTY) LTD
Manufacturer/Vervaardiger:	ELI LILLY, FLORENCE ITALY
Packer/Verpakker:	ELI LILLY, FLORENCE ITALY
Laboratory/Laboratoriu m:	ELI LILLY, FLORENCE ITALY ELI LILLY, BRYANSTON RSA CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
Shelf-life/Raklee ftyd:	24 months/maande
Date of registration: Datum van registrasie	27 JUNE 2000 27 JUNIE 2000

Registration number/Registrasienommer: 33/20. 1. 1/0224

Name of medicine/Naam van medisyne: DISTA-CEFACLOR BD FORTE 375

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredientslAktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/
ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR . . 375,0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer /Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
ELI LILLY, BRYANSTON RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/7.1.3/0479

Name of medicine/Naam van medisyne: PHARMAPRESS 10 MG

Dosage forrn/Doseringsvorrn: TABLET

Active ingredients/Aktiewe bests.m.idele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ENALAPRIL MALEATE . ..10.0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7, 8a, 9

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON, PORT ELIZABETH RSA

Packer/Verpakker: LENNON, PORT ELIZABETH RSA

Laboratory/Laboratorium: LENNON, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: **27** JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/7.1.310480

Name of medicine/Naam van medisyne: PHARMAPRESS 20MG

Dosage forrn/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
ENALAPRIL MALEATE 20,0 mg
Conditions of registration/Voorwaardes vir registrasie:
1,2,3,4, 5a, 6,7, 8a, 9

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: LENNON, PORT ELIZABETH RSA

Packer/Verpakker: LENNON, PORT ELIZABETH RSA

Laboratory/Laboratoriu m: LENNON, PORT ELIZABETH RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/20. 1. 1/0228

Name of medicine/Naam van medisyne: LENACLOR 250P

Dosage forrrdDoseringsvorrn: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/
ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR 250,0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
ELI LILLY, FLORENCE ITALY
ELI LILLY, BRYANSTON RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNE 2000

Registration number/Registrasienommer: 3312610102

Name of medicine/Naam van medisyne: ADRIBLASTINA CSV 10 MG/5 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT:
DOXORUBICIN HYDROCHLORIDE/
DOKSORUBISIENHIDROCHLORIED . ..10.0 mg

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

Applicant/Applikant: PHARMACIA & UPJOHN (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Packer/Verpakker: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 33/26/0104

Name of medicine/Naam van medisyne: ADRIBLASTINA CSV 50 MG/25 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

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

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

Applicant/Applikant: PHARMACIA & UPJOHN (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Packer/Verpakker: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 27 JUNE 2000
Datum van registrasie 27 JUNIE 2000

Registration number/Registrasienommer: 3 1/2.7/0466

Name of medicine/Naam van medisyne: NUROFEN FOR CHILDREN SUGAR FREE

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, 8a, 9

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

Manufacturer/Vervaardiger: BOOTS, NOTTINGHAM UK

Packer/Verpakker: BOOTS, NOTTINGHAM UK

Laboratory/Laboratorium: BOOTS, NOTTINGHAM UK
R&C PHARMACEUTICALS, MOBENI RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 33/26/0105

Name of medicine/Naam van medisyne: AD RIBLASTINA CSV 200 MG/100 ML

Dosage forrn/Dosenngsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 100,0 ml SOLUTION CONTAINS/ELKE 100,0 ml OPLOSSING BEVAT:
DOXORUBICIN HYDROCHLORIDE/
DOKSORUBISIENHIDROCHLORIED . ..200.0 mg

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

Applicant/Applikant: PHARMACIA & UPJOHN (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

Packer/Verpakker: PHARMACIA & UPJOHN, BENTLEY AUSTRALIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 3 1/3. l/0636

Name of medicine/Naam van medisyne: PROFLEX 500

Dosage form/Toseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
NAPROXEN . ..500.0 mg

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND

Packer/Verpakker: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND

DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratoriu m: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND

DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON

PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 32/26/0533

Name of medicine/Naam van medisyne: CAELYX

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

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml CONCENTRATE CONTAINS/
ELKE 1,0 ml KONSENTRAAT BEVAT:
DOXORUBICIN HYDROCHLORIDE/
DOKSORUBISIENHIDROCHLORIED ,.. 2,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: BEN VENUE LABORATORIES, OHIO USA

Packer/Verpakker: BEN VENUE LABORATORIES, OHIO USA
SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: BEN VENUE LABORATORIES, OHIO USA
SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 32/3.1/0353

Name of medicine/Naam van medisyne: ARTHROTEC 75

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DICLOFENAC SODI WATRIUMDIKLOFENAK . ..75.0 mg
MISOPROSTOL . ..200.0 mcg

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

Applicant/Applikant: SEARLE, DIVISION OF MONSANTO SA (PTY) LTD

Manufacturer/Vervaardiger: SEARLE, MORPETH NORTHUMERLAND UK

Packer/Verpakker: SEARLE, MORPETH NORTHUMERLAND UK

Laboratory/Laboratonum: SEARLE, MORPETH NORTHUMERLAND UK
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA
RSA
SEARLE, DIVISION OF MONSANTO SA, MIDRAND RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 33/7. 1.3/(?506

Name of medicine/Naam van medisyne: ENALAHEXAL 5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ENALAPRIL MALEATE 5.0 mg

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

Applicant/Applikant: HEXAL PHARMA (S.4) (PTY) LTD

Manufacturer/Vervaardiger: GEA FARMACEUTISK, HVIDOVRE, DENMARK

Packer/Verpakker: GEA FARMACEUTISK, HVIDOVRE, DENMARK
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: GEA FARMACEUTISK, HVIDOVRE, DENMARK
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registra.sienommer: 33/7.1.3/0507

Name of medicine/Naam van medisyne: ENALAHEXAL 10

Dosage form/Dosenngsvorrn: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ENALAPRIL MALEATE . ..10.0 mg

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

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

Manufacturer/Vervaardiger: GEA FARMACEUTISK, HVIDOVRE, DENMARK

Packer/Verpakker: GEA FARMACEUTISK, HVIDOVRE, DENMARK
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: GEA FARMACEUTISK, HVIDOVRE, DENMARK
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 33/7, 1.3/05 08

Name of medicine/Naam van medisyne: ENALAHEXAL 20

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ENALAPRIL MALEATE . . . 20,0 mg

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

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

Manufacturer/Vervaardiger: GEA FARMACEUTISK, HVIDOVRE, DENMARK

Packer/Verpakker: GEA FARMACEUTISK, HVIDOVRE, DENMARK
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: GEA FARMACEUTISK, HVIDOVRE, DEN W
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 3217. I/0556

Name of medicine/Naam van medisyne: CARDURA XL 4 mg TABLETS

Dosage form/Doseringsvorrn: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DOXAZOSIN . ..4.0 mg

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, BROOKLYN NY USA

Packer/Verpakker: HEINRICH MACK NACHFOLGER,
ILLERTISSEN GERMANY
PFIZER, AMBOISE FRANCE

Laboratory/Laboratorium: PFIZER, BROOKLYN NY USA
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 32/7 1/0557

Name of medicine/Naam van medisyne: CARDURA XL 8 mg TABLETS

Dosage forrn/Dosenngsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DOXAZOSIN '. 8,0 mg

Conditions of registrationNoorwaardes vir registrasie:
1,2,3, 4,546,7

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, BROOKLYN NY USA

Packer/Verpakker: HEINRICH MACK NACHFOLGER, ILLERTISSEN GERMANY
PFIZER, AMBOISE FRANCE

Laboratory/Laboratorium: PFIZER, BROOKLYN NY USA
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 JUNE 2000
Datum van registrasie 28 JUNIE 2000

Registration number/Registrasienommer: 32/1 1.4.3/0604

Name of medicine/Naam van medisyne: HISTAK 75 TABLETS

Dosage forrn/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
RANITIDINE HYDROCHLORIDE/
RANITIDIENHIDROCHLORIED
EQUIVALENT TO/EKWIVALENT AAN
RANITIDINE/RANITIDIEN . ..75.0 mg

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

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

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium: RANBAXY, PAONTA SAHIB INDIA
RANBAXY, BRYANSTON RSA
ALLIANCE PHARMA, VILLAGE MAIN RSA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS, HILTON RSA
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 30 JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 33/20.1,1/0511

Name of medicine/Naam van medisyne: ROLAB-CEPHALEXIN 500C

Dosage form/Doseringsvorm: CAPSULEWKAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSUUL BEVAT:
CEPHALEXIN . ...500.0 mg

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

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: BIOCHEMIE GmbH, KUNDL TIROL AUSTRIA

Packer/Verpakker: BIOCHEMIE GmbH, KUNDL TIROL AUSTRIA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

Laboratory/Laboratorium: BIOCHEMIE GmbH> KUNDL TIROL AUSTRIA
NOVARTIS, SPARTAN KEMPTON PARK RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 30 JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 34/20. 1. 1/0002

Name of medicine/Naam van medisyne: TAVANIC I.V. 250

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

Active ingredients/Aktiewe bestanddele:
EACH 50,0 ml SOLUTION CONTAINS/ELKE 50,0 ml OPLOSSING BEVAT :
LEVOFLOXACIN . ..250.0 mg

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: HOECHST WON ROUSSEL, FRANKFURT W/GERMANY

Packer/Verpakker: HOECHST MARION ROUSSEL, FRANKFURT W/GERMANY

HOECHST WON ROUSSEL, WALTLOO RSA

Laboratory/Laboratoriu m: HOECHST MARION ROUSSEL, FRANKFURT W/GERMANY

HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 30 JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 33/20.1.1/0225

Name of medicine/Naam van medisyne: LENACLOR 250

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSUUL BEVAT:
CEFACLOR . ..250.0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY. FLORENCE ITALY
CONSULTING CHEMICAL LAB. STAR STREET
BOKSBURG, RSA
ELI LILLY. BRYANSTON RSA
S(.) U-I-I I AFRICAN BUREAU OF STANDARDS.
PRETORIA RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 30 JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 33/20.1.1/0226

Name of medicine/Naam van medisyne: LENACLOR 500

Dosage forrrdDoseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSUUL BEVAT:
CEFACLOR . ..500.0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
ELI LILLY, BRYANSTON RSA FPRR
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 30 JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 33/20. 1. 1/0227

Name of medicine/Naam van medisyne: LENACLOR 125 P

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE:
CEFACLOR . ..125.0 mg

Conditions of registrationNoorwaardes vir registrasie:
1,2, 3,4. 5a, 6, 7

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
ELI LILLY, BRYANSTON RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Raklee ftyd: 24 months/maande

Date of registration: 30 JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 33/20. 1. 1/0229

Name of medicine/Naam van medisyne: LENACLOR BD 187

Dosage forrn/Dosenngsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR ,.. 187,5 mg

Conditions of registration/Voorwaardes vir registrasie:
1.2, 3,4, 5a, 6, 7

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

LaboratoryiLaboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
ELI LILLY, BRYANSTON RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: **30** JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 33/20.1.1/0230

Name of medicine/Naam van medisyne: LENACLOR BD FORTE 375

Dosage forrn/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
CEFACLOR . ..375.0 mg

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

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

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
ELI LILLY, BRYANSTON RSA FPRR
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 30 JUNE 2000
Datum van registrasie 30 JUNIE 2000

Registration number/Registrasienommer: 32/1 1.5/0607

Name of medicine/Naam van medisyne: SOFLAX TABLETS

Dosage fern-dlloseringsvorin: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS /ELKE TABLET BEVAT:
SENNOSIDE A & B, CALCIUM SALTS/
SENOSIEDE A & B, KALSIUM SOUTE 13,5 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: CIPLA LTD, BANGALORE INDIA

Packer/Verpakker: CIPLA LTD, BANGALORE INDIA

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

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 07 JULY 2000
Datum van registrasie 07 JULIE 2000

Registration number/Registrasienommer: 32/11.5/565

Name of medicine/Naam van medisyne: BLACK FOREST APRICOT-APPLE

Dosage form/Doseringsvorm: DECOCTION/AFKOOKSEL

Active ingredients/Aktiewe bestanddele:
EACH 2,5 g TEA CONTAINS/ELKE 2,5 g TEE BEVAT:
SENNOSIDE B ... 27,81 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: TECHNIKON LABORATORIES, FLORIDA RSA

Packer/Verpakker: TECHNIKON LABORATORIES. FLORIDA RSA

Laboratory/Laboratoriu m: TECHNIKON LABORATORIES, FLORIDA RSA
NOVARTIS, SPARTAN KEMPTON PARK RSA
INSPECTORATE M & L, ORMONDE RSA

Shelf-l ife/Rakleeftyd: 24 months/maande

Date of registration: 07 JULY 2000
Datum van registrasie 07 JULIE 2000

Registration number/Registras ienommer: 32/1 1,5/0566

Name of medicine/Naam van medisyne: BLACK FOREST LEMON-LIME

Dosage form/Doseringsvorm: DECOCTION/AFKOOKSEL

Active ingredients/Aktiewe bestanddele:
EACH 2,5 g TEA CONTAINS/ELKE 2,5 g TEE BEVAT:
SENNOSIDE B . 27,81 mg

Conditions of registrationNoorwaardes vir registrasie:
1,2, 3,4,6,7

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: TECHNIKON LABORATORIES, FLORIDA RSA

Packer/Verpakker: TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: TECHNIKON LABORATORIES, FLORIDA RSA
NOVARTIS, SPARTAN KEMPTON PARK RSA
INSPECTORATE M & L, ORMONDE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 07 JULY 2000
Datum van registrasie 07 JULIE 2000

Registration number/Registrasienommer: 33/26/0360

Name of medicine/Naam van medisyne: CHIRON IL-2

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml CONTAINS/ELKE 1.0 ml BEVAT:
ALDESLEUKIN . ..18 MILLION IU

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

Applicant/Applikant: KEY ONCOLOGIC (PTY) LTD

Manufacturer/Vervaardiger: CHIRON CORPORATION EMERYWLLE CA, USA
CHIRON BV, AMSTERDAM NETHERLANDS

Packer/Verpakker: CHIRON CORPORATION EMERYVILLE CA, USA
CHIRON BV. AMSTERDAM NETHERLANDS

Laboratory/Laboratorium: CHIRON CORPORATION EMERYVILLE CA, USA
CHIRON BV, AMSTERDAM NETHERLANDS
CENTRAL LAB OF NETHERLANDS, AMSTERDAM NETHERLANDS
KEY ONCOLOGIC, SANDTON RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 JULY 2000
Datum van registrasie 20 JULIE 2000

Registration number/Registrasienommer: 33/10.2.1/0270

Name of medicine/Naam van medisyne: SABAX IPRATROPIUM Br 0,25 MG/2 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 n-d SOLUTION CONTAINS/ELKE 2,0 ml OPLOSSING BEVAT:
IPRATROPIUM
BROMIDE/BROMIED . . . 0,25 mg

Conditions of registration/Voorwaardes vir registrasie:
1,2.3, 4, 5a, 6, 7

Applicant/Applikant: ADCOCK INGRAM LTD (CRITICAL CARE)

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Packer/Verpakker: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Laboratory/Laboratoriu m: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 34/20.2.8/0175

Name of medicine/Naam van medisyne: NORVIR SEC 100 mg

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
RITONAVIR . ..100.0 mg

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

Applicant/Applikant: ABBOTT LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: R P SCHERER, ST PETERSBURG USA

Packer/Verpakker: ABBOTT, KENT UK

Laboratory/Laboratorium: R P SCHERER, ST PETERSBURG USA
ABBOTT, KENT UK
ABBOTT, AEROTON RSA

Shelf-life/Rakleeftyd: 12 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 33/7.3/01 26

Name of medicine/Naam van medisyne: MIGRANAL NASAL SPRAY

Dosage form/Doseringsvorm: . NASAL SPRAY/'NEUSSPROEI

Active ingredients/Aklic\ve bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
DIHYDROERGOTAMINE MESYLATE . ..4.0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, MILAN, ITALY

Packer/Verpakker: NOVARTIS, MILAN, ITALY
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, MILAN, ITALY
NOVARTIS, SPARTAN KEMPTON PARK RSA

Sl~clf-life/R;lklccfi!'d: 24 months/maande

Date of registration: 3 I JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 32/11.4.3/0665

Name of medicine/Naam van medisyne: ACITIDIN

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
RANITIDINE HYDROCHLORIDE/RANITIDIENHIDROCHLORIED
EQUIVALENT TO/EKWIVALENT AAN
RANITIDINE/RANITIDIEN 75.0 mg

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

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

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Vwpakker: RANBAXY, PAONTA SAHIB INDIA

Laboratory/Laboratorium RANBAXY, PAONTA SAHIB INDIA
ALLIANCE PHARMA, VILLAGE MAIN RSA
BIOCHEMICAL & SCIENTIFIC CONSULTANTS.
HILTON RSA
KHULULEKANI LABORATORY SERVICES,
MIDRAND RSA
RANBAXY, BRYANSTON RSA

Sl~clf-life/RaklcefiJd: 24 months/maande

Date of registration: 31 JULY 2000"
Datum van registrasie 3 1 JULIE 2000

Registration number/Registrasienommer: 33/10,2/0416

Name of medicine/Naam van medisyne: NUELIN SA 200

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
THEOPHYLLINE . . . 200,0 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

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

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

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 33/10.2/0417

Name of medicine/Naam van medisyne: NUELIN SA 300

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
THEOPHYLLINE . ..300.0 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

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

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

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 32/21.5.1/0532

Name of medicine/Naam van medisyne: INFLANAZE 50

Dosage form/Doseringsvorm: NASAL SPRAY/NEUSSPROEI

Active ingredients/Aktiewe bestanddele:
EACH METERED DOSE CONTAINS/ELKE AFGEMETE DOSIS BEVAT:
BUDESONIDE . . . 50,0 ug

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: RHONE-POULENC RORER, PORT ELIZABETH RSA

Packer/Verpakker: RHONE-POULENC RORER, PORT ELIZABETH RSA

Laboratory/Laboratorium: RHONE-POULENC RORER, PORT ELIZABETH RSA
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 31/3.1/0635

Name of medicine/Naam van medisyne: PROFLEX 250

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
NAPROXEN ,.. 250,0 mg

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND

Packer/Verpakker: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND

DIVPHARM MANUFACTURING AND PACKAGING> LONGDALE RSA

Laboratory/Laboratorium: CLONMEL CHEMICALS(HEALTHCARE), TIPPERARY IRELAND
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
INSTITUTE FOR PHARM & CHEM SERVICE, TECHNIKON PRETORIA RSA
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 31/2.9/0047

Name of medicine/Naam van medisyne: NOBLIGAN CAPSULES

Dosage form/Doseringsvorm: CA f? SULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
TRAMADOL
HYDROCHLORIDE/HIDROCHLORIED . ..50.0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICAL (PTY) LTD

Manufacturer/Vervaardiger: GRUNENTHAL, STOLBERG, GERMANY

Packer/Verpakker: GRUNENTHAL, STOLBERG, GERMANY

Laboratory/Laboratorium: GRUNENTHAL, STOLBERG, GERMANY
JANSSEN PHARMACEUTICA,
HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration numb er/Registrasienommer: 28/5.7.2/0210

Name of medic ine/Naam van medisyne: MERCK-METOCLOPRAMIDE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
METOCLOPRAMIDE HYDROCHLORIDE (MONOHYDRATE)/
METOKLOPRAMIEDHIDROCHLORIED (MONOHIDRAAT)
EQUIVALENT TO/EKWIVALENT AAN
METOCLOPRAMIDE HYDROCHLORIDE/
METOKLOPRAMIEDHIDROCHLORIED . ..10.0 mg

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

Applicant/Applikant: MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD

Manufacturer/Vervaardiger: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA

Packer /Verpakker: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: BE-TABS PHARMACEUTICALS, ROODEPOORT RSA
MERCK PHARMACEUTICALS MANUFACTURING (PTY) LTD

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 33/34/0726

Name of medicine/Naam van medisyne: INTRON A (I-ISA-FREE) REDIPEN 3 MILLION I.U.

Dosage form/Doseringsvorm: INJECTION/INS PUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,2 ml SOLUTION CONTAINS/ELKE 0,2 ML OPLOSSING BEVAT:
INTERFERON ALFA -2b . ..3 million i.u.

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, INNISHANNON IRELAND

Packer/Verpakker: SCHER.ING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH. ISANDO RSA

Shelf-life/Rakleeftyd: 15 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 33134/0327

Name of medicine/Naam van medisyne: INTRON A (HSA-FREE) REDIPEN 5 MILLION I.U.

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,2 ml SOLUTION CONTAINS/ELKE 0,2 ml OPLOSSING BEVAT:
INTERFERON ALFA-2b ... 5 million i.u.

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

Applicant/Applikant: SCHERJNG-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, INNISHANNON IRELAND

Packer/Verpakker: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 1 5 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 33/34/0328

Name of medicine/Naam van medisyne: INTRON-A (HSA-FREE) REDIPEN 10 MILLION I.U.

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0,2 ml SOLUTION CONTAINS/ELKE 0,2 ml OPLOSSING BEVAT:
INTERFERON ALFA-2b . ..10 million i.u.

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, INNISHANNON IRELAND

Packer/Verpakker: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 15 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienommer: 32/15.4/0401

Name of medicine/Naam van medisyne: HYPOTEARS PLUS

Dosage form/Dosenngsvorm: SOLUTION/OPLOSSING

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

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: LABORATOIRES CIBA VISION, CEDEX,FRANCE

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

Laboratory/Laboratorium: LABORATOIRES CIBA VISION, CEDEX,FRANCE
NOVO NORDISK, JOHANNESBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 31 JULIE 2000

Registration number/Registrasienomn~er: 33/26/0198

Name of medicine/Naam van medisyne: XELODA 150

Dosage form/Doseringsvorm: TABLET

Active ingredients/Ah-tie\ve bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CAPECITABINE . ..150.0 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
F HOFFMANN-LA ROCHE, WURMISWEG KAISERAUGST SWITZERLAND
ROCHE, ISANDO RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 JULY 2000
Datum van registrasie 3 I JULIE 2000

Registration number/Registrasienommer: 30/5.4,1/0446

Name of medicine/Naam van medisyne: CABASER 1 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CABERGOLINE . ..1.0 mg

Conditions of registration/Voorwaardes vir registrasie:
1.2, 3,4, 5a, 6,7

Applicant/Applikant: PHARMACIA & UPJOHN (PTY) LTD

Manufacturer/Vervaardiger: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY

Packer/Verpakker: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY

Laboratory/Laborato rium: PHARMACIA & UPJOHN, NERVIANO MILAN ITALY
PHARMACIA & UPJOHN, ASCOLI PICENO ITALY
KHULULEKANI LABORATORY SERVICES, MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMACIA & UPJOHN. MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number/Registrasienommer: 32/2.5/0662

Name of medicine/Naam van medisyne: TOPAMAX 15 MG SC

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

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

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

Applicant/Applikant: JANSSEN PHARMACEUTICAL (PTY) LTD

Manufacturer/Vervaardiger: INTERNATIONAL PROCES CORP, WINCHESTER KENTUCKY USA
MC NEIL PHARMACEUTICAL. DORADO PUERTO RICO

Packer/Verpakker: MC NEIL PHARMACEUTICAL, DORADO PUERTO RICO
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Laboratory/Laboratonum: MC NEIL PHARMACEUTICAL, DORADO PUERTO RICO
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Shelf-! ife/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number/Registrasienonm~er: 32/2,5/0663

Name of medicine/Naam van medisyne: TOPAMAX 25 MG SC

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT
TOPIRAMATE ... 25,0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICAL (PTY) LTD

Manufacturer/Vervaardiger: INTERNATIONAL PROCES CORP, WINCHESTER KENTUCKY USA

Packer/Verpakker: MC NEIL PHARMACEUTICAL, DORADO PUERTO RICO
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Laboratory/Laboratoriu m: MC NEIL PHARMACEUTICAL, DORADO PUERTO RICO
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number/Registrasienommer: 32/2.5/0664

Name of medicine/Naam van medisyne: TOPAMAX 50 MG SC

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
TOPIRAMATE . ..50.0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: INTERNATIONAL PROCESCORP, WINCHESTER KENTUCKY USA
MC NEIL PHARMACEUTICAL, DORADO PUERTO Rico

Packer/Verpakker: MC NEIL PHARMACEUTICAL, DORADO PUERTO RICO
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Laboratory/Laboratorium: MC NEIL PHARMACEUTICAL, DORADO PUERTO Rico
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number/Registrasienommer: 34/20.2.6/0161

Name of medicine/Naam van medisyne: RIAMET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ARTEMETHER . ...20.0 mg
LUMEFANTRINE 120,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND

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

Laboratory/Laboratorium: NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number/Registrasienommer: E/11.8/668

Name of medicine/Naam van medisyne: SCHERIPROCT SUPPOSITORIES

Dosage form/Doseringsvorm: SUPPOSITORY/SETPIL

Active ingredients/Aktiewe bestanddele:
EACH SUPPOSITORY CONTAINS/ELKE SETPIL BEVAT :
CINCHOCAINE HYDROCHLORIDE . . . 1,0 mg
PREDNISOLONE HEXANOATE . . . 1,3 mg

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, FLORENCE ITALY
SCHERING, BERLIN GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, FLORENCE ITALY
SCHERING, BERLIN GERMANY

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, FLORENCE ITALY
SCHERING, BERLIN GERMANY
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number/Registrasienommer: E/l 1.8/667

Name of medicine/Naam van medisyne: SCHERIPROCT OINTMENT

Dosage form/Doseringsvorm: OINTMENT/SALF

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g OINTMENT CONTAIN S/ELKE 100,0 g SALF ONTVANG:
CINCHOCAINE HYDROCHLORIDE . ..0.5 g
PREDNISOLONE HEXANOATE . ..0.19 g

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, BERLIN GERMANY
SCHERING, MILANO ITALY

Packer/Verpakker: SCHERING, BERLIN GERMANY
SCHERING, MILANO ITALY

Laboratory/Laboratorium: SCHERING, BERLIN GERMANY
SCHERING, MILANO ITALY
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number /Registrasienommer: 32/8. 310166

Name of medicine/Naam van medisyne: VENOFER

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml AMPOULE CONTAINS/ELKE 5,0 ml AMPULE BEVAT:
IRON/YSTER . . . 100,0 mg

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

Applicant/Applikant: BYK MADAUS (PTY) LTD

Manufacturer/Vervaardiger: BYK GULDEN, SINGEN, GERMANY

Packer/Verpakker: BYK GULDEN, SINGEN, GERMANY

Laboratory/Laboratorium: BYK GULDEN, SINGEN, GERMANY
VIFOR (INT.), SWITZERLAND
BYK MADAUS, MIDRAND RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 03 AUGUST 2000
Datum van registrasie 03 AUGUSTUS 2000

Registration number/Registrasienommer: 33/16.4/0280

Name of medicine/Naam van medisyne: PERIOCHIP

Dosage form/Doseringsvorm: CHIP (DENTAL) /SKYFIE(TANDHEELKUNDIG)

Active ingredients/.4ktiewe bestanddele:
EACH CHIP CONTAINS/ELKE SKYFIE BEVAT:
CHLORHEXIDINE
GLUCONATE/GLUKONAAT 2,5 mg

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

Applicant/Applikant: MC PHARMA CC

Manufacturer/Vervaardiger: PERIO PRODUCTS, JERUSALEM, ISRAEL

Packer/Verpakker: PERIO PRODUCT-S, JERUSALEM, ISRAEL

Laboratory/Laboratorium: PERJO PRODUCTS, JERUSALEM, ISRAEL
INSPECTORATE M & L, ORMONDE RSA
MC PHARMA CC, MEYERSPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 04 AUGUST 2000
Datum van registrasie 04 AUGUSTUS 2000

Registration number/Registrasienommer: 29/9/0242

Name of medicine/Naam van medisyne: ESPERAL IMPLANTS

Dos :ge form/Doseringsvorm: IMPLANT/INPLANTERING

Active ingredients/Aktiewe bestanddele:
EACH IMPLANT CONTAINS/ELKE INPLANTERING BEVAT:
DISULFIRAM . ..100.0 mg

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

Applicant/Applikant: M KATOVSKY CC

Manufacturer/Vervaardiger: KELA LABORATORIA NV, HOOGSTRATEN BELGIUM

Packer/Verpakker: KELA LABORATORIA NV, HOOGSTRATEN BELGIUM
PHARMACEUTICAL ENTERPRISES, HOWARD
PLACE RSA

Laboratory/Laboratorium: KELA LABORATORLA NV, HOOGSTRATEN BELGIUM
M KATOVSKY, SEA POINT

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 07 AUGUST 2000
Datum van registrasie 07 AUGUSTUS ‘2000

Registration number/Registrasienommer: 33/21.5.4/0413

Name of medicine/Naam van medisyne: SERETIDE 50/100 ACCUHALER

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH BLISTER CONTAINS/ELKE STULPVERPAKKING BEVAT:
FLUTICASONE PROPIONATIYFLUTIKASOONPROPIONAAT . ..100.0 ug
SALMETEROL XINAFOATE
EQUIVALENT TO/EKWIVALENT AAN
SALMETEROL ..... 50,0 Ug

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

Packer/Verpakker: GLAXO WELLCOME, HERTFORDSHIRE UK
GLAXO WELLCOME, MIDRAND RSA
GLAXO WELLCOME, BAD OLDESLOE GERMANY

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

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 11 AUGUST 2000
Datum van registrasie 11 AUGUSTUS 2000

Registration number/Registrasienommer: 33/21,5,4/0414

Name of medicine/Naam van rnedisyne: SERETIDE 50/250 ACCUHALER

Dosage form/Doseringsvorm: INHALER/INHALEERDER

Active ingredients/Aktiewe bestanddele:
EACH BLISTER CONTAINS/ELKE STULPVERPAKKING BEVAT:
FLUTICASONE PROPIONATE/FLUTIKAS OONPROPIONAAT . ..250.0 ug
SALMETEROL XINAFOATE
EQUIVALENT TO/EKWIVALENT AAN
SALMETEROL 50,0 ug

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

Packer /Verpakker: GLAXO WELLCOME, HERTFORDSHIRE UK
GLAXO WELLCOME, BAD OLDESLOE GERMANY
GLAXO WELLCOME, MIDRAND RSA

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

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 11 AUGUST 2000
Datum van registrasie 11 AUGUSTUS 2000

Registration number/Registrasienommer: 33/21,5.4/0415

Name of medicine/Naam van medisyne: SERETIDE 50/500 ACCUHALER

Dosage form/Dosenngsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH BLISTER CONTAINS/ELKE STULPVERPAKKING BEVAT:
FLUTICASONE PROPIONATE/FLUTIKAS OONPROPIONAAT 500,0 ug
SALMETEROL XINAFOATE
EQUIVALENT TO/EKWIVALENT AAN
SALMETEROL . . . 50,0 ug

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

Packer /Verpakker: GLAXO WELLCOME, HERTFORDSHIRE UK
GLAXO WELLCOME, MIDRAND RSA
GLAXO WELLCOME, BAD OLDESLOE GERMANY

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

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 11 AUGUST 2000
Datum van registrasie 11 AUGUSTUS 2000

Registration number/Registrasienommer: 33/5,8/0089

Name of medicine/Naam van medisyne: DIMUCON PAEDIATRIC ELIXIR

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml LIQUID CONTAINS/ELKE 5,0 ml VLOEISTOF BEVAT:
BROMPHENIRAMINE MALEATE/
BROMFENIRAMIENMALEAAT . . 1,0 mg
PHENYLPROPANOLAMINE HYDROCHLORIDE/
FENIELPROPANOLAMIENHIDROCHLORIED . . . 6,25 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: SAD SELF MEDICATION, EAST LONDON RSA

Packer/Verpakker: SAD SELF MEDICATION, EAST LONDON RSA

Laboratory/Laboratorium: SAD SELF MEDICATION, EAST LONDON RSA
BIODAT, PORT ELIZABETH RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 11 AUGUST 2000
Datum van registrasie 11 AUGUSTUS 2000

Registration number/Registrasienommer: 33/20. 1,210461

Name of medicine/Naam van medisyne: EFFICLAV 375 TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
AMOXYCILLIN TRIHYDRATE/AMOKSISILLIENTRIHIDRAAT
EQUIVALENT TO/EKWIVALENT AAN
AMOXYCILLIN/AMOKSISILLIEN . ..250.0 mg
POTASSIUM CLAVULANATE/KALIUMKLAVULANAAT
EQUIVALENT TO/EKWIVALENT AAN
CLAVULANIC ACID/KLAVULAANSUUR . ..125.0 mg

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

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

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 11 AUGUST 2000
Datum van registrasie 11 AUGUSTUS 2000

Registration number/Registrasienommer: 33/20.1.2/0462

Name of medicine/Naam van medisyne: EFFICLAV 625 TABLETS

Dosage form/Dosenngsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
AMOXYCILLIN TRIHYDRATE/AMOKSISILLIENTRIHIDRAAT
EQUIVALENT TO/EKWIVALENT AAN
AMOXYCILLIN/AMOKSISILLIEN . ..500.0 mg
POTASSIUM CLAVULANATE/KALIUMKLAVULANAAT
EQUIVALENT TO/EKWIVALENT AAN
CLAVULANIC ACID/KLAVULAANSUUR . ..125.0 mg

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

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

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 11 AUGUST 2000
Datum van registrasie 11 AUGUSTUS 2000

Registration number/Registrasienommer: 32/34/0328

Name of medicine/Naam van medisyne: ADENOSCAN

Dosage form/Doseringsvorm: SOLUTION/OPLOSING

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml VIAL CONTAINS/ELKE 10,0 ml FLESSIE BEVAT :
ADENOSIN 30,0 mg

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI, NOTRE DAME DE BONNEVILLE FRANCE

Packer/Verpakker: SANOFI, NOTRE DAME DE BONDEWLLE FRANCE

Laboratory/Laboratorium: SANOFI, NOTRE DAME DE BONNEVILLE FRANCE
SANOFI - SYNTHELABO, WOODMEAD RSA
INSPECTORATE M & L, ORMONDE RSA
PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 11 AUGUST 2000
Datum van registrasie 11 AUGUSTUS 2000

Registration number/Registrasienommer: 32/5.7,2/0498

Name of medicine/Naam van medisyne: ZAMANON 50 MG IV

Dosage forrn/Dosenngsvorm: INJECTION/DISPUITING

Acti ve ingredients/Aktiewe bestanddele:
EACH 2,5 ml SOLUTION CONTAINS/ELKE 2,5 ml OPLOSSING BEVAT:
DOLASETRON MESYLATE . ..50.0 mg

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

Applicant/Applikant HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: GRUPPO LEPITIT SPA, ANAGNI ITALY

Packer/Verpakker: GRUPPO LEPITIT SPA, ANAGNI ITALY
HOECHST MARION ROUSSEL> WALTLOO RSA

Laboratory/Laboratorium: GRUPPO LEPITIT SPA, ANAGNI ITALY
HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 AUGUST 2000
Datum van registrasie 15 AUGUSTUS 2000

Registration number/Registrasienommer: 32/5.7,210496

Name of medicine/Naam van medisyne: ZAMANON 12,5 MG I.V

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 0.625 ml SOLUTION CONTAINS/ELKE 0,625 ml OPLOSSING BEVAT:
DOLASETRON MESYLATE . ..12.5 mg

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: GRUPPO LEPITIT SPA, ANAGNI ITALY

Packer/Verpakker: GRUPPO LEPITIT SPA. ANAGNI ITALY
HOECHST MARJON ROUSSEL, WALTLOO RSA

Laboratory/Laboratoriu m: GRUPPO LEPITIT SPA, ANAGNI ITALY
HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 AUGUST 2000
Datum van registrasie 15 AUGUSTUS 2000

Registration number/Registrasienommer: 315.7.2/0499

Name of medicine/Naam van medisyne: ZAMANON 100 MG IV

Dosage forrn/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bests.rdele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT:
DOLASETRON MESYLATE . ..100.0 *mg*

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: GRUPPO LEPITIT SPA, ANAGNI ITALY

Packer/Verpakker: GRUPPO LEPITIT SPA, ANAGNI ITALY
HOECHST WON ROUSSEL, WALTLOO RSA

Laboratory/Laboratorium: GRUPPO LEPITIT SPA, ANAGNI ITALY
HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 AUGUST 2000
Datum van registrasie 15 AUGUSTUS 2000

Registration number/Registrasienommer: 32/5 7 2/00497

Name of medicine/Naam van medisyne: ZAMANON 25 MG IV

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,25 ml SOLUTION CONTAINS/ELKE 1,25 ml OPLOSSING BEVAT:
DOLASETRON MESYLATE . ..25.0 mg

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: GRUPPO LEPITIT SPA, ANAGNI ITALY

Packer/Verpakker: GRUPPO LEPITIT SPA, ANAGNI ITALY
HOECHST MARION ROUSSEL, WALTLOO RSA

Laboratory/'Laboratorium: GRUPPO LEPITIT SPA, ANAGNI ITALY
HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 15 AUGUST 2000
Datum van registrasie 15 AUGUSTUS 2000

Registration number/Registrasienommer: 33120.2,810399

Name of medicine/Naam van medisyne: FLU-STOP CAPSULES

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
AMANTADINE HYDROCHLORIDE . ..100.0 mg

Conditions of registration/Voorwaardes vir registrasie:
1,2,3,4, 5a, 6. 7, 8a, 9

Applicant/Applikant: Y.M. BHYAT

Manufacturer/Vervaardiger: BEIGE PHARMACEUTICALS, EDENVALE RSA

Packer/Verpakker: BEIGE PHARMACEUTICALS, EDENVALE RSA

Laboratory/Laboratorium: BEIGE PHARMACEUTICALS, EDENVALE RSA
Y. M. BHYAT

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 16 AUGUST 2000
Datum van registrasie 16 AUGUSTUS 2000

Registration number/Registrasienommer: 33/1 1,4.3/0134

Name of medicine/Naam van medisyne: RENNIE DEFLATINE

Dosage form/Doseringsvorm: TABLET

Active ingredients /Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CALCIUM CARBONATE/KALSIUMKARBONAAT . ..680.0 mg
MAGNESIUM CARBONATE/MAGNESIUMKARBONAAT . ..80.0 mg
SIMETHICONE/SIMETIKOON . ..25.0 mg

Conditions of registrationNoorwaardes vir registrasie:
1,2, 3,4, 5a, 6, 7

Applicant/Applikant: ROCHE PRODUCTS (PTY) LTD

Manufacturer/Vervaardiger: LABORATORIES ROCHE NICHOLAS, GAILLARD FRANCE

Packer/Verpakker: LABORATORIES ROCHE NICHOLAS, GAILLARD FRANCE
ROCHE, ISANDO RSA

Laboratory/Laboratorium: LABORATORIES ROCHE NICHOLAS, GAILLARD FRANCE
ROCHE, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 16 AUGUST 2000
Datum van registrasie 16 AUGUSTUS 2000

Registration number/Registrasienommer: 32/20.2.8/0719

Name of medicine/Naam van medisyne: ACITOP

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:
EACH 5,0 g CREAM CONTAINS/ELKE 5,0 g ROOM BEVAT:
ACICLOVIR . . . 250,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1,?, 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/Rakleeftyd: 24 months/maande

Date of registration: 18 AUGUST 2000
Datum van registrasie 18 AUGUSTUS 2000

Registration number/Registrasienommer: 3 1/5.7.2/0331

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

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT :
DOMPERIDONE . ..1.0 mg

Conditions of registrationNoorwaardes 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/Rakleeftyd: 24 months/maande

Date of registration: 18 AUGUST 2000
Datum van registrasie 18 AUGUSTUS 2000

Registration number/Registrasienommer. 3 1/5.7,2/0330

Name of medicine/Naam van medisyne: BE-TABS DOMPERIDONE TABLETS

Dosage form/Dosseringsvorm: 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: BE-TABS PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: CADILA, AHMEDABAD INDIA

Packer/Verpakker CADILA, AHMEDABAD INDIA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 18 AUGUST 2000
Datum van registrasie 18 AUGUSTUS 2000

Registration number/Registrasienommer: 31/11.4.3/0287

Name of medicine/Naam van medisyne: BE-TABS RANITIDINE 50mg INJECTION

Dosage fonn/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
RANITIDINE HYDROCHLORIDE/
RANITIDIENHIDROCHLORIED
EQUIVALENT TO/EKWIVALENT AAN
RANITIDINE/RANITIDIEN . ..25.0 mg

Conditions of registration/Voorwaardes vir registrasie:
1,2, 3,4, 5< 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/Rakleeftyd: 24 months/maande

Date of registration: 18 AUGUST 2000
Datum van registrasie 18 AUGUSTUS 2000

Registration number/Registrasienommer: 31/10.1/0487

Name of medicine/Naam van medisyne: BRONCHOSPECT

Dosage form/Dosenngsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :
GUAIFENESIN . . 66,5 mg
TERBUTALINE SULFATE . ..1.50 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7, 8a, 9

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/Rakleeftyd: 24 months/maande

Date of registration: 18 AUGUST 2000
Datum van registrasie 18 AUGUSTUS 2000

Registration number/Registrasienommer: 32/2,8/0605

Name of medicine/Naam van medisyne: ADCO-FLEX

Dosage form/Dosenngsvorln: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ORPHENADRINE CITRATE/ORFENADRIENSITRAAT ,.. 35,0 mg
PARACETAMOL/PARASETAMOL 450,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3,4, 5a, 6, 7, 8a, 9

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: PHARMA-Q, INDUSTRIA RSA

Packer /Verpakker: PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratoriu m: PHARMA-Q, INDUSTRIA RSA
ADCOCK INGRAM LTD, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 21 AUGUST 2000
Datum van registrasie 21 AUGUSTUS 2000

Registration number/Registrasienommer: 33/11.4.3/0284

Name of medicine/Naam van medisyne: GASTRO-FIZZ 75

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH EFFERVESCENT TABLET CONTAINS/ELKE BRUISTABLET BEVAT :
RANITIDINE HYDROCHLORIDE/RANITIDIENHIDROCHLORIED
EQUIVALENT TO/EKWIVALENT AAN
RANITIDINE/RANITIDIEN ,.. 75,0 mg

Conditions of registration/Voorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 1, 8a, 9

. Applicant/Applikant: Y M. BHYAT

Manufacturer/Vervaardiger: BEIGE PHARMACEUTICALS, EDENVALE RSA

Packer/Verpakker: BEIGE PHARMACEUTICALS, EDENVALE RSA

Laboratory/Laboratorium: BEIGE PHARMACEUTICALS, EDENVALE RSA
Y. M. BHYAT

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 21 AUGUST 2000
Datum van registrasie 21 AUGUSTUS 2000

Registration number/Registrasienommer: 29/20.1.1/0675

Name of medicine/Naam van medisyne: VANCOMYCIN-FAULDING I g

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
VANCOMYCIN HYDROCHLORIDE
VANKOMISIENHIDROCHLORIED
EQUIVALENT TO/EKWIVALENT AAN
VANCOMYCIN/VANKOMISIEN . ..1000.0 mg

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

Applicant/Applikant: PHARMAPLAN (PTY) LTD

Manufacturer/Vervaardiger F H FAULDING & CO, VICTORIA AUSTRALIA

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

Laboratory/Laboratorium: F H FAULDING & CO, VICTORIA AUSTRALIA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 21 AUGUST 2000
Datum van registrasie 21 AUGUSTUS 2000

Registration number/Registrasienommer: 33/11.4.3/0041

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

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
PANTOPRAZOLE . ..40.0 mg

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

Applicant/Applikant: BYK MADAUS (PTY) LTD

Manufacturer/Vervaardiger: DR MADAUS GmbH, WASSERBURG, GERMANY

Packer/Verpakker: DR MADAUS GmbH, WASSERBURG, GERMANY

Laboratory/Laboratorium: DR MADAUS GmbH, WASSERBURG, GERMANY
BYK GULDEN LOMBERG, KONSTANZ GERMANY
BYK MADAUS, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 22 AUGUST 2000
Datum van registrasie 22 AUGUSTUS 2000

Registration number/Registrasienommer: 33/18.8/0364

Name of medicine/Naam van medisyne: MIRELLE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH PALE-YELLOW ACTIVE TABLET CONTAINS/ELKE LIG-GEEL AKTIEWE TABLET BEVAT:
ETHINYLESTRADIOL 0,015 mg
GESTODENE „„0,06 mg
4 WHITE INACTIVE TABLETS/4 WIT ONAKTIEWE TABLETTE

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

Applicant/Applikant: SCHERING (PTY) LTD

Manufacturer/Vervaardiger: WYETH PHARMACEUTICALS CO, GUAYAMA PUERTO RICO
WYETH MEDICA IRELAND, KILDARE IRELAND

Packer/Verpakker: SCHERING, BERLIN GERMANY

Laboratory/Laboraton urn: WYETH PHARMACEUTICALS CO, GUAYAMA PUERTO RICO
WYETH MEDICA IRELAND, KILDARE IRELAND
SCHERING, BERLIN GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 AUGUST 2000
Datum van registrasie 24 AUGUSTUS 2000

Registration number/Registrasienommer: H/18.4/1773

Name of medicine/Naam van medisyne: URALYT-U

Dosage form/Doseringsvorm: GRANULES

Active ingredients/Aktiewe bestanddele:
EACH 100,0 g GRANULES CONTAIN/ELKE 1,00,0 g GRANULES BEVAT:
CITRIC ACID/SITROENSUUR . . . 13,044 g
POTASSIUM CITRATE/KALIUMSITRAAT 45,397 g
SODIUM CITRATE/NATRIUMSITRAAT ..,41,153 g

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

Applicant/Applikant: BYK MADAUS (PTY) LTD

Manufacturer/Vervaardiger: MADAUS AG, COLOGNE GERMANY

Packer/Verpakker: MADAUS AG, COLOGNE GERMANY

Laboratory/Laboratorium: MADAUS AG, COLOGNE GERMANY
BYK MADAUS, MIDRAND RSA

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 24 AUGUST 2000
Datum van registrasie 24 AUGUSTUS 2000

Registration number/Registrasienommer: 33/34/0242

Name of medicine/Naam van medisyne: SANDOSTATIN LAR SUSPENSION VEHICLE

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

Active ingredients/Aktiewe bestanddele:
EACH AMPOULE CONTAINS/ELKE AMPULE BEVAT:
WATER FOR INJECTIONS . ..1.98 mg
CARMELLOSE SODIUM .,. 10,0 mg
MANNITOL 12,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND

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

Laboratory/Laboratorium: NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 24 AUGUST 2000
Datum van registrasie 24 AUGUSTUS 2000

Registration number/Registrasienommer: 33/10.2.1/0271

Name of medicine/Naam van medisyne: SABAX IPRATROPIUM Br 0,5 MG/2 ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml SOLUTION CONTAINS/ELKE 2,0 ml OPLOSSING BEVAT:
IPRATROPIUM BROMIDE . ..0.5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: ADCOCK INGRAM LTD (CRITICAL CARE)

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD,1 SABAX RD JHB

Packer/Verpakker: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Laboratory/Laboratorium: ADCOCK INGRAM LTD, 1 SABAX RD JHB

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 AUGUST 2000
Datum van registrasie 24 AUGUSTUS 2000

Registration number/Registrasienommer: 33/26/0199

Name of medicine/Naam van medisyne: XELODA 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CAPECITABINE 500,0 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
F HOFFMANN-LA ROCHE, KAISERAUGST, SWITZERLAND
ROCHE, ISANDO RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 AUGUST 2000
Datum van registrasie 24 AUGUSTUS 2000

Registration number/Registrasienommer: 33/16/0112

Name of medicine/Naam van medisyne: ATRONAZE COLD 0,06 %

Dosage form/Doseringsvorrn: NASAL SPRAY/'NEUSSPROEI

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT :
IPRATROPIUM BROMIDE . ..0.60 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, FLORENCE ITALY

Packer/Verpakker: BOEHRINGER INGELHEIM, FLORENCE ITALY

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, FLORENCE ITALY
HOECHST WON ROUSSEL, WALTLOO RSA
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 AUGUST 2000
Datum van registrasie 24 AUGUSTUS 2000

Registration number/Registrasienommer: 30/10,2.1/0179

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

Dosage form/Doseringsvorm: INHALER/INHALLEERDER

Active ingredients/Aktiewe bestanddele:
EACH METERED DOSE CONTAINS/ELKE EFGEMETE DOSIS BEVAT:
SALBUTAMOL . ..100.0 ug

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

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: CHIESI FARMACEUTICI SPA, PARMA ITALY

Packer/Verpakker: CHIESI FARMACEUTICI SPA, PARMA ITALY
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratonu m: CHIESI FARMACEUTICI SPA, PARMA ITALY
NOVARTIS, SPARTAN KEMPTON PARK RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months /maande

Date of registration: 25 AUGUST 2000
Datum van registrasie 25 AUGUSTUS 2000

Registration number/Registrasienommer: 3 3/5 .4/0411

Name of medicine/Naam van medisyne: LENDITRO

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
OXYBUTYNIN CHLORIDE . ..5.0 mg

Conditions of registration/Voorwaardes vir registrasie:
1,2,3,4, 5a, 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/Rakleeftyd: 24 months/maande

Date of registration: 25 AUGUST 2000
Datum van registrasie 25 AUGUSTUS 2000

Registration number/Registrasienornmer: 33/20.2.8/0400

Name of medicine/Naam van medisyne: FLU-STOP 0R4L SOLUTION

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT:
AMANTADINE HYDROCHLORIDE 50,0 mg

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

Applicant/Applikant: Y.M. BHYAT

Manufacturer/Vervaardiger: BEIGE PHARMACEUTICALS, EDENVALE RSA

Packer/Verpakker: BEIGE PHARMACEUTICALS, EDENVALE RSA

Laboratory/Laboratorium: BEIGE PHARMACEUTICALS, EDENVALE RSA
Y. M. BHYAT

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 AUGUST 2000
Datum van registrasie 25 AUGUSTUS 2000

Registration number/Registrasienommer: 33/20.1.1/0351

Name of medicine/Naam van medisyne: ROLAB-CEFACLOR CD 375

Dosage forrn/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFACLOR ... 375,0 mg

Conditions of registration/Voonvaardes vir registrasie:
1,2,3,4,546, 7

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
NOVARTIS, SPARTAN KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 AUGUST 2000
Datum van registrasie 25 AUGUSTUS 2000

Registration number/Registrasienommer: 33/20,1.1/0352

Name of medicine/Naam van medisyne: ROLAB-CEFACLOR CD 500

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CEFACLOR . ..500.0 mg

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

Applicant/Applikant: ROLAB (PTY) LTD

Manufacturer/Vervaardiger: ELI LILLY, FLORENCE ITALY

Packer/Verpakker: ELI LILLY, FLORENCE ITALY

Laboratory/Laboratorium: ELI LILLY, FLORENCE ITALY
NOVARTIS, SPARTAN KEMPTON PARK RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
ELI LILLY, BRYANSTON RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 25 AUGUST 2000
Datum van registrasie 25 AUGUSTUS 2000

Registration number/Registrasienommer: 33/2 1.8. 1/0428

Name of medicine/Naam van medisyne: FEM775

Dosage form/Doseringsvorm: TR4NSDERMAL THERAPEUTIC SYSTEM/
TRANSDERMALE TERAPEUTIESE SISTEEM

Active ingredients/Aktiewe bestanddele: EACH PATCH CONTAINS/ELKE PLAKKER BEVAT:
OESTRADIOL HEMIHYDRATE . . . 2,25 mg

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

Applicant/Applikant: MERCK (PTY) LTD

Manufacturer/Vervaardiger: LTS LOHMANN, ANDERNACHT GERMANY

Packer /Verpakker: LTS LOHMANN, ANDERNACHT GERMANY

Laboratory/Laboratorium: LTS LOHMANN, ANDERNACHT GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
MERCK, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 AUGUST 2000
Datum van registrasie 25 AUGUSTUS 2000

Registration number/Registrasienommer: 33/21.8.1/0429

Name of medicine/Naam van medisyne: FEM 7100

Dosage forrn/Dosenngsvorm: TRANSDERMAL THERAPEUTIC SYSTEM/
TRANSDERMALE TERAPEUTIESE SISTEEM

Active ingredients/Aktiewe bestanddele:
EACH TRANSDERMAL PATCH CONTAINS/
ELKE TRANSDERMALE PLAKKER BEVAT:
OESTRADIOL HEMIHYDRATE . . . 3.0 mg

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

Applicant/Applikant: MERCK (PTY) LTD

Manufacturer/Vervaardiger: LTS LOHMANN, ANDERNACHT GERMANY

Packer/Verpakker: LTS LOHMANN, ANDERNACHT GERMANY

Laboratory/Laboratorium: LTS LOHMANN, ANDERNACHT GERMANY
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
MERCK, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 25 AUGUST 2000
Datum van registrasie 25 AUGUSTUS 2000

Registration number/Registrasienommer: 31/34/0617

Name of medicine/Naam van medisyne: GERBER SALINE SOLUTION

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
SODIUM CHLORIDE/NATRIUMCHLORIED . ..7.40 mg

Conditions of registrationNoorwaardes vir registrasie:
1, 2, 3, 4, 5a, 6, 7

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, NYON SWITZERLAND

Packer/Verpakker: NOVARTIS, NYON SWITZERLAND

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 AUGUST 2000
Datum van registrasie 28 AUGUSTUS 2000

Registration number/Registrasienornmer: 22/34/020 I

Name of medic ine/Naam van medisyne: VIRAFERON 3 MILLION I.U.

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 2,0 ml VIAL CONTAINS/ELKE 2,0 ml FLESSIE BEVAT:
INTERFERON ALFA-2b . ..3.0 million i.u.

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, INNISHANNON IRELAND

Packer/Verpakker: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 28 AUGUST 2000
Datum van registrasie 28 AUGUSTUS 2000

Registration number/Registrasienommer: 32134/0202

Name of medicine/Naam van medisyne: VIRAFERON 5 MILLION I.U

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele: EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
INTERFERON ALFA-2b ,,. 5,0 million i.u.

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

Applicant/Applikant:	SCHERING-PLOUGH (PTY) LTD
Manufacturer/Vervaardiger:	SCHERING-PLOUGH, INNISHANNON IRELAND
Packer/Verpakker:	SCHERING-PLOUGH, INNISHANNON IRELAND SCHERING-PLOUGH, ISANDO RSA
Laboratory/Laboratorium:	SCHERING-PLOUGH, INNISHANNON IRELAND SCHERING-PLOUGH, ISANDO RSA
Shelf-life/Rakleeftyd:	36 months/maande
Date of registration: Datum van registrasie	28 AUGUST 2000 28 AUGUSTUS 2000

Registration number/Registrasienommer: 32/34/0203

Name of medicine/Naam van medisyne: VIRAFERON 10 MILLION I.U

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ ELKE FLESSIE BEVAT:
INTERFERON ALFA-2b 10 million i.u.

Conditions of registration/Voorwaardes vir registrasie:
1.2, 3,4, 5a, 6, 7

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, INNISHANNON IRELAND

Packer/Verpakker: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratoriu m: SCHERING-PLOUGH, INNISHANNON IRELAND
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 28 AUGUST 2000
Datum van registrasie 28 AUGUSTUS 2000

Registration number/Registrasienommer: 31/7.1/0654

Name of medicine/Naam van medisyne: UNITENS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
FELODIPINE . ..2.50 mg
RAMIPRIL . ..2.50 mg

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

Applicant/Applikant: ASTRA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRA ZENECA AB, SODERTALJE SWEDEN

Packer/Verpakker: ASTRA ZENECA AB, SODERTALJE SWEDEN
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Laboratory/Laboratorium: ASTRA ZENECA AB, SODERTALJE SWEDEN
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
ANALYTICON, KEMPTON PARK RSA
ASTRA, SUNNINGHILL RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 31 AUGUST 2000
Datum van registrasie 31 AUGUSTUS 2000

Registration number/Registrasienommer: 31/7.1/0655

Name of medicine/Naam van rnedisyne: UNITENS FORTE

Dosage fonn/Dosenngsvorm: TABLET

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

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

Applicant/Applikant: ASTRA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: ASTRA ZENECA AB, SODERTALJE SWEDEN

Packer/Verpakker: ASTRA ZENECA AB, SODERTALJE SWEDEN
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA

Laboratory/Laboratonum: ASTRA ZENECA AB, SODERTALJE SWEDEN
JANSSEN PHARMACEUTICAL, HALFWAY HOUSE RSA
ANALYTICON, KEMPTON PARK RSA
ASTRA, SUNNINGHILL RSA

Shelf-l ife/Rakleeftyd: 24 months/maande

Date of registration: 31 AUGUST 2000
Datum van registrasie 31 AUGUSTUS 2000

Registration number/Registrasienommer: 31/5.7.1/0507

Name of medicine/Naam van medisyne: S-P LORATADINE TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
LORATADINE . ..10.0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, ISANDO RSA

Packer/Verpakker: SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 31 AUGUST 2000
Datum van registrasie 31 AUGUSTUS 2000