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REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

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AIDS HELPLINE: 0800-123-22 Prevention is the cure

CONTENTS

INHOUD

GENERAL NOTICE
ALGEMENE KENNISGEWING

NOTICE 815 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 815 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. Bemarking 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 vrystellingsertifikaat 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.

MBR 15

Registration number/Registrasienommer: 33/34/0173

Name of medicine/Naam van medisyne: HYDROGEN PEROXIDE SOLUTION 20 VOLUMES-DAROL

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 100,0 ml SOLUTION CONTAINS/ELKE 100,0 ml OPLOSSING BEVAT :
HYDROGEN PEROXIDE SOLUTION ... 12,84 g

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

Applicant/Applikant: BARRS PHARMACEUTICAL INDUSTRIES CC

Manufacturer/Vervaardiger: BARRS PHARM INDUSTRIES, OBSERVATORY RSA

Packer/Verpakker: BARRS PHARM INDUSTRIES, OBSERVATORY RSA

Laboratory/Laboratorium: BARRS PHARM INDUSTRIES, OBSERVATORY RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 DECEMBER 2000
Datum van registrasie 13 DESEMBER 2000

MBR 15

Registration number/Registrasienommer: 32/14.2/0511

Name of medicine/Naam van medisyne: BACTRAZINE C

Dosage form/Doseringsvorm: CREAM

Active ingredients/Aktiewe bestanddele: EACH 1,0 g CREAM CONTAINS
CHLORHEXIDINE GLUCONATE ... 0,002 g
SILVER SULFADIAZINE ... 0,01 g

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

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

Manufacturer/Vervaardiger: SMITH & NEPHEW, PINETOWN RSA RSA

Packer/Verpakker: SMITH & NEPHEW, PINETOWN RSA RSA

Laboratory/Laboratorium: SMITH & NEPHEW, PINETOWN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 08 DECEMBER 2000
Datum van registrasie 08 DESEMBER 2000

MBR 15

Registration number/Registrasienommer: 99/3.1/7

Name of medicine/Naam van medisyne: RIMADYL 75

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CARPROFEN ... 75,0 mg

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, LINCOLN, USA

Packer/Verpakker: PFIZER, LINCOLN, USA
PFIZER LABS, PIETERMARITZBURG RSA

Laboratory/Laboratorium: PFIZER, LINCOLN, USA
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 12 JANUARY 2001
Datum van registrasie 12 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 99/3.1/6

Name of medicine/Naam van medisyne: RIMADYL 25

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, LINCOLN, USA

Packer/Verpakker: PFIZER, LINCOLN, USA
PFIZER LABS, PIETERMARITZBURG RSA

Laboratory/Laboratorium: PFIZER, LINCOLN, USA
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 12 JANUARY 2001
Datum van registrasie 12 JANUARIE 2001

Registration number/Registrasienommer: 99/21.1/11

Name of medicine/Naam van medisyne: PULMOTIL A.C.

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
TILMICOSIN ... 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: COC FARMACEUTICI,BOLOGNESE,MODERNA,ITALY

Packer/Verpakker : COC FARMACEUTICI,BOLOGNESE,MODERNA,ITALY

Laboratory/Laboratorium COC FARMACEUTICI,BOLOGNESE,MODERNA,ITALY
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: 12 JANUARY 2000
Datum van registrasie 12 JANUARIE 2000

Registration number/Registrasienommer: 99/3.1/8

Name of medicine/Naam van medisyne: RIMADYL 100

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
CARPROFEN ... 100,0 mg

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, LINCOLN, USA

Packer/Verpakker: PFIZER, LINCOLN, USA
PFIZER LABS, PIETERMARITZBURG RSA

Laboratory/Laboratorium: PFIZER, LINCOLN, USA
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 12 JANUARY 2001
Datum van registrasie 12 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 32/20.2.2/0564

Name of medicine/Naam van medisyne: LAMISIL DERMGEL

Dosage form/Doseringsvorm: GEL/JEL

Active ingredients/Aktiewe bestanddele:
EACH 1,0 g GEL CONTAINS/ELKE 1,0 g JEL BEVAT :
TERBINAFINE ... 10,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: NOVARTIS, WEHR GERMANY

Packer/Verpakker: NOVARTIS, WEHR GERMANY
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: NOVARTIS, WEHR GERMANY
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 31/11.4.3/0519

Name of medicine/Naam van medisyne: LESACID 200

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
CIMETIDINE ... 200.0 mg

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

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, GLEN ANIL, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 12 JANUARY 2001
Datum van registrasie 12 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/7.1.3/0034

Name of medicine/Naam van medisyne: RENACE 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: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/7.1.3/0033

Name of medicine/Naam van medisyne: RENACE 10

Dosage form/Doseringsvorm: 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: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/7.1.3/0036

Name of medicine/Naam van medisyne: ENALTEC 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, 7

Applicant/Applikant: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/7.1.3/0035

Name of medicine/Naam van medisyne: ENALTEC 2,5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ENALAPRIL MALEATE ... 2,5 mg

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

Applicant/Applikant: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

Registration number/Registrasienommer: 33/7.1.3/0038

Name of medicine/Naam van medisyne: ENALTEC 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: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

Registration number/Registrasienommer: 33/7.1.3/0037

Name of medicine/Naam van medisyne: ENALTEC 10

Dosage form/Doseringsvorm: 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: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/7.1.3/0031

Name of medicine/Naam van medisyne: RENACE 2,5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ENALAPRIL MALEATE ... 2,5 mg

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

Applicant/Applikant: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 97/3.1.1/3

Name of medicine/Naam van medisyne: ADEQUAN IA

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1.0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
MUCOPOLYSACCHARIDE POLYSULFATE ... 250,0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: LUITPOLD PHARM, NEW YORK, U.S.A.

Packer/Verpakker: LUITPOLD PHARM, NEW YORK, U.S.A.
JANSSEN PHARMACEUTICA NV, BEERSE BELGIUM
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

Registration number/Registrasienommer: 33/1.2/0354

Name of medicine/Naam van medisyne: FAVERIN 100

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
FLUVOXAMINE MALEATE ... 100,0 mg

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

Applicant/Applikant: SOLVAY PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SOLVAY PHARM BV, OLST, NETHERLANDS

Packer/Verpakker: SOLVAY PHARM BV, OLST, NETHERLANDS
HOECHST MARION ROUSSEL, WALTLOO RSA

Laboratory/Laboratorium: SOLVAY PHARM BV, OLST, NETHERLANDS
HOECHST MARION ROUSSEL, WALTLOO RSA
SOLVAY PHARM BV, WEESP THE NETHERLANDS
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA
SCHERING, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JANUARY 2001
Datum van registrasie 26 JANUARIE 2001

Registration number/Registrasienommer: 33/7.1.3/0032

Name of medicine/Naam van medisyne: RENACE 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, 7

Applicant/Applikant: 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, MONTAGUE GARDENS RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 24 JANUARY 2001
Datum van registrasie 24 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 31/21.8.1/0695

Name of medicine/Naam van medisyne: ESTRADERM MX 50

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

Active ingredients/Aktiewe bestanddele:
EACH TRANSDERMAL PATCH CONTAINS/
ELKE TRANSDERMALE PLAKKER BEVAT:
ESTRADIOL ... 1,5 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: LTS LOHMANN, ANDERNACHT GERMANY

Packer/Verpakker: LTS LOHMANN, ANDERNACHT GERMANY
NOVARTIS, SPARTAN KEMPTON PARK RSA
NOVARTIS, STEIN SWITZERLAND

Laboratory/Laboratorium: LTS LOHMANN, ANDERNACHT GERMANY
NOVARTIS, SPARTAN KEMPTON PARK RSA
NOVARTIS, STEIN SWITZERLAND

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JANUARY 2001
Datum van registrasie 26 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 31/21.8.1/0694

Name of medicine/Naam van medisyne: ESTRADERM MX 25

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

Active ingredients/Aktiewe bestanddele:
EACH TRANSDERMAL PATCH CONTAINS/
ELKE TRANSDERMALE PLAKKER BEVAT:
ESTRADIOL ... 0,75 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: LTS LOHMANN, ANDERNACHT GERMANY

Packer/Verpakker: LTS LOHMANN, ANDERNACHT GERMANY
NOVARTIS, SPARTAN KEMPTON PARK RSA
NOVARTIS, STEIN SWITZERLAND

Laboratory/Laboratorium: LTS LOHMANN, ANDERNACHT GERMANY
NOVARTIS, SPARTAN KEMPTON PARK RSA
NOVARTIS, STEIN SWITZERLAND

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JANUARY 2001
Datum van registrasie 26 JANUARIE 2001

Registration number/Registrasienommer: 33/7.1.3/0324

Name of medicine/Naam van medisyne: APROVEL CO 150/12,5

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
HYDROCHLOROTHIAZIDE ... 12.5 mg
IRBESARTAN ... 150,0 mg

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: BRISTOL-MYERS SQUIBB, EVANSVILLE INDIANA USA

Packer/Verpakker: DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
SANOFI WINTHROP, AMBARES FRANCE
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK

Laboratory/Laboratorium: BRISTOL-MYERS SQUIBB, EVANSVILLE INDIANA USA
SANOFI WINTHROP, AMBARES FRANCE
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK
INSPECTORATE M & L, ORMONDE RSA
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JANUARY 2001
Datum van registrasie 26 JANUARIE 2001

Registration number/Registrasienommer: 31/21.8.1/0696

Name of medicine/Naam van medisyne: ESTRADERM MX 100

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

Active ingredients/Aktiewe bestanddele:
EACH TRANSDERMAL PATCH CONTAINS/
ELKE TRANSDERMALE PLAKKER BEVAT:
ESTRADIOL ... 3,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: LTS LOHMANN, ANDERNACHT GERMANY

Packer/Verpakker: LTS LOHMANN, ANDERNACHT GERMANY
NOVARTIS, STEIN SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: LTS LOHMANN, ANDERNACHT GERMANY
NOVARTIS, STEIN SWITZERLAND
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JANUARY 2001
Datum van registrasie 26 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 32/1.2/0104

Name of medicine/Naam van medisyne: PROHEXAL 40 T

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
FLUOXETINE HYDROCHLORIDE EQUIVALENT
TO FLUOXETINE ... 40,0 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: SALUTAS PHARMA, BARLEBEN GERMANY
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JANUARY 2001
Datum van registrasie 26 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/5.7.1/0455

Name of medicine/Naam van medisyne: MIZOLLEN 10 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SYNTHELABO GROUPE,TOURS.CEDEX,FRANCE

Packer/Verpakker: SYNTHELABO GROUPE,TOURS,CEDEX,FRANCE
HOECHST MARION ROUSSEL, WALTLOO RSA

Laboratory/Laboratorium: SYNTHELABO GROUPE,TOURS.CEDEX,FRANCE
HOECHST MARION ROUSSEL, WALTLOO RSA
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 26 JANUARY 2001
Datum van registrasie 26 JANUARIE 2001

Registration number/Registrasienommer: H/19/1963

Name of medicine/Naam van medisyne: SYNTOCINON (10 IU)

Dosage form/Doseringsvorm: INJECTION

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
OXYTOCIN ... 10 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
NOVARTIS, SPARTAN KEMPTON PARK RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 JANUARY 2001
Datum van registrasie 29 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/15.4/0330

Name of medicine/Naam van medisyne: LEVOBUNOLOL HCl 0,5 %,ALCON

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

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

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

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

Manufacturer/Vervaardiger: ALCON-COUVREUR, PUURS BELGIUM

Packer/Verpakker: ALCON-COUVREUR, PUURS BELGIUM

Laboratory/Laboratorium: ALCON-COUVREUR, PUURS BELGIUM
ALCON, RANDBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 JANUARY 2001
Datum van registrasie 29 JANUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/21.8.2/0532

Name of medicine/Naam van medisyne: ACTIVELLE

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
NORETHISTERONE ACETATE 0,50 mg
OESTRADIOL HEMIHYDRATE EQUIVALENT
TO OESTRADIOL 1,0 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, MAALOEV DENMARK

Packer/Verpakker: NOVO NORDISK A/S, MAALOEV DENMARK

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 06 February 2001
Datum van registrasie 06 Februarie 2001

MBR 15

Registration number/Registrasienommer: H/19/1967

Name of medicine/Naam van medisyne: SYNTOCINON (5 IU)

Dosage form/Doseringsvorm: INJECTION

Active ingredients/Aktiewe bestanddele:
EACH 1.0 ml SOLUTION CONTAINS/ELKE 1.0 ml OPLOSSNING BEVAT :
OXYTOCIN ... 5 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
NOVARTIS, SPARTAN KEMPTON PARK RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 29 JANUARY 2001
Datum van registrasie 29 JANUARIE 2001

Registration number/Registrasienommer: 32/7.1.3/0406

Name of medicine/Naam van medisyne: CATEXAN

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
INDAPAMIDE 2.5 mg

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

Applicant/Applikant: MEDI CHALLENGE (PTY) LTD

Manufacturer/Vervaardiger: LES LABORATORY SERVIER, GIDY, FRANCE
SERVIER, WICKLOW, IRELAND

Packer/Verpakker: TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: LES LABORATORY SERVIER, GIDY, FRANCE
SERVIER, WICKLOW, IRELAND
INSPECTORATE M & L, ORMONDE RSA
MEDI CHALLENGE (PTY) LTD

Shelf-life/Rakleeftyd: 60 months/maande

Date of registration: 07 February 2001
Datum van registrasie 07 Februarie 2001

Registration number/Registrasienommer: 32/9/0097

Name of medicine/Naam van medisyne: SOBRIAL

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
ACAMPROSATE CALCIUM ... 333,0 mg

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

Applicant/Applikant: MERCK (PTY) LTD

Manufacturer/Vervaardiger: LIPHA, MEYZIEU, FRANCE

Packer/Verpakker: LIPHA, MEYZIEU, FRANCE
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: LIPHA, MEYZIEU, FRANCE
MERCK PHARMACEUTICALS MANUFACTURING,
WADEVILLE GERMISTON RSA
SOUTH AFRICAN BUREAU OF STANDARDS,
PRETORIA RSA
MERCK, MIDRAND RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 06 February 2001
Datum van registrasie 06 Februarie 2001

MBR 15

Registration number/Registrasienommer: 33/12/0490

Name of medicine/Naam van medisyne: PADAX SYRUP - BLACKCURRANT FLAVOUR

Dosage form/Doseringsvorm: SYRUP/STROOP

Active ingredients/Aktiewe bestanddele:
EACH 5.0 ml SYRUP CONTAINS/ELKE 5,0 ml STROOP BEVAT:
PIPERAZINE CITRATE ... 850,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: PHARMA-Q, INDUSTRIA RSA

Packer/Verpakker: PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: PHARMA-Q, INDUSTRIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 07 FEBRUARY 2001
Datum van registrasie 07 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 93/21.1/1

Name of medicine/Naam van medisyne: SYNULOX RTU

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 1.0 ml SUSPENSION CONTAINS/ELKE 1,0 ml SUSPENSIE BEVAT:
AMOXYCILLIN TRIHYDRATE EQUIVALENT TO
AMOXYCILLIN ... 140,0 mg
POTASSIUM CLAVULANATE EQUIVALENT TO
CLAVULANIC ACID ... 35,0 mg

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, LATINA ITALY

Packer/Verpakker: PFIZER, LATINA ITALY

Laboratory/Laboratorium: PFIZER, LATINA ITALY
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 07 February 2001
Datum van registrasie 07 Februarie 2001

MBR 15

Registration number/Registrasienommer: E/24/1287

Name of medicine/Naam van medisyne: SALTIX SALT TABLETS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
DEXTROSE MONOHYDRATE ... 150,0 mg
POTASSIUM CHLORIDE ... 75,0 mg
SODIUM CHLORIDE ... 235,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: PHARMA-Q, INDUSTRIA RSA

Packer/Verpakker: PHARMA-Q, INDUSTRIA RSA

Laboratory/Laboratorium: PHARMA-Q, INDUSTRIA RSA
CONSULTING CHEMICAL LAB, STAR STREET, BOKSBURG, RSA

Shelf-life/Rakleeftyd: 12 months/maande

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

MBR 15

Registration number/Registrasienommer: 33/16.3/0495

Name of medicine/Naam van medisyne: MEDI-KEEL A BLACKCURRANT THROAT LOZENGES

Dosage form/Doseringsvorm: LOZENGES/SUIGTABLETTE

Active ingredients/Aktiewe bestanddele:
EACH LOZENGE CONTAINS/ELKE SUIGTABLET BEVAT:
BENZOCAINE ... 12,0 mg
CETYLPYRIDINIUM CHLORIDE ... 1,5 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, CLAYVILLE RSA

Packer/Verpakker: ADCOCK INGRAM LTD, CLAYVILLE RSA

Laboratory/Laboratorium: ADCOCK INGRAM LTD, CLAYVILLE RSA
ADCOCK INGRAM LTD, WADEVILLE RSA

Shelf-life/Rakleeftyd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 34/12/0058

Name of medicine/Naam van medisyne: VERMOX SD SUSPENSION

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 10,0 ml SUSPENSION CONTAINS/ELKE 10,0 ml SUSPENSIE BEVAT:
MEBENDAZOLE ... 500.0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: JANSSEN PHARMACEUTICA. HALFWAY HOUSE RSA

Packer/Verpakker: JANSSEN PHARMACEUTICA. HALFWAY HOUSE RSA

Laboratory/Laboratorium: JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 12 FEBRUARY 2001
Datum van registrasie 12 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/7.3/0381

Name of medicine/Naam van medisyne: MIGROMAR

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT :
DOMPERIDONE MALEATE EQUIVALENT TO
DOMPERIDONE ... 10,0 mg
PARACETAMOL ... 500,0 mg

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

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

Packer/Verpakker: SANOFI WINTHROP, CARCAVELOS, PORTUGAL
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Laboratory/Laboratorium: SANOFI WINTHROP, CARCAVELOS, PORTUGAL
SANOFI WINTRHOP, NEWCASTLE-UPON TYNE UK
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0134

Name of medicine/Naam van medisyne: TEQUIN 400 mg TABLET

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: SQUIBB MANUFACTURING INC. HUMACAO PUERTO RICO

Packer/Verpakker: SQUIBB MANUFACTURING INC. HUMACAO PUERTO RICO
MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA
BRISTOL-MYERS SQUIBB, MELBOURNE AUSTRALIA

Laboratory/Laboratorium: SQUIBB MANUFACTURING INC. HUMACAO PUERTO RICO
MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RS RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 FEBRUARY 2001
Datum van registrasie 13 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0133

Name of medicine/Naam van medisyne: TEQUIN 200 mg TABLET

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: SQUIBB MANUFACTURING INC. HUMACAO PUERTO RICO

Packer/Verpakker: SQUIBB MANUFACTURING INC. HUMACAO PUERTO RICO
MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA
BRISTOL-MYERS SQUIBB, MELBOURNE AUSTRALIA

Laboratory/Laboratorium: SQUIBB MANUFACTURING INC. HUMACAO PUERTO RICO
MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 FEBRUARY 2001
Datum van registrasie 13 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0136

Name of medicine/Naam van medisyne: TEQUIN 400 mg/40 ml INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 40,0 ml SOLUTION CONTAINS/ELKE 40,0 ml OPLOSSING BEVAT:
GATIFLOXACIN 400,0 mg

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

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

Manufacturer/Vervaardiger: BRISTOL LABORATORIES, MAYAGUEZ PUERTO RICO

Packer/Verpakker: BRISTOL LABORATORIES, MAYAGUEZ PUERTO RICO
BRISTOL-MYERS SQUIBB, MELBOURNE AUSTRALIA
MERCK PHARMACEUTICALS MANUFACTURING WADEVILLE GERMISTON RSA

Laboratory/Laboratorium: BRISTOL LABORATORIES, MAYAGUEZ PUERTO RICO
MERCK PHARMACEUTICALS MANUFACTURING WADEVILLE GERMISTON RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 FEBRUARY 2001
Datum van registrasie 13 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0135

Name of medicine/Naam van medisyne: TEQUIN 200 mg/20 ml INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH 20,0 ml SOLUTION CONTAINS/ELKE 20,0 ml INSPUITING BEVAT :
GATIFLOXACIN ... 200,0 mg

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

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

Manufacturer/Vervaardiger: BRISTOL LABORATORIES, MAYAGUEZ PUERTO RICO

Packer/Verpakker: BRISTOL LABORATORIES, MAYAGUEZ PUERTO RICO
MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA
BRISTOL-MYERS SQUIBB, MELBOURNE AUSTRALIA

Laboratory/Laboratorium: BRISTOL LABORATORIES, MAYAGUEZ PUERTO RICO
MERCK PHARMACEUTICALS MANUFACTURING , WADEVILLE GERMISTON RSA
CONSULTING CHEMICAL LAB, STAR STREET BOKSBURG, RSA
BRISTOL-MYERS SQUIBB, BEDFORDVIEW RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 FEBRUARY 2001
Datum van registrasie 13 FEBRUARIE 2001

Registration number/Registrasienommer: 32/20.1.1/0443

Name of medicine/Naam van medisyne: RALCLOR GRANULES FOR ORAL SUSPENSION 187 mg/5 ml

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

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

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

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

Manufacturer/Vervaardiger: RANBAXY, DEWAS INDIA

Packer/Verpakker: RANBAXY, DEWAS INDIA

Laboratory/Laboratorium: RANBAXY, DEWAS INDIA
CENTRE FOR QUALITY ASSURANCE OF MEDICINES, UNIVERSITY, POTCHEFSTROOM RSA
RANBAXY, CENTURION RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 FEBRUARY 2001
Datum van registrasie 14 FEBRUARIE 2001

Registration number/Registrasienommer: 31/20.2.2/0602

Name of medicine/Naam van medisyne: XEROCAN TOPICAL 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: COMPU PHARMACEUTICAL PRODUCTS LTD

Manufacturer/Vervaardiger: WRAPSA, CENTURION RSA

Packer/Verpakker: WRAPSA, CENTURION RSA

Laboratory/Laboratorium: WRAPSA, CENTURION RSA
COMPU PHARMACEUTICAL PRODUCTS, LYNNWOOD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 13 FEBRUARY 2001
Datum van registrasie 13 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 31/15.4/0321

Name of medicine/Naam van medisyne: LECROLYN 40 mg/ml SDU

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 1.0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
SODIUM CROMOGLYCATE ... 40,0 mg

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

Applicant/Applikant: ALLIANCE PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SANTEN OY, TAMPERE FINLAND

Packer/Verpakker: SANTEN OY, TAMPERE FINLAND
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
ALLIANCE PHARMA, VILLAGE MAIN RSA

Laboratory/Laboratorium: SANTEN OY, TAMPERE FINLAND
ALLIANCE PHARMA, VILLAGE MAIN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 FEBRUARY 2001
Datum van registrasie 14 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 31/15.4/0320

Name of medicine/Naam van medisyne: LECROLYN 20 mg/ml SDU

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 1.0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
SODIUM CROMOGLYCATE ... 20,0 mg

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

Applicant/Applikant: ALLIANCE PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SANTEN OY, TAMPERE FINLAND

Packer/Verpakker: ALLIANCE PHARMA, VILLAGE MAIN RSA
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
SANTEN OY, TAMPERE FINLAND

Laboratory/Laboratorium: ALLIANCE PHARMA, VILLAGE MAIN RSA
SANTEN OY, TAMPERE FINLAND

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 FEBRUARY 2001
Datum van registrasie 14 FEBRUARIE 2001

Registration number/Registrasienommer: 31/15.4/0323

Name of medicine/Naam van medisyne: LECROLYN 40 MG/ML

Dosage form/Doseringsvorm: DROPS/DRUPPELS

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

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

Applicant/Applikant: ALLIANCE PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SANTEN OY, TAMPERE FINLAND

Packer/Verpakker: SANTEN OY, TAMPERE FINLAND
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
ALLIANCE PHARMA, VILLAGE MAIN RSA

Laboratory/Laboratorium: SANTEN OY, TAMPERE FINLAND
ALLIANCE PHARMA, VILLAGE MAIN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 FEBRUARY 2001
Datum van registrasie 14 FEBRUARIE 2001

Registration number/Registrasienommer: 31/15.4/0322

Name of medicine/Naam van medisyne: LECROLYN 20 mg/ml

Dosage form/Doseringsvorm: DROPS/DUPPELS

Active ingredients/Aktiewe bestanddele:
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:
SODIUM CROMOGLYCATE ... 20,0 mg

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

Applicant/Applikant: ALLIANCE PHARMA (PTY) LTD

Manufacturer/Vervaardiger: SANTEN OY, TAMPERE FINLAND

Packer/Verpakker: SANTEN OY, TAMPERE FINLAND
DIVPHARM MANUFACTURING AND PACKAGING, LONGDALE RSA
ALLIANCE PHARMA, VILLAGE MAIN RSA

Laboratory/Laboratorium: SANTEN OY, TAMPERE FINLAND
ALLIANCE PHARMA, VILLAGE MAIN RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 14 FEBRUARY 2001
Datum van registrasie 14 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/7.1.3/0281

Name of medicine/Naam van medisyne: FORTZAAR

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
HYDROCHLOROTHIAZIDE ... 25,0 mg
LOSARTAN POTASSIUM ... 100,0 mg

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

Applicant/Applikant: MSD (PTY) LTD

Manufacturer/Vervaardiger: MERCK SHARP & DOHME, NORTHUMBERLAND UK

Packer/Verpakker: MERCK SHARP & DOHME, HAARLEM HOLLAND
MSD, HALFWAY HOUSE RSA

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 35/20.2.2/0187

Name of medicine/Naam van medisyne: DIFLUCAN TABLETS 200 MG

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: PFIZER LABORATORIES (PTY) LTD

Manufacturer/Vervaardiger: PFIZER, BARCELONETA PUERTO RICO

Packer/Verpakker: PFIZER, BARCELONETA PUERTO RICO

Laboratory/Laboratorium: PFIZER, BARCELONETA PUERTO RICO
PFIZER LABS, PIETERMARITZBURG RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 19 FEBRUARY 2001
Datum van registrasie 19 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/3.1/0065

Name of medicine/Naam van medisyne: VIOXX 25 ORAL SUSPENSION

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5.0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:
ROFECOXIB ... 25,0 mg

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

Applicant/Applikant: MSD (PTY) LTD

Manufacturer/Vervaardiger: MERCK & CO.-WESTPOINT PENSYLVANIA USA

Packer/Verpakker: MERCK & CO, WESTPOINT PENSYLVANIA USA
MSD, HALFWAY HOUSE RSA

Laboratory/Laboratorium: MERCK & CO, WESTPOINT PENSYLVANIA USA
MSD, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/3.1/0064

Name of medicine/Naam van medisyne: VIOXX 12.5 ORAL SUSPENSION

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml SUSPENSION CONTAINS/
ELKE 5,0 ml SUSPENSIE BEVAT: ROFECOXIB ... 12,5 mg

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

Applicant/Applikant: MSD (PTY) LTD

Manufacturer/Vervaardiger: MERCK & CO, WESTPOINT PENSYLVANIA USA

Packer/Verpakker: MERCK & CO, WESTPOINT PENSYLVANIA USA
MSD, HALFWAY HOUSE RSA

Laboratory/Laboratorium: MERCK & CO, WESTPOINT PENSYLVANIA USA
MSD, HALFWAY HOUSE RSA

Shelf-life/Rakleeftyd: 18 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0217

Name of medicine/Naam van medisyne: TOTAM-1000

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME ... 1000.0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: HIKMA PHARMACEUTICA, SINTRA, PORTUGAL

Packer/Verpakker: HIKMA PHARMACEUTICA, SINTRA, PORTUGAL

Laboratory/Laboratorium: HIKMA PHARMACEUTICA, SINTRA, PORTUGAL
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0216

Name of medicine/Naam van medisyne: TOTAM-500

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME ... 500.0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: HIKMA PHARMACEUTICA, SINTRA, PORTUGAL

Packer/Verpakker: HIKMA PHARMACEUTICA, SINTRA, PORTUGAL

Laboratory/Laboratorium: HIKMA PHARMACEUTICA, SINTRA, PORTUGAL
CIPLA-MEDPRO, ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

Registration number/Registrasienommer: 34/20.1.1/0008

Name of medicine/Naam van medisyne: AVELON

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT TO
MOXIFLOXACIN ... 400.0 mg

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

Applicant/Applikant: BAYER (PTY) LTD

Manufacturer/Vervaardiger: BAYER AG. LEVERKUSEN GERMANY

Packer/Verpakker: BAYER AG. LEVERKUSEN GERMANY
DIVPHARM MANUFACTURING AND PACKAGING.
LONGDALE RSA
GLAXO WELLCOME. MIDRAND RSA
PHARMACEUTICAL CONTRACTORS. ISANDO RSA

Laboratory/Laboratorium: BAYER AG. LEVERKUSEN GERMANY
GLAXO WELLCOME. MIDRAND RSA
SOUTH AFRICAN BUREAU OF STANDARDS. PRETORIA
RSA
BAYER. ISANDO RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0218

Name of medicine/Naam van medisyne: TOTAM-2000

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:
CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME ... 2000.0 mg

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

Manufacturer/Vervaardiger: HIKMA PHARMACEUTICA. SINTRA. PORTUGAL

Packer/Verpakker: HIKMA PHARMACEUTICA. SINTRA. PORTUGAL

Laboratory/Laboratorium: HIKMA PHARMACEUTICA. SINTRA. PORTUGAL
CIPLA-MEDPRO. ROSENPARK RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/11.4.3/0081

Name of medicine/Naam van medisyne: OMILOC 20

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
OMEPRAZOLE ... 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, DENMARK
CONSULTING CHEMICAL LAB. STAR STREET BOKSBURG, RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 22 FEBRUARY 2001
Datum van registrasie 22 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/21.5.1/0071

Name of medicine/Naam van medisyne: CIPLA-MEDPRO BECLO-AQUA

Dosage form/Doseringsvorm: NASAL SPRAY/NEUSSPROEI

Active ingredients/Aktiewe bestanddele:
EACH 10.0 ml SUSPENSION CONTAINS/ELKE 10,0 ml SUSPENSIE BEVAT:
BECLOMETHASONE DIPROPIONATE ... 12,4 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
CIPLA LTD, VIKHROLI INDIA

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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 20 FEBRUARY 2001
Datum van registrasie 20 FEBRUARIE 2001

Registration number/Registrasienommer: 34/3.1/0095

Name of medicine/Naam van medisyne: CIPLA-MEDPRO PIROXICAM DT

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: CIPLA-MEDPRO (PTY) LTD

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

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

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

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 22 FEBRUARY 2001
Datum van registrasie 22 FEBRUARIE 2001

Registration number/Registrasienommer: 34/11.4.3/0082

Name of medicine/Naam van medisyne: OPRASEC 20

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
OMEPRAZOLE ... 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, DENMARK
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA
HEXAL PHARMA , WESTMEAD RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 22 FEBRUARY 2001
Datum van registrasie 22 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 32/5.8/0550

Name of medicine/Naam van medisyne: CLARITYNE D OD

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH TABLET CONTAINS/ELKE TABLET BEVAT:
LORATADINE ... 10,0 mg
PSEUDOEPHEDRINE SULPHATE ... 240,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING-PLOUGH, MADRID SPAIN

Packer/Verpakker: SCHERING-PLOUGH, MADRID SPAIN
SCHERING-PLOUGH, ISANDO RSA

Laboratory/Laboratorium: SCHERING-PLOUGH, MADRID SPAIN
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleeftyd: 36 months/maande

Date of registration: 28 FEBRUARY 2001
Datum van registrasie 28 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/34/0428

Name of medicine/Naam van medisyne: RAPAMUNE 1 MG/ML

Dosage form/Doseringsvorm: SOLUTION/OPLOSSING

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

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

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

Manufacturer/Vervaardiger: WYETH-AYERST, NEW YORK USA

Packer/Verpakker: WYETH-AYERST, NEW YORK USA
PACO PHARMACEUTICALS, NEW JERSEY USA
PHARMA-Q, INDUSTRIA RSA
WYETH MEDICA IRELAND, KILDARE IRELAND

Laboratory/Laboratorium: WYETH-AYERST, NEW YORK USA
PHARMA-Q, INDUSTRIA RSA
WYETH S.A., MIDRAND, RSA
CONSULTING CHEMICAL LAB, STAR STREET
BOKSBURG, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 FEBRUARY 2001
Datum van registrasie 23 FEBRUARIE 2001

Registration number/Registrasienommer: 34/21.8.2/0181

Name of medicine/Naam van medisyne: PREFESTA

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:
EACH PINK TABLET CONTAINS/ELKE PIENK TABLET BEVAT:
ESTRADIOL HEMIHYDRATE ... 1,0 mg

EACH WHITE TABLET CONTAINS/ELKE WIT TABLET BEVAT:
ESTRADIOL HEMIHYDRATE ... 1,0 mg
NORGESTIMATE ... 90,0 ug

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

Applicant/Applikant: JANSSEN PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: ORTHO PHARMACEUTICAL, MANATI PUERTO RICO

Packer/Verpakker: CILAG AG, HOCHSTRASSE SWITZERLAND

Laboratory/Laboratorium: CILAG AG, HOCHSTRASSE SWITZERLAND
JANSSEN PHARMACEUTICA, HALFWAY HOUSE RSA
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 FEBRUARY 2001
Datum van registrasie 28 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 33/16.4/0261

Name of medicine/Naam van medisyne: STERIDINE MOUTHWASH AND GARGLE

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:
EACH 5,0 ml LIQUID CONTAINS/ELKE 5,0 ml VLOEISTOF BEVAT:
POVIDONE-IODINE ... 0,05 g

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

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, GLEN ANIL, RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 28 FEBRUARY 2001
Datum van registrasie 28 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 34/11.4.3/0084

Name of medicine/Naam van medisyne: MEPRASEC 40

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:
OMEPRAZOLE ... 40,0 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: 02 MARCH 2001
Datum van registrasie 02 MAART 2001

MBR 15

Registration number/Registrasienommer: 34/11.4.3/0083

Name of medicine/Naam van medisyne: OPRASEC 40

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :
OMEPRAZOLE ... 40,0 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: 02 MARCH 2001
Datum van registrasie 02 MAART 2001

MBR 15

Registration number/Registrasienommer: 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/Rakleeftyd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 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/Rakleeftyd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 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 BOTTLE CONTAINS/ELKE BOTTEL 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/Rakleeftyd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 34/20.1.1/0045

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

Dosage form/Doseringsvorm: INJECTION/INSPUITING

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/Rakleeftyd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 35/25.2/0059

Name of medicine/Naam van medisyne: CLINOMEL N5-800

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

Active ingredients/Aktiewe bestanddele:

EACH 100,0 ml INFUSION CONTAINS/ELKE 100,0 ml INFUSIE BEVAT:	
CALCIUM CHLORIDE DIHYDRATE	0,066 g
DEXTROSE MONOHYDRATE	27,50 g
GLYCINE	0,721 g
L-ALANINE	1,449 g
L-ARGININE MONOHYDROCHLORIDE	0,805 g
L-HISTIDINE	0,336 g
L-ISOLEUCINE	0,420 g
L-LEUCINE	0,511 g
L-METHIONINE	0,280 g
L-PHENYLALANINE	0,392 g
L-PROLINE	0,476 g
L-SERINE	0,350 g
L-THREONINE	0,294 g
L-TRYPTOPHAN	0,126 g
L-TYROSINE	0,028 g
L-VALINE	0,406 g
LYSINE HYDROCHLORIDE	0,507 g
MAGNESIUM CHLORIDE HEXAHYDRATE	0,103 g
DIPOTASSIUM PHOSPHATE	0,522 g
SODIUM ACETATE	0,515 g
SODIUM CHLORIDE	0,188 g
SOYA OIL	20,0 g

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

Applicant/Applikant: ADCOCK INGRAM LTD (CRITICAL CARE)

Manufacturer/Vervaardiger: CLINTEC PARENTERAL S.A., CEDEX FRANCE

Packer/Verpakker: CLINTEC PARENTERAL S.A., CEDEX FRANCE
ADCOCK INGRAM LTD, 1 SABAX RD JHB RSA

Laboratory/Laboratorium: CLINTEC PARENTERAL S.A., CEDEX FRANCE
ADCOCK INGRAM LTD, 1 SABAX RD JHB RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 FEBRUARY 2001
Datum van registrasie 23 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 35/25.2/0060

Name of medicine/Naam van medisyne: CLINOMEL N6-900

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

Active ingredients/Aktiewe bestanddele:
EACH 100,0 ml INFUSION CONTAINS/ELKE 100,0 ml INFUSIE BEVAT:

CALCIUM CHLORIDE DIHYDRATE	0,066 g
DEXTROSE MONOHYDRATE	33,0 g
GLYCINE	0,876 g
L-ALANINE	1,760 g
L-ARGININE MONOHYDROCHLORIDE	0,978 g
L-HISTIDINE	0,408 g
L-ISOLEUCINE	0,510 g
L-LEUCINE	0,621 g
L-METHIONINE	0,340 g
L-PHENYLALANINE	0,476 g
L-PROLINE	0,578 g
L-SERINE	0,425 g
L-THREONINE	0,357 g
L-TRYPTOPHAN	0,513 g
L-TYROSINE	0,034 g
L-VALINE	0,493 g
LYSINE HYDROCHLORIDE	0,493 g
MAGNESIUM CHLORIDE HEXAHYDRATE	0,102 g
DIPOTASSIUM PHOSPHATE	0,522 g
SODIUM ACETATE	0,594 g
SODIUM CHLORIDE	0,154 g
SOYA OIL	20,000 g

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

Applicant/Applikant: ADCOCK INGRAM LTD (CRITICAL CARE)

Manufacturer/Vervaardiger: CLINTEC PARENTERAL S.A., CEDEX FRANCE

Packer/Verpakker: CLINTEC PARENTERAL S.A., CEDEX FRANCE
ADCOCK INGRAM LTD, 1 SABAX RD JHB RSA

Laboratory/Laboratorium: CLINTEC PARENTERAL S.A., CEDEX FRANCE
ADCOCK INGRAM LTD, 1 SABAX RD JHB RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 FEBRUARY 2001
Datum van registrasie 23 FEBRUARIE 2001

MBR 15

Registration number/Registrasienommer: 35/25.2/0061

Name of medicine/Naam van medisyne: CLINOMEL N7-1000

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

Active ingredients/Aktiewe bestanddele:
EACH 100, 0 ml INFUSION CONTAINS/ELKE 1,00 ml OPLOSSING BEVAT :

CALCIUM CHLORIDE DIHYDRATE	0,066 g
DEXTROSE MONOHYDRATE	44,0 g
GLYCINE	1,030 g
L-ALANINE	2,070 g
L-ARGININE MONOHYDROCHLORIDE	1,150 g
L-HISTIDINE	0,480 g
L-ISOLEUCINE	0,600 g
L-LEUCINE	0,730 g
L-METHIONINE	0,400 g
L-PHENYLALANINE	0,560 g
L-PROLINE	0,680 g
L-SERINE	0,500 g
L-THREONINE	0,420 g
L-TRYPTOPHAN	0,180 g
L-TYROSINE	0,040 g
L-VALINE	0,580 g
LYSINE HYDROCHLORIDE	0,725 g
MAGNESIUM CHLORIDE HEXAHYDRATE	0,103 g
DIPOTASSIUM PHOSPHATE	0,522 g
SODIUM ACETATE	0,680 g
SODIUM CHLORIDE	0,118 g
SOYA OIL	20,0 g

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

Applicant/Applikant: ADCOCK INGRAM LTD (CRITICAL CARE)

Manufacturer/Vervaardiger: CLINTEC PARENTERAL S.A., CEDEX FRANCE

Packer/Verpakker: CLINTEC PARENTERAL S.A., CEDEX FRANCE
ADCOCK INGRAM LTD, 1 SABAX RD JHB RSA

Laboratory/Laboratorium: CLINTEC PARENTERAL S.A., CEDEX FRANCE
ADCOCK INGRAM LTD, 1 SABAX RD JHB RSA

Shelf-life/Rakleeftyd: 24 months/maande

Date of registration: 23 FEBRUARY 2001
Datum van registrasie 23 FEBRUARIE 2001


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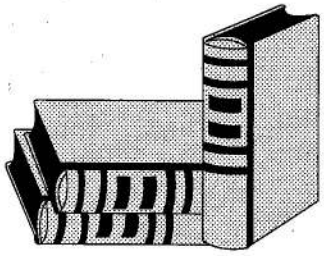
Where is the largest amount of meteorological information in the whole of South Africa available?



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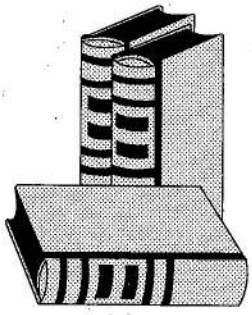

Waar is die meeste weerkundige inligting in die hele Suid-Afrika beskikbaar?

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Departement van Omgewingsake en Toerisme

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