



# Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA

Vol. 426 Pretoria, 8 December 2000/8 Desember 2000  
No. 21841



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

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## GENERAL NOTICE ALGEMENE KENNISGEWING

### NOTICE 1578 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 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 1578 VAN 1999**

#### **DEPARTEMENT VAN GESONDHEID**

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

#### **REGISTRASIE VAN MEDISYNE**

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

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

#### **Voorwaardes vir registrasie:**

- 1a. 'n Aanvaarbare standaard van Goeie Vervaardigingspraktyk moet by die plek van vervaardiging gehandhaaf word.
- 1b. Die applikant sal verseker dat die medisyne vervaardig en beheer word in terme van huidige Goeie Vervaardigingspraktyk soos bepaal deur die Medisynebeheerraad.
2. Die applikant moet voldoen aan al die wetlike vereistes van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965).
3. Die registrasie van die produk is onderhewig aan hersiening elke drie jaar.
4. Die inligting in die voubiljet moet op 'n gereelde basis opgedateer word in ooreenstemming met 'n voubiljet onlangs deur die Raad goedgekeur.
- 5a. Die eerste twee produksielotte moet ten volle gevalideer word en die volle besonderhede van die voorgestelde prosesvalidasieprogram wat gevolg gaan word deur die Applikant en/of die vervaardiger moet ingedien word.
- 5b. Die eerste twee produksielotte van die plaaslik vervaardigde produk moet gevalideer word.
- 5c. Die eerste twee produksielotte na registrasie moet gevalideer word, tensy die dokumentasie beskikbaar is.
- 5d. Die eerste twee produksielotte moet gevalideer word.
- 5e. Die eerste twee produksielotte van elke plaaslike vervaardiger moet gevalideer word.
6. Die vervaardiging van hierdie medisyne is onderhewig aan gereelde ondersoeke en inspeksies deur inspekteurs om die nakoming van Goeie Vervaardigingspraktyke te bepaal.

7. Die registrasie-aansoek is onderhewig aan hersiening met tussenpose soos deur die Raad bepaal.
- 8a. 'n Na-registrasie-inspeksie moet op die eerste produksielot van die plaaslik vervaardigde produk uitgevoer word.
- 8b. 'n Na-registrasie-inspeksie moet op die eerste produksielot van elke plaaslike vervaardiger uitgevoer word.
- 8c. 'n Na-registrasie-inspeksie moet op die eerste produksielot uitgevoer word.
9. Bemaking van die produk mag slegs 'n aanvang neem nadat 'n bevredigende na-registrasie-inspeksieverslag gedien het.
10. Die produk mag slegs aan die professies geadverteer word.
11. Een monster van elke lot moet tesame met vier kopieë van die protokolle vir die toets van die finale lot en die vullot ingedien word by die Raad vir lotvrystellingsdoeleindes.
12. Een monster van elke lot moet tesame met ses kopieë van die protokolle vir die toets van die finale lot en die vullot sowel as ses kopieë van die vrystellingstifikaat wat uitgereik is deur die verantwoordelike beheerliggaam in die land waar die produk vervaardig word, ingedien word by die Raad vir lotvrystellingsdoeleindes.
13. Die vervaldatum toegeken moet verander word deur 'n toegevoegde stelling dat die virusstamme wat tans aanbeveel word vir Suid-Afrikaanse gebruik is vir die gespesifiseerde jaar.
14. Die stamme van die oorspronklike saadvirusse moet elke jaar deur die Departement van Gesondheid goedgekeur word.

# SCHEDULE • BYLAE

MBR 15

Registration number/Registrasiënommer: 32/8.2/0405

Name of medicine/Naam van medisyne: PLAVIX

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ ELKE TABLET BEVAT:  
CLOPIDOGREL  
HYDROGEN SULPHATE/WATERSTOPSULFAAT  
EQUIVALENT TO/EKWIVALENT AAN  
CLOPIDOGREL ... 75,0 mg

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

Applicant/Applikant: SANOFI -SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI WINTHROP, AMBARES FRANCE

Packer/Verpakker: SANOFI WINTHROP, AMBARES FRANCE

Laboratory/Laboratorium: SANOFI WINTHROP, AMBARES FRANCE  
INSPECTORATE M & L, ORMONDE RSA  
PHARMACEUTICAL CONTRACTORS, ISANDO RSA  
SANOFI -SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 APRIL 2000  
Datum van registrasie: 18 APRIL 2000

MBR 15

Registration number/Registrasiënommer: 29/1.2/0556

Name of medicine/Naam van medisyne: XIXIA PAROXETINE 20

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
PAROXETINE HYDROCHLORIDE/  
PAROKSETIENHYDROCHLORIED  
EQUIVALENT TO/EKWIVALENT AAN  
PAROXETINE/PAROKSETIEN ... 20,0 mg

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

Applicant/Applikant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, CRAWLEY SUSSEX UK

Packer/Verpakker: SMITHKLINE BEECHAM, EPPING RSA

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

Shelf-life/Rakleefityd: 60 months/maande

Date of registration: 29 MAY 2000  
Datum van registrasie: 29 MEI 2000

Registration number/Registrasienommer: 32/1.2/0103

Name of medicine/Naam van medisyne: PROHEXAL 20 T

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

FLUOXETINE HYDROCHLORIDE/

FLUOKSETIENHIDROCHLORIED

EQUIVALENT TO/EKWIVALENT AAN

FLUOXETINE/FLUOKSETIEN ... 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: 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  
HEXAL PHARMA, WESTMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 24 AUGUST 2000

Datum van registrasie: 24 AUGUSTUS 2000

Registration number/Registrasienommer: 32/1.2/0102

Name of medicine/Naam van medisyne: PROHEXAL 10 T

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

FLUOXETINE HYDROCHLORIDE

FLUOKSETIENHIDROCHLORIED

EQUIVALENT TO/EKWIVALENT AAN

FLUOXETINE/FLUOKSETIEN ... 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: 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  
HEXAL PHARMA, WESTMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 24 AUGUST 2000

Datum van registrasie: 24 AUGUSTUS 2000

MBR 15

Registration number/Registrasiënommer: 83/21.1/643

Name of medicine/Naam van medisyne: POTENCIL

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 100,0 ml SUSPENSION CONTAINS/ELKE 100,0 ml SUSPENSIE BEVAT:  
AMOXYCILLIN TRIHYDRATE/AMOKSISILLIENTRIHIDRAAT  
EQUIVALENT TO/EKWIVALENT AAN  
AMOXYCILLIN/AMOKSISILLIEN ... 10,0 g  
COLISTIN SULPHATE/KOLISTIENSULFAAT ... 25,0 million iu

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

Applicant/Applikant: LOGOS AGVET (PTY) LTD

Manufacturer/Vervaardiger: VIRBAC SA, CARROS FRANCE

Packer/Verpakker: VIRBAC SA, CARROS FRANCE

Laboratory/Laboratorium: VIRBAC SA, CARROS FRANCE  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA  
LOGOS AGVET, HALFWAY HOUSE RSA

Shelf-life/Rakleefyd: 24 months/maande

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

MBR 15

Registration number/Registrasiënommer: 33/34/0239

Name of medicine/Naam van medisyne: SANDOSTATIN LAR 10 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:  
OCTREOTIDE ... 10,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA

Packer/Verpakker: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA  
NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleefyd: 24 months/maande

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

MBR 15

Registration number/Registrasiënommer: 33/34/0240

Name of medicine/Naam van medisyne: SANDOSTATIN LAR 20 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:  
OCTREOTIDE ... 20,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA

Packer/Verpakker: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA  
NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA  
NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleefityd: 24 months/maande

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

MBR 15

Registration number/Registrasiënommer: 27/8.3/0151

Name of medicine/Naam van medisyne: ABIC LEUCOVORIN 100 mg/10 ml  
INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 10,0 ml SOLUTION CONTAINS/ELKE 10,0 ml OPLOSSING BEVAT:  
CALCIUM FOLINATE PENTAHYDRATE/  
KALSIUMFOLINAAT PENTAHIDRAAT  
EQUIVALENT TO/EKWIVALENT AAN  
LEUCOVORIN ANHYDROUS/  
ANHIDRIESE LEUKOVORIEN ... 100,0 mg

Conditions of registration/Voorwaardes vir registrasie:

1, 2, 3, 4, 6, 7

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: PHARMACHEMIE BV, HAARLEM NETHERLANDS

Packer/Verpakker: PHARMACHEMIE BV, HAARLEM NETHERLANDS

Laboratory/Laboratorium: PHARMACHEMIE BV, HAARLEM NETHERLANDS  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA  
TEVA, INDUSTRIA RSA

Shelf-life/Rakleefityd: 24 months/maande

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

## MBR 15

Registration number/Registrasienommer: 27/8.3/0152

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

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 20,0 ml SOLUTION CONTAINS/ELKE 20,0 ml OPLOSSING BEVAT:  
CALCIUM FOLINATE PENTAHYDRATE/  
KALSIMUMFOLINAAT PENTAHIDRAAT  
EQUIVALENT TO/EKWIVALENT AAN  
LEUCOVORIN ANHYDROUS/  
ANHIDRIESE LEUKOVORIEN ... 200,0 mg

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

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD  
Manufacturer/Vervaardiger: PHARMACHEMIE BV, HAARLEM NETHERLANDS  
Packer/Verpakker: PHARMACHEMIE BV, HAARLEM NETHERLANDS  
Laboratory/Laboratorium: PHARMACHEMIE BV, HAARLEM NETHERLANDS  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA  
TEVA, INDUSTRIA RSA  
Shelf-life/Rakleef tyd: 24 months/maande  
Date of registration: 28 AUGUST 2000  
Datum van registrasie: 28 AUGUSTUS 2000

## MBR 15

Registration number/Registrasienommer: 27/8.3/0153

Name of medicine/Naam van medisyne: ABIC LEUCOVORIN 300 mg/30 ml  
INJECTION

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 30,0 ml SOLUTION CONTAINS/ELKE 30,0 ml OPLOSSING BEVAT:  
CALCIUM FOLINATE PENTAHYDRATE/  
KALSIMUMFOLINAAT PENTAHIDRAAT  
EQUIVALENT TO/EKWIVALENT AAN  
LEUCOVORIN ANHYDROUS/  
ANHIDRIESE LEUKOVORIEN ... 300,0 mg

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

Applicant/Applikant: TEVA PHARMACEUTICALS (PTY) LTD  
Manufacturer/Vervaardiger: PHARMACHEMIE BV, HAARLEM NETHERLANDS  
Packer/Verpakker: PHARMACHEMIE BV, HAARLEM NETHERLANDS  
Laboratory/Laboratorium: PHARMACHEMIE BV, HAARLEM NETHERLANDS  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA  
TEVA, INDUSTRIA RSA  
Shelf-life/Rakleef tyd: 24 months/maande  
Date of registration: 28 AUGUST 2000  
Datum van registrasie: 28 AUGUSTUS 2000

MBR 15

Registration number/Registrasienommer: 32/11.4.2/0211

Name of medicine/Naam van medisyne: CO-GEL

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:  
 EACH 10,0 ml SUSPENSION CONTAINS/ELKE 10,0 ml SUSPENSIE BEVAT:  
 DICYCLOMINE HYDROCHLORIDE ... 5,0 mg  
 DRIED ALUMINIUM HYDROXIDE ... 400,0 mg  
 LIGHT MAGNESIUM OXIDE ... 200,0 mg

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

Applicant/Applikant: BRAINWARE COMPU (PTY) LTD

Manufacturer/Vervaardiger: ALLIANCE PHARMA, VILLAGE MAIN RSA

Packer/Verpakker: ALLIANCE PHARMA, VILLAGE MAIN RSA

Laboratory/Laboratorium: ALLIANCE PHARMA, VILLAGE MAIN RSA  
 BRAINWARE COMPU, LYNWOOD RSA

Shelf-life/Rakleef tyd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 33/34/0241

Name of medicine/Naam van medisyne: SANDOSTATIN LAR 30 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
 EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :  
 OCTREOTIDE ... 30,0 mg

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

Applicant/Applikant: NOVARTIS SOUTH AFRICA (PTY) LTD

Manufacturer/Vervaardiger: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA

Packer/Verpakker: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA  
 NOVARTIS, LICHTSTRASSE BASLE SWITZERLAND  
 NOVARTIS, SPARTAN KEMPTON PARK RSA

Laboratory/Laboratorium: BIOCHEMIE GmbH, SCHAFTENAU TIROL AUSTRIA  
 NOVARTIS, SPARTAN KEMPTON PARK RSA

Shelf-life/Rakleef tyd: 24 months/maande

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

## MBR 15

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Registration number/Registrasienommer: 34/21.1/0250

Name of medicine/Naam van medisyne: LANTUS 1 000 IU/10 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 10,0 ml SOLUTION CONTAINS/ELKE 10,0 ml OPLOSSING BEVAT:  
INSULIN GLARGINE ... 1 000,0 iu

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: HOECHST MARION ROUSSEL, FRANKFURT  
WESTERN GERMANY

Packer/Verpakker: HOECHST MARION ROUSSEL, FRANKFURT  
WESTERN GERMANY

Laboratory/Laboratorium: HOECHST MARION ROUSSEL, FRANKFURT  
WESTERN GERMANY  
HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 18 SEPTEMBER 2000  
Datum van registrasie: 18 SEPTEMBER 2000

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## MBR 15

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Registration number/Registrasienommer: 33/30.1/0251

Name of medicine/Naam van medisyne: RABIPOR

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml DOSE CONTAINS/ELKE 1,0 ml DOSIS BEVAT:  
RABIES VIRUS ... 2,5 i.u.

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

Applicant/Applikant: BIOVAC SA (PTY) LTD

Manufacturer/Vervaardiger: CHIRON BEHRING, MARBURG, GERMANY

Packer/Verpakker: CHIRON BEHRING, MARBURG, GERMANY  
BIOVAC SA, WADEVILLE RSA

Laboratory/Laboratorium: CHIRON BEHRING, MARBURG, GERMANY  
BIOVAC SA, WADEVILLE RSA

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 18 SEPTEMBER 2000  
Datum van registrasie: 18 SEPTEMBER 2000

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MBR 15

Registration number/Registrasienommer: 33/1.2/0444

Name of medicine/Naam van medisyne: RITAPHEN 20

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET ONTVANG :  
METHYLPHENIDATE HYDROCHLORIDE ... 20,0 mg

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: DANBURY PHAMACAL, CARMEL, NEW YORK USA

Packer/Verpakker: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA

Laboratory/Laboratorium: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 SEPTEMBER 2000  
Datum van registrasie: 18 SEPTEMBER 2000

MBR 15

Registration number/Registrasienommer: 32/20.1.1/0254

Name of medicine/Naam van medisyne: RANDOCLIN 100 CAPSULES

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:  
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:  
DOXYCYCLINE HYDROCHLORIDE/DOKSISIKLIENHIDROCHLORIED  
EQUIVALENT TO/EKWIVALENT AAN  
DOXYCYCLINE/DOKSISIKLIEN ... 100,0 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  
ALLIANCE PHARMA, VILLAGE MAIN RSA  
BIOCHEMICAL & SCIENTIFIC CONSULTANTS,  
HILTON RSA  
KHULULEKANI LABORATORY SERVICES,  
MIDRAND RSA  
RANBAXY, BRYANSTON RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 SEPTEMBER 2000  
Datum van registrasie: 18 SEPTEMBER 2000

MBR 15

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Registration number/Registrasiënommer: 34/21.1/0249

Name of medicine/Naam van medisyne: LANTUS 500 IU/5 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 5,0 ml SOLUTION CONTAINS/ELKE 5,0 ml OPLOSSING BEVAT :  
INSULIN GLARGINE ... 500,0 iu

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: HOECHST MARION ROUSSEL, FRANKFURT  
WESTERN GERMANY

Packer/Verpakker: HOECHST MARION ROUSSEL, FRANKFURT  
WESTERN GERMANY

Laboratory/Laboratorium: HOECHST MARION ROUSSEL, FRANKFURT  
WESTERN GERMANY  
HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 SEPTEMBER 2000  
Datum van registrasie: 18 SEPTEMBER 2000

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MBR 15

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Registration number/Registrasiënommer: 34/21.1/0248

Name of medicine/Naam van medisyne: LANTUS 300 IU/3 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 3,0 ml SOLUTION CONTAINS/ELKE 3,0 ml OPLOSSING BEVAT  
INSULIN GLARGINE ... 300,0 iu

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: HOECHST MARION ROUSSEL, FRANKFURT WESTERN  
GERMANY

Packer/Verpakker: HOECHST MARION ROUSSEL, FRANKFURT WESTERN  
GERMANY

Laboratory/Laboratorium: HOECHST MARION ROUSSEL, FRANKFURT WESTERN  
GERMANY  
HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 SEPTEMBER 2000  
Datum van registrasie: 18 SEPTEMBER 2000

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MBR 15

Registration number/Registrasiënommer: 33/21.5.1/0329

Name of medicine/Naam van medisyne: FLIXONASE NASULES

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:  
EACH DOSE CONTAINS/ELKE DOSIS BEVAT:  
FLUTICASONE PROPIONATE ... 400,0 mcg

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, VICTORIA AUSTRALIA

Packer/Verpakker: GLAXO WELLCOME, VICTORIA AUSTRALIA  
GLAXO WELLCOME, MIDRAND RSA

Laboratory/Laboratorium: GLAXO WELLCOME, VICTORIA AUSTRALIA  
GLAXO WELLCOME, MIDRAND RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 SEPTEMBER 2000  
Datum van registrasie: 18 SEPTEMBER 2000

MBR 15

Registration number/Registrasiënommer: 33/3.1/0294

Name of medicine/Naam van medisyne: IP-MELOXICAM 7,5 MG TABLET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
MELOXICAM ... 7,5 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN,  
GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN,  
GERMANY  
HOECHST MARION ROUSSEL, WALTLOO RSA

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN,  
GERMANY  
HOECHST MARION ROUSSEL, WALTLOO RSA  
INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleefityd: 60 months/maande

Date of registration: 19 SEPTEMBER 2000  
Datum van registrasie: 19 SEPTEMBER 2000

MBR 15

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Registration number/Registrasiënommer: 32/20.1.1/0596

Name of medicine/Naam van medisyne: SUMADAX SUSPENSION 90 MG/5 ML

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:  
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:  
CEFTIBUTEN ... 90,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, MIAMI FLORIDA USA

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

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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2000  
Datum van registrasie: 19 SEPTEMBER 2000

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MBR 15

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Registration number/Registrasiënommer: 32/20.1.1/0597

Name of medicine/Naam van medisyne: SUMADAX SUSPENSION 180 MG/5 ML

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:  
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:  
CEFTIBUTEN ... 180,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: SCHERING, MIAMI FLORIDA USA

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

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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2000  
Datum van registrasie: 19 SEPTEMBER 2000

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## MBR 15

Registration number/Registrasienommer: 29/8.3/0358

Name of medicine/Naam van medisyne: LEUCOVORIN - FAULDING 3mg/ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:  
CALCIUM FOLINATE EQUIVALENT TO LEUCOVORIN ... 3,0 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  
CONSULTING CHEMICAL LAB, STAR STREET,  
BOKSBURG, RSA  
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 19 SEPTEMBER 2000  
Datum van registrasie: 19 SEPTEMBER 2000

## MBR 15

Registration number/Registrasienommer: 33/11.4.1/0497

Name of medicine/Naam van medisyne: NEUTRACID ANTACID

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, WADEVILLE RSA

Packer/Verpakker: ADCOCK INGRAM LTD, WADEVILLE RSA

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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 26 SEPTEMBER 2000  
Datum van registrasie: 26 SEPTEMBER 2000

## MBR 15

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Registration number/Registrasiënommer: 34/7.1.3/0016

Name of medicine/Naam van medisyne: ALAPREN 20 TABLETS

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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: 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

Shelf-life/Rakleefyd: 24 months/maande

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

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## MBR 15

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Registration number/Registrasiënommer: 34/7.1.3/0015

Name of medicine/Naam van medisyne: ALAPREN 10 TABLETS

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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA

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

Shelf-life/Rakleefyd: 24 months/maande

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

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MBR 15

Registration number/Registrasienommer: 34/7.1.3/0014

Name of medicine/Naam van medisyne: ALAPREN 5 TABLETS

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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: 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

Shelf-life/Rakleefityd: 24 months/maande

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

MBR 15

Registration number/Registrasienommer: 34/7.1.3/0013

Name of medicine/Naam van medisyne: ALAPREN 2,5 TABLETS

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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: 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

Shelf-life/Rakleefityd: 24 months/maande

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

## MBR 15

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Registration number/Registrasienommer: 32/13.1/0396

Name of medicine/Naam van medisyne: BAXIDIN

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:  
EACH 100,0 ml LIQUID CONTAINS/ELKE 100,0 ml VLOEISTOF BEVAT :  
CETRIMIDE ... 15,0 g  
CHLORHEXIDINE GLUCONATE ... 1,5 g

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

Applicant/Applikant: ZEDCHEM (PTY) LTD

Manufacturer/Vervaardiger: ZEDCHEM, DIEP RIVER RSA

Packer/Verpakker: ZEDCHEM, DIEP RIVER RSA

Laboratory/Laboratorium: ZEDCHEM, DIEP RIVER RSA  
S A FOUNDATION FOR PROCESS,  
CAPE TOWN RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000  
Datum van registrasie 28 SEPTEMBER 2000

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## MBR 15

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Registration number/Registrasienommer: 34/7.1.3/0009

Name of medicine/Naam van medisyne: RENA 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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: 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

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000  
Datum van registrasie 28 SEPTEMBER 2000

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MBR 15

Registration number/Registrasiënommer: 34/7.1.3/0010

Name of medicine/Naam van medisyne: RENA 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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: 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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000  
Datum van registrasie: 28 SEPTEMBER 2000

MBR 15

Registration number/Registrasiënommer: 34/7.1.3/0011

Name of medicine/Naam van medisyne: RENA 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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: RANBAXY, PAONTA SAHIB INDIA

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000  
Datum van registrasie: 28 SEPTEMBER 2000

## MBR 15

Registration number/Registrasienommer: 34/7.1.3/0012

Name of medicine/Naam van medisyne: RENA 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: RANBAXY (SA) (PTY) LTD

Manufacturer/Vervaardiger: RANBAXY, PAONTA SAHIB INDIA

Packer/Verpakker: 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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000

Datum van registrasie: 28 SEPTEMBER 2000

## MBR 15

Registration number/Registrasienommer: 30/20.1.2/0293

Name of medicine/Naam van medisyne: MOXYCLAV S

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

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

AMOXYCILLIN TRIHYDRATE/AMOKSISILLIENTRIHIDRAAT

EQUIVALENT TO/EKWIVALENT AAN

AMOXYCILLIN/AMOKSISILLIEN ... 125,0 mg

POTASSIUM CLAVULANATE/ KALIUMKLAVULANAAT

EQUIVALENT TO/EKWIVALENT AAN

CLAVULANIC ACID/KLAVULAANSUUR ... 31,25 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, WORTHING SUSSEX UK

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

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000

Datum van registrasie: 28 SEPTEMBER 2000

MBR 15

Registration number/Registrasienommer: 30/20.1.2/0317

Name of medicine/Naam van medisyne: CLAVUMOX S

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSION

Active ingredients/Aktiewe bestanddele:

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

AMOXYCILLIN TRIHYDRATE/AMOKSISILLIENTRIHIDRAAT

EQUIVALENT TO/EKWIVALENT AAN

AMOXYCILLIN/AMOKSISILLIEN ... 125,0 mg

POTASSIUM CLAVULANATE/KALIUMKLAVULANAAT

EQUIVALENT TO/EKWIVALENT AAN

CLAVULANIC ACID/KLAVULAANSUUR ... 31,25 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, WORTHING SUSSEX UK

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

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000  
Datum van registrasie: 28 SEPTEMBER 2000

MBR 15

Registration number/Registrasienommer: 33/34/0159

Name of medicine/Naam van medisyne: ARACHIS OIL-DAROL

Dosage form/Doseringsvorm: OIL/OLIE

Active ingredients/Aktiewe bestanddele:

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

ARACHIS OIL ... 100,0 ml

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/Rakleefityd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000  
Datum van registrasie: 28 SEPTEMBER 2000

MBR 15

Registration number/Registrasiënommer: 30/20.1.2/0318

Name of medicine/Naam van medisyne: CLAVUMOX SF

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:

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

AMOXYCILLIN TRIHYDRATE/AMOKSISILLIENTRIHIDRAAT

EQUIVALENT TO/EKWIVALENT AAN

AMOXYCILLIN/AMOKSISILLIEN .. . 250,0 mg

POTASSIUM CLAVULANATE/KALIUMKLAVULANAAT

EQUIVALENT TO/EKWIVALENT AAN

CLAVULANIC ACID/KLAVULAANSUUR .. . 62,5 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, WORTHING SUSSEX UK

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

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 28 SEPTEMBER 2000

Datum van registrasie 28 SEPTEMBER 2000

MBR 15

Registration number/Registrasiënommer: 33/34/0138

Name of medicine/Naam van medisyne: ALUM POWDER-DAROL

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:

EACH 50,0 g POWDER CONTAINS/ELKE 50,0 g POEIER BEVAT:

ALUM ... 50,0 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/Rakleefityd: 24 months/maande

Date of registration: 29 SEPTEMBER 2000

Datum van registrasie 29 SEPTEMBER 2000

MBR 15

Registration number/Registrasienommer: 33/34/0137  
 Name of medicine/Naam van medisyne: ALOES POWDER-DAROL  
 Dosage form/Doseringsvorm: POWDER/POEIER  
 Active ingredients/Aktiewe bestanddele:  
 EACH 25,0 g POWDER CONTAINS/ELKE 25,0 g POEIER BEVAT :  
 ALOES ... 25,0 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/Rakleefityd: 24 months/maande  
 Date of registration: 29 SEPTEMBER 2000  
 Datum van registrasie: 29 SEPTEMBER 2000

MBR 15

Registration number/Registrasienommer: 31/7.1/0644  
 Name of medicine/Naam van medisyne: PARKE-MED - CAPTOPRIL 25 MG  
 Dosage form/Doseringsvorm: TABLET  
 Active ingredients/Aktiewe bestanddele:  
 EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
 CAPTOPRIL ... 25,0 mg

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

Applicant/Applikant: WARNER-LAMBERT SA (PTY) LTD  
 Manufacturer/Vervaardiger: WARNER-LAMBERT, RETREAT RSA  
 Packer/Verpakker: WARNER-LAMBERT, RETREAT RSA  
 Laboratory/Laboratorium: WARNER-LAMBERT, RETREAT RSA  
 Shelf-life/Rakleefityd: 24 months/maande  
 Date of registration: 29 SEPTEMBER 2000  
 Datum van registrasie: 29 SEPTEMBER 2000

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Registration number/Registrasienommer: 31/7.1/0645

Name of medicine/Naam van medisyne: PARKE-MED - CAPTOPRIL 50 MG

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: WARNER-LAMBERT, RETREAT RSA

Packer/Verpakker: WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 29 SEPTEMBER 2000  
Datum van registrasie: 29 SEPTEMBER 2000

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Registration number/Registrasienommer: 34/20.2.3/0030

Name of medicine/Naam van medisyne: RIFINAH JUNIOR 60/30

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:  
EACH SACHET CONTAINS/ELKE SAKKIE BEVAT:  
ISONIAZID ... 30,0 mg  
RIFAMPICIN ... 60,0 mg

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: HOECHST MARION ROUSSEL, WALTLOO RSA

Packer/Verpakker: HOECHST MARION ROUSSEL, WALTLOO RSA  
PHARMA-Q, INDUSTRIA RSA  
TECHNIKON LABORATORIES, FLORIDA RSA  
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: HOECHST MARION ROUSSEL, WALTLOO RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 29 SEPTEMBER 2000  
Datum van registrasie: 29 SEPTEMBER 2000

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MBR 15

Registration number/Registrasienommer: 34/20.2.3/0031

Name of medicine/Naam van medisyne: RIFATER JUNIOR

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:

EACH SACHET CONTAINS/ELKE SAKKIE BEVAT:

ISONIAZID ... 30,0 mg

PYRAZINAMIDE ... 150,0 mg

RIFAMPICIN ... 60,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: HOECHST MARION ROUSSEL LTD

Manufacturer/Vervaardiger: HOECHST MARION ROUSSEL, WALTLOO RSA

Packer/Verpakker: HOECHST MARION ROUSSEL, WALTLOO RSA  
PHARMA-Q, INDUSTRIA RSA  
TECHNIKON LABORATORIES, FLORIDA RSA  
WRAPSA, CENTURION RSA

Laboratory/Laboratorium: HOECHST MARION ROUSSEL, WALTLOO RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 29 SEPTEMBER 2000

Datum van registrasie: 29 SEPTEMBER 2000

MBR 15

Registration number/Registrasienommer: 31/20.2.8/0585

Name of medicine/Naam van medisyne: RAVUCLIR CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:

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

ACICLOVIR ... 50,0 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, DURHAM UK

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

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

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 29 SEPTEMBER 2000

Datum van registrasie: 29 SEPTEMBER 2000

MBR 15

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Registration number/Registrasienommer: 33/34/0148

Name of medicine/Naam van medisyne: BORACIC ACID POWDER BP-DAROL

Dosage form/Doseringsvorm: POWDER/POEIER

Active ingredients/Aktiewe bestanddele:  
EACH 50,0 g CONTAINER CONTAINS/ELKE 50,0 g POEIER BEVAT:  
BORIC ACID ... 50,0 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/Rakleef tyd: 24 months/maande

Date of registration: 29 SEPTEMBER 2000  
Datum van registrasie: 29 SEPTEMBER 2000

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MBR 15

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Registration number/Registrasienommer: 33/34/0157

Name of medicine/Naam van medisyne: LINSEED OIL-DAROL

Dosage form/Doseringsvorm: OIL/OLIE

Active ingredients/Aktiewe bestanddele:  
EACH 100,0 ml BOTTLE CONTAINS/ELKE 100,0 ml BOTTEL BEVAT:  
LINSEED OIL ... 100,0 ml

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

Applicant/Applikant: BARRS PHARMACEUTICAL INDUSTRIES CC

Manufacturer/Vervaardiger: BARRS PHARMACEUTICAL INDUSTRIES,  
OBSERVATORY RSA

Packer/Verpakker: BARRS PHARMACEUTICAL INDUSTRIES,  
OBSERVATORY RSA

Laboratory/Laboratorium: BARRS PHARMACEUTICAL INDUSTRIES,  
OBSERVATORY RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 29 SEPTEMBER 2000  
Datum van registrasie: 29 SEPTEMBER 2000

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MBR 15

Registration number/Registrasiënommer: 30/20.1.2/0344

Name of medicine/Naam van medisyne: MENTIN 375

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:

AMOXYCILLIN TRIHYDRATE/AMOKSISILLIEN TRIHIDRAAT

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: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, VICTORIA AUSTRALIA

Packer/Verpakker: SMITHKLINE BEECHAM, EPPING RSA

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 09 OCTOBER 2000

Datum van registrasie: 09 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 34/7.1.3/0029

Name of medicine/Naam van medisyne: ENALAHEXAL 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: 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/Rakleefityd: 24 months/maande

Date of registration: 09 OCTOBER 2000

Datum van registrasie: 09 OKTOBER 2000

MBR 15

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Registration number/Registrasienommer: 33/5.2/0231

Name of medicine/Naam van medisyne: XATRAL 2,5 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT :  
ALFUZOSIN HYDROCHLORIDE ... 2,5 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: HOECHST MARION ROUSSEL, WALTLOO RSA

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 09 OCTOBER 2000  
Datum van registrasie: 09 OKTOBER 2000

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MBR 15

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Registration number/Registrasienommer: 30/5.2/0182

Name of medicine/Naam van medisyne: XATRAL SR 5,0 mg

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
ALFUZOSIN HYDROCHLORIDE ... 5,0 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/Rakleefityd: 36 months/maande

Date of registration: 09 OCTOBER 2000  
Datum van registrasie: 09 OKTOBER 2000

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MBR 15

Registration number/Registrasiënommer: 30/11.4.3/0497

Name of medicine/Naam van medisyne: SUCOSA

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
SUCRALFATE ... 1,0 g

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

Applicant/Applikant: GAREC (PTY) LTD

Manufacturer/Vervaardiger: APOTEX INC, SIGNET DRIVE WESTON,  
ONTARIO CANADA

Packer/Verpakker: APOTEX INC, WESTON ROAD, WESTON,  
ONTARIO CANADA

Laboratory/Laboratorium: APOTEX INC, SIGNET DRIVE, WESTON,  
ONTARIO CANADA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
GAREC, WOODMEAD SANDTON RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 33/7.1.3/0363

Name of medicine/Naam van medisyne: COVERSYL PLUS

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
INDAPAMIDE ... 1,25 mg  
PERINDOPRIL ... 4,0 mg

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

Applicant/Applikant: SERVIER LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: LES LABORATORY SERVIER, FLEURY-LES-AUBRAIS  
FRANCE

Packer/Verpakker: LES LABORATORY SERVIER, FLEURY-LES-AUBRAIS  
FRANCE  
TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: LES LABORATORY SERVIER, FLEURY-LES-AUBRAIS  
FRANCE  
INSPECTORATE M & L, ORMONDE RSA  
SERVIER LABORATORIES, RIVONIA

Shelf-life/Rakleefyd: 36 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

MBR 15

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Registration number/Registrasiënommer: 32/2.5/0459

Name of medicine/Naam van medisyne: LAMICTIN P50

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, HERTFORDSHIRE UK  
GLAXO WELLCOME, KENT UK

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

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

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

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MBR 15

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Registration number/Registrasiënommer: 32/2.5/0460

Name of medicine/Naam van medisyne: LAMICTIN P200

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: GLAXO WELLCOME, HERTFORDSHIRE UK  
GLAXO WELLCOME, KENT UK

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

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

Shelf-life/Rakleef tyd: 36 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

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MBR 15

Registration number/Registrasiënommer: 31/8.2/0581

Name of medicine/Naam van medisyne: FRAXIPARINE 1 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml SOLUTION CONTAINS/ELKE 1,0 ml OPLOSSING BEVAT:  
NADROPARIN CALCIUM ... 9500,0 iu axa

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Packer/Verpakker: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Laboratory/Laboratorium: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE  
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 31/8.2/0580

Name of medicine/Naam van medisyne: FRAXIPARINE 0,8 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 0,8 ml SOLUTION CONTAINS/ELKE 0,8 ml OPLOSSING BEVAT:  
NADROPARIN CALCIUM ... 7600 iu axa

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Packer/Verpakker: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Laboratory/Laboratorium: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE  
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

MBR 15

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Registration number/Registrasienommer: 31/8.2/0579

Name of medicine/Naam van medisyne: FRAXIPARINE 0,6 ml

Dosage form/Doseringsvorm: INJECTION/INSPIUTING

Active ingredients/Aktiewe bestanddele:  
EACH 0,6 ml SOLUTION CONTAINS/ELKE 0,6 ml OPLOSSING BEVAT:  
NADROPARIN CALCIUM ... 5700,0 iu axa

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Packer/Verpakker: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Laboratory/Laboratorium: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE  
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

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MBR 15

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Registration number/Registrasienommer: 33/8/0289

Name of medicine/Naam van medisyne: AGRYLIN 1 MG

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:  
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:  
ANAGRELIDE HYDROCHLORIDE MONOHYDRATE EQUIVALENT TO  
ANAGRELIDE ... 1,0 mg

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

Applicant/Applikant: TEMA MEDICAL (PTY) LTD

Manufacturer/Vervaardiger: MALLINCKRODT CHEM, RAILROAD AVE, HOBART USA  
MALLINCKRODT CHEM, PEARL STREET, HOBART USA

Packer/Verpakker: MALLINCKRODT CHEM, PEARL STREET, HOBART USA  
TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: MALLINCKRODT CHEM, PEARL STREET, HOBART USA  
BIOCON RESEARCH LAB, PRETORIA, RSA  
INSTITUTE FOR INDUSTRIAL PHARMACY,  
POTCHEFSTROOM UNIVERSITY RSA  
NUCRO-TECHNICS, ONTARIO, CANADA  
TEMA MEDICAL, SANDTON, RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

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MBR 15

Registration number/Registrasiënommer: 33/8/0288

Name of medicine/Naam van medisyne: AGRYLIN 0,5 mg

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:  
EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT :  
ANAGRELIDE HYDROCHLORIDE MONOHYDRATE EQUIVALENT TO  
ANAGRELIDE ... 0,5 mg

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

Applicant/Applikant: TEMA MEDICAL (PTY) LTD

Manufacturer/Vervaardiger: MALLINCKRODT CHEM, RAILROAD AVE, HOBART USA  
MALLINCKRODT CHEM, PEARL STREET, HOBART USA

Packer/Verpakker: MALLINCKRODT CHEM, PEARL STREET, HOBART USA  
TECHNIKON LABORATORIES, FLORIDA RSA

Laboratory/Laboratorium: MALLINCKRODT CHEM, PEARL STREET, HOBART USA  
BIOCON RESEARCH LAB, PRETORIA, RSA  
INSTITUTE FOR INDUSTRIAL PHARMACY,  
POTCHEFSTROOM UNIVERSITY RSA  
NUCRO-TECHNICS, ONTARIO, CANADA  
TEMA MEDICAL, SANDTON, RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 33/7.3/0312

Name of medicine/Naam van medisyne: IMIGRAN SUPPOSITORY

Dosage form/Doseringsvorm: SUPPOSITORY/SETPIL

Active ingredients/Aktiewe bestanddele:  
EACH SUPPOSITORY CONTAINS/ELKE SETPIL BEVAT:  
SUMATRIPTAN ... 25,0 mg

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

Applicant/Applikant: GLAXO WELLCOME SA (PTY) LTD

Manufacturer/Vervaardiger: LABORATORY GLAXO WELLCOME SA, EVREUX  
FRANCE

Packer/Verpakker: LABORATORY GLAXO WELLCOME SA, EVREUX  
FRANCE  
GLAXO WELLCOME, MIDRAND RSA RSA

Laboratory/Laboratorium: LABORATORY GLAXO WELLCOME SA, EVREUX  
FRANCE  
GLAXO WELLCOME, MIDRAND RSA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

## MBR 15

Registration number/Registrasiënommer: 33/10.2.1/0194

Name of medicine/Naam van medisyne: SABAX FENOTEROL HBr 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:  
FENOTEROL HYDROBROMIDE ... 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 RSA

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

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

## MBR 15

Registration number/Registrasiënommer: 28/30.1/0318

Name of medicine/Naam van medisyne: MORUPAR

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 0,5 ml CONTAINS AT LEAST/ELKE 0,5 ml BEVAT TENMINSTE:  
MEASLES VIRUS (SCHWARTZ STRAIN) ... 1 000 TCID/50  
MUMPS VIRUS (URABE AM9 STRAIN) ... 5 000 TCID/50  
RUBELLA VIRUS (WISTAR RA 27/3) ... 1 000 TCID/50

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

Applicant/Applikant: BIOVAC SA (PTY) LTD

Manufacturer/Vervaardiger: CHIRON S.P.A., SIENA ITALY

Packer/Verpakker: CHIRON S.P.A., SIENA ITALY  
BIOVAC SA, WADEVILLE RSA

Laboratory/Laboratorium: CHIRON S.P.A., SIENA ITALY  
BIOVAC SA, WADEVILLE RSA  
THE DEPARTMENT OF VIROLOGY, MEDUNSA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

MBR 15

Registration number/Registrasienommer: 31/8.2/0578

Name of medicine/Naam van medisyne: FRAXIPARINE 0,4 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 0,4 ml SOLUTION CONTAINS/ELKE 0,4 ml OPLOSSING BEVAT :  
NADROPARIN CALCIUM ... 3800,0 iu. axa

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Packer/Verpakker: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Laboratory/Laboratorium: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE  
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

MBR 15

Registration number/Registrasienommer: 31/8.2/0577

Name of medicine/Naam van medisyne: FRAXIPARINE 0,3 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 0,3 ml SOLUTION CONTAINS/ELKE 0,3 ml OPLOSSING BEVAT :  
NADROPARIN CALCIUM ... 2850,0 iu axa

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Packer/Verpakker: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Laboratory/Laboratorium: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE  
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

## MBR 15

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Registration number/Registrasiënommer: 31/20.1.1/0410

Name of medicine/Naam van medisyne: ZOLIN 500

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH VIAL CONTAINS/ELKE FLESSIE BEVAT:  
CEFAZOLIN SODIUM/NATRIUMKEFASOLIEN  
EQUIVALENT TO/EKWIVALENT AAN  
CEFAZOLIN/KEFASOLIEN ... 500,0 mg

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

Applicant/Applikant: COMPU PHARMACEUTICAL PRODUCTS LTD

Manufacturer/Vervaardiger: IBSA, LUGANO SWITZERLAND

Packer/Verpakker: IBSA, LUGANO SWITZERLAND

Laboratory/Laboratorium: IBSA, LUGANO SWITZERLAND  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
COMPU PHARMACEUTICAL PRODUCTS,  
LYNNWOOD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 10 OCTOBER 2000  
Datum van registrasie: 10 OKTOBER 2000

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## MBR 15

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Registration number/Registrasiënommer: 33/20.1.1/0530

Name of medicine/Naam van medisyne: SCHEIN CEFZAZOLIN 1 G

Dosage form/Doseringsvorm: INJECTION/INSPUITING

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

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Packer/Verpakker: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

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

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

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MBR 15

Registration number/Registrasiënommer: 33/20.1.1/0529

Name of medicine/Naam van medisyne: SCHEIN CEFAZOLIN 500 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :

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

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

Packer/Verpakker: MARSAM PHARMACEUTICALS INC, NEW JERSEY USA

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

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 11 OCTOBER 2000

Datum van registrasie 11 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 29/26/0673

Name of medicine/Naam van medisyne: DOXORUBICIN HCL-FAULDING 50 MG

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :

DOXORUBICIN HYDROCHLORIDE ... 50,0 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  
CONSULTING CHEMICAL LAB, STAR STREET  
BOKSBURG, RSA  
PHARMAPLAN, MIDRAND RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 11 OCTOBER 2000

Datum van registrasie 11 OKTOBER 2000

## MBR 15

Registration number/Registrasienommer: 33/2.2/0029

Name of medicine/Naam van medisyne: ALCHERA

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT :  
ZOPICLONE ... 7,5 mg

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: WULFING PHARMA GmbH, GRONAU GERMANY

Packer/Verpakker: AKROMED PRODUCTS, CLAYVILLE RSA

Laboratory/Laboratorium: WULFING PHARMA GmbH, GRONAU GERMANY  
AKROMED PRODUCTS, CLAYVILLE RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

## MBR 15

Registration number/Registrasienommer: 33/26/0103

Name of medicine/Naam van medisyne: ADRIBLASTINA CSV 20 MG/10 ML

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:

EACH 10,0 ml SOLUTION CONTAINS/ELKE 10,0 ml OPLOSSING BEVAT:  
DOXORUBICIN HYDROCHLORIDE ... 20,0 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  
SOUTH AFRICAN BUREAU OF STANDARDS, PRETORIA  
RSA  
PHARMACIA & UPJOHN, MIDRAND RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

**MBR 15**

Registration number/Registrasiënommer: 34/7.5/0127

Name of medicine/Naam van medisyne: BAYCOL 0,4

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
CERIVASTATIN SODIUM ... 0,4 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  
JANSSEN-CILAG, MIDRAND RSA  
PHARMACEUTICAL CONTRACTORS, ISANDO RSA

Laboratory/Laboratorium: BAYER AG, LEVERKUSEN GERMANY  
LAXO WELLCOME, MIDRAND RSA  
JANSSEN-CILAG, MIDRAND RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA  
BAYER, ISANDO RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

**MBR 15**

Registration number/Registrasiënommer: 33/15.4/0396

Name of medicine/Naam van medisyne: NACLOF SDU

Dosage form/Doseringsvorm: DROPS/DRUPPELS

Active ingredients/Aktiewe bestanddele:  
EACH 1,0 ml DROPS CONTAIN/ELKE 1,0 ml DRUPPELS BEVAT:  
DICLOFENAC SODIUM ...1,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: CIBA VISION, ANNONAY FRANCE

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

Laboratory/Laboratorium: CIBA VISION, ANNONAY FRANCE  
NOVO NORDISK, JOHANNESBURG RSA  
ADCOCK INGRAM LTD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

MBR 15

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Registration number/Registrasienommer: H/18/1728

Name of medicine/Naam van medisyne: PYRIDIUM

Dosage form/Doseringsvorm: TABLET

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

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

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

Manufacturer/Vervaardiger: ABLE LABORATORIES, NEW JERSEY USA

Packer/Verpakker: WARNER-LAMBERT, CALI COLOMBIA

Laboratory/Laboratorium: ABLE LABORATORIES, NEW JERSEY USA  
WARNER-LAMBERT, CALI COLOMBIA  
WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleef tyd: 24 months/maande in amber glass bottles  
36 month/maande in securitainers

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

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MBR 15

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Registration number/Registrasienommer: 33/16.3/0496

Name of medicine/Naam van medisyne: MEDI-KEEL A HONEY AND LEMON  
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/Aplikant: 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/Rakleef tyd: 24 months/maande

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

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MBR 15

Registration number/Registrasienommer: 31/8.2/0576

Name of medicine/Naam van medisyne: FRAXIPARINE 0,2 ml

Dosage form/Doseringsvorm: INJECTION/INSPUITING

Active ingredients/Aktiewe bestanddele:  
EACH 0,2 ml SOLUTION CONTAINS/ELKE 0,2 ml OPLOSSING BEVAT:  
NADROPARIN CALCIUM ... 1900,0 iu axa

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

Applicant/Applikant: SANOFI - SYNTHELABO (PTY) LTD

Manufacturer/Vervaardiger: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Packer/Verpakker: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE

Laboratory/Laboratorium: SANOFI, NOTRE DAME DE BONDEVILLE FRANCE  
SANOFI - SYNTHELABO, WOODMEAD RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 11 OCTOBER 2000  
Datum van registrasie: 11 OKTOBER 2000

MBR 15

Registration number/Registrasienommer: 33/16.4/0374

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

Dosage form/Doseringsvorm: LOZENGES/SUIGTABLETTE

Active ingredients/Aktiewe bestanddele:  
EACH LOZENGE CONTAINS/ELKE SUIGTABLET BEVAT:  
BENZYDAMINE HYDROCHLORIDE ... 3,0 mg  
CETYLPYRIDINIUM CHLORIDE ... 1,33 mg

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

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

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

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

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

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 12 OCTOBER 2000  
Datum van registrasie: 12 OKTOBER 2000

## MBR 15

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Registration number/Registrasienommer: 33/11.4.3/0519

Name of medicine/Naam van medisyne: CONTROLOC 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/Rakleefityd: 24 months/maande

Date of registration: 12 OCTOBER 2000  
Datum van registrasie: 12 OKTOBER 2000

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## MBR 15

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Registration number/Registrasienommer: 31/20.1.2/0327

Name of medicine/Naam van medisyne: AMFLUPEN S

Dosage form/Doseringsvorm: SUSPENSION/SUSPENSIE

Active ingredients/Aktiewe bestanddele:  
EACH 5,0 ml SUSPENSION CONTAINS/ELKE 5,0 ml SUSPENSIE BEVAT:  
AMOXYCILLIN TRIHYDRATE/AMOKSISILLIENTRIHIDRAAT  
EQUIVALENT TO/EKWIVALENT AAN  
AMOXYCILLIN/AMOKSISILLIEN ... 125,0 mg  
FLUCLOXACILLIN SODIUM/NATRIUMFLUKLOKSASILLIEN  
EQUIVALENT TO/EKWIVALENT AAN  
FLUCLOXACILLIN/FLUKLOKSASILLIEN .... 125,0 mg

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

Applicant/Applikant: SMITHKLINE BEECHAM PHARMACEUTICALS  
(PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, EPPING RSA

Packer/Verpakker: SMITHKLINE BEECHAM, EPPING RSA

Laboratory/Laboratorium: SMITHKLINE BEECHAM, EPPING RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 12 OCTOBER 2000  
Datum van registrasie: 12 OKTOBER 2000

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MBR 15

Registration number/Registrasienommer: 31/3.1/0274

Name of medicine/Naam van medisyne: APO-NAPROXEN SODIUM 275 MG

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:  
EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
NAPROXEN SODIUM/NATRIUM NAPROKSEEN ... 275,0 mg

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

Applicant/Applikant: APOTEX SA (PTY) LTD

Manufacturer/Vervaardiger: APOTEX INC, SIGNET DRIVE WESTON,  
ONTARIO CANADA

Packer/Verpakker: APOTEX INC, WESTON ROAD WESTON,  
ONTARIO CANADA

Laboratory/Laboratorium: APOTEX INC, SIGNET DRIVE WESTON,  
ONTARIO CANADA  
APOTEX INC, WESTON ROAD WESTON  
ONTARIO CANADA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
APOTEX, SANDTON, RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 12 OCTOBER 2000  
Datum van registrasie: 12 OKTOBER 2000

MBR 15

Registration number/Registrasienommer: 33/5.8/0345

Name of medicine/Naam van medisyne: BENYLIN FOUR FLU LIQUID

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:  
EACH 20,0 ml LIQUID CONTAINS/ELKE 20,0 ml VLOEISTOF BEVAT:  
DIPHENHYDRAMINE HYDROCHLORIDE ... 25,0 mg  
PARACETAMOL ... 1000,0 mg  
PSEUDOEPHEDRINE HYDROCHLORIDE ... 45,0 mg

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

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

Manufacturer/Vervaardiger: WARNER-LAMBERT, RETREAT RSA

Packer/Verpakker: WARNER-LAMBERT, RETREAT RSA

Laboratory/Laboratorium: WARNER-LAMBERT, RETREAT RSA

Shelf-life/Rakleefityd: 36 months/maande

Date of registration: 13 OCTOBER 2000  
Datum van registrasie: 13 OKTOBER 2000

MBR 15

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Registration number/Registrasienommer: 33/21.8.2/0471

Name of medicine/Naam van medisyne: NORLEVO

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: MEDI CHALLENGE (PTY) LTD

Manufacturer/Vervaardiger: LABORATOIRES CASSENNE, OSNY, FRANCE

Packer/Verpakker: LABORATOIRES CASSENNE, OSNY, FRANCE

Laboratory/Laboratorium: LABORATOIRES CASSENNE, OSNY, FRANCE  
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY,  
POTCHEFSTROOM  
MEDI CHALLENGE (PTY) LTD RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 19 OCTOBER 2000  
Datum van registrasie: 19 OKTOBER 2000

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MBR 15

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Registration number/Registrasienommer: 33/16.4/0263

Name of medicine/Naam van medisyne: PIN-POVIDONE-IODINE  
(ORAL ANTISEPTIC)

Dosage form/Doseringsvorm: LIQUID/VLOEISTOF

Active ingredients/Aktiewe bestanddele:  
EACH 100,0 ml LIQUID CONTAINS/ELKE 100,0 ml VLOEISTOF BEVAT:  
POVIDONE-IODINE ... 1,0 g

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

Applicant/Applikant: MEDPRO PHARMACEUTICA (PTY) LTD

Manufacturer/Vervaardiger: PHARMA-Q, INDUSTRIA RSA  
ZENECA, ALRODE RSA

Packer/Verpakker: PHARMA-Q, INDUSTRIA RSA  
ZENECA, ALRODE RSA

Laboratory/Laboratorium: PHARMA-Q, INDUSTRIA RSA  
ZENECA, ALRODE RSA  
MEDPRO PHARMACEUTICA, ROSENPARK RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 13 OCTOBER 2000  
Datum van registrasie: 13 OKTOBER 2000

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MBR 15

Registration number/Registrasiënommer: 31/20.1.2/0136

Name of medicine/Naam van medisyne: CLAVESYL 375

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: GROUP LABORATORIES SA (PTY) LTD

Manufacturer/Vervaardiger: SMITHKLINE BEECHAM, VICTORIA AUSTRALIA

Packer/Verpakker: SMITHKLINE BEECHAM, EPPING RSA

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

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 13 OCTOBER 2000  
 Datum van registrasie: 13 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 33/10.1/0299

Name of medicine/Naam van medisyne: BISOLVON 8 MG QDT

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
 BROMHEXINE HYDROCHLORIDE ... 8,0 mg

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

Applicant/Applikant: INGELHEIM PHARMACEUTICALS (PTY) LTD

Manufacturer/Vervaardiger: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN,  
 GERMANY

Packer/Verpakker: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN,  
 GERMANY

Laboratory/Laboratorium: BOEHRINGER INGELHEIM, INGELHEIM AM RHEIN,  
 GERMANY  
 HOECHST MARION ROUSSEL, WALTLOO RSA  
 INGELHEIM PHARMACEUTICALS, RANDBURG RSA

Shelf-life/Rakleefyd: 24 months/maande

Date of registration: 13 OCTOBER 2000  
 Datum van registrasie: 13 OKTOBER 2000

## MBR 15

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Registration number/Registrasienommer: 33/1.2/0442

Name of medicine/Naam van medisyne: RITAPHEN 5

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: DANBURY PHAMACAL, CARMEL, NEW YORK USA

Packer/Verpakker: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA

Laboratory/Laboratorium: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
TRIOMED, DURBANVILLE RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 OCTOBER 2000  
Datum van registrasie: 18 OKTOBER 2000

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## MBR 15

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Registration number/Registrasienommer: 33/1.2/0443

Name of medicine/Naam van medisyne: RITAPHEN 10

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: DANBURY PHAMACAL, CARMEL, NEW YORK USA

Packer/Verpakker: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA

Laboratory/Laboratorium: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 OCTOBER 2000  
Datum van registrasie: 18 OKTOBER 2000

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MBR 15

Registration number/Registrasienommer: 33/1.2/0441

Name of medicine/Naam van medisyne: RALITIN 20

Dosage form/Doseringsvorm: TABLET

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

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

Applicant/Applikant: TRIOMED (PTY) LTD

Manufacturer/Vervaardiger: DANBURY PHAMACAL, CARMEL, NEW YORK USA

Packer/Verpakker: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA

Laboratory/Laboratorium: DANBURY PHAMACAL, CARMEL, NEW YORK USA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
TRIOMED, MONTAGUE GARDENS RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 18 OCTOBER 2000  
Datum van registrasie: 18 OKTOBER 2000

MBR 15

Registration number/Registrasienommer: 33/11.10/0531

Name of medicine/Naam van medisyne: REVELLEX 100 mg

Dosage form/Doseringsvorm: SOLUTION

Active ingredients/Aktiewe bestanddele:  
EACH 10,0 ml VIAL CONTAINS/ELKE 10,0 ml FLESSIE BEVAT:  
INFLIXIMAB ... 100,0 mg

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

Applicant/Applikant: SCHERING-PLOUGH (PTY) LTD

Manufacturer/Vervaardiger: PARKE DAVIS, MICHIGAN, U.S.A.

Packer/Verpakker: PARKE DAVIS, MICHIGAN, U.S.A.  
CENTOCOR BV, LEIDEN NETHERLANDS

Laboratory/Laboratorium: PARKE DAVIS, MICHIGAN, U.S.A.  
CENTOCOR BV, LEIDEN NETHERLANDS  
SCHERING-PLOUGH, ISANDO RSA

Shelf-life/Rakleefityd: 24 months/maande stored at 2 C - 8 C

Date of registration: 20 OCTOBER 2000  
Datum van registrasie: 20 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 33/1.2/0541

Name of medicine/Naam van medisyne: DEPROZAN

Dosage form/Doseringsvorm: CAPSULES/KAPSULES

Active ingredients/Aktiewe bestanddele:

EACH CAPSULE CONTAINS/ELKE KAPSULE BEVAT:  
FLUOXETINE HYDROCHLORIDE/FLUOKSETIENHIDROCHLORIED  
EQUIVALENT TO/EKWIVALENT AAN  
FLUOXETINE/FLUOKSETIEN ... 20,0 mg

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

Applicant/Applikant: ELTTAB PHARMACEUTICALS CC

Manufacturer/Vervaardiger: GEDEON RICHTER, BUDAPEST HUNGARY

Packer/Verpakker: GEDEON RICHTER, BUDAPEST HUNGARY

Laboratory/Laboratorium: GEDEON RICHTER, BUDAPEST HUNGARY  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA  
ELTTAB PHARM, MOWBRAY.RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 20 OCTOBER 2000  
Datum van registrasie: 20 OKTOBER 2000

MBR 15

Registration number/Registrasiënommer: 31/20.2.8/0549

Name of medicine/Naam van medisyne: BETA-VIRA TOPICAL CREAM

Dosage form/Doseringsvorm: CREAM/ROOM

Active ingredients/Aktiewe bestanddele:

EACH 1 g CREAM CONTAINS/ ELKE 1.0 g ROOM BEVAT:  
ACICLOVIR ... 5,0 mg

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

Applicant/Applikant: ADCOCK INGRAM LTD

Manufacturer/Vervaardiger: ADCOCK INGRAM LTD, WADEVILLE RSA

Packer/Verpakker: ADCOCK INGRAM LTD, WADEVILLE RSA

Laboratory/Laboratorium: ADCOCK INGRAM LTD, WADEVILLE RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA

Shelf-life/Rakleefityd: 24 months/maande

Date of registration: 25 October 2000  
Datum van registrasie: 25 Oktober 2000

**MBR 15**

Registration number/Registrasienommer: **30/15.4/0376**

Name of medicine/Naam van medisyne: **TILAVIST**

Dosage form/Doseringsvorm: **DROPS/DRUPPELS**

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

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

Applicant/Applikant: **RHONE-POULENC RORER SA (PTY) LTD**

Manufacturer/Vervaardiger: **LABORATORY FISONS SA, SEINE-MARITIME FRANCE**

Packer/Verpakker: **LABORATORY FISONS SA, SEINE-MARITIME FRANCE**

Laboratory/Laboratorium: **LABORATORY FISONS SA, SEINE-MARITIME FRANCE**  
**RHONE-POULENC RORER, PORT ELIZABETH RSA**

Shelf-life/Rakleefityd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

**MBR 15**

Registration number/Registrasienommer: **33/21.5.1/0482**

Name of medicine/Naam van medisyne: **RINELON**

Dosage form/Doseringsvorm: **NASAL SPRAY/NEUS SPROEI**

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

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

Applicant/Applikant: **SCHERING-PLOUGH (PTY) LTD**

Manufacturer/Vervaardiger: **SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM**

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

Laboratory/Laboratorium: **SCHERING-PLOUGH, HEIST-OP-DEN-BERG BELGIUM**  
**SCHERING-PLOUGH, ISANDO RSA**

Shelf-life/Rakleefityd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

## MBR 15

Registration number/Registrasiënommer: 33/16.3/0235

Name of medicine/Naam van medisyne: **MEDI-KAIN ORANGE**

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, 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/Rakleefyd: **18 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

## MBR 15

Registration number/Registrasiënommer: 33/30.4/0318

Name of medicine/Naam van medisyne: **EPREX 3 000/0,3 ML**

Dosage form/Doseringsvorm: **INJECTION/INSPUITING**

Active ingredients/Aktiewe bestanddele:  
**EACH 0,3 ml PRE-FILLED SYRINGE CONTAINS/ELKE 0,3 ml SPUIT BEVAT :  
EPOETIN ALFA ...25,2 ug (3 000 iu)**

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

Applicant/Applikant: **JANSSEN PHARMACEUTICA (PTY) LTD**

Manufacturer/Vervaardiger: **VETTERPHARMA, SCHUTZENSTR,  
RAVENSBURG GERMANY**

Packer/Verpakker: **VETTER PHARMA, SCHUTZENSTR,  
RAVENSBURG GERMANY**

Laboratory/Laboratorium: **CILAG AG, HOCHSTRASSE  
SWITZERLAND  
JANSSEN PHARMACEUTICA,  
HALFWAY HOUSE RSA**

Shelf-life/Rakleefyd: **18 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

Registration number/Registrasienommer: **33/2.2/0451**

Name of medicine/Naam van medisyne: **PARKE-MED ZOPICLONE**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:  
**EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
ZOPICLONE ... 7,5 mg**

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

Applicant/Aplikant: **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/Rakleefyd: **24 months/maande**

Date of registration: **30 OCTOBER 2000**  
Datum van registrasie **30 OKTOBER 2000**

Registration number/Registrasienommer: **32/21.2/0025**

Name of medicine/Naam van medisyne: **LIMARCAN 50**

Dosage form/Doseringsvorm: **TABLET**

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

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

Applicant/Aplikant: **SANOFI - SYNTHELABO (PTY) LTD**

Manufacturer/Vervaardiger: **BAYER AG, LEVERKUSEN GERMANY**

Packer/Verpakker: **DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA  
PHARMACEUTICAL CONTRACTORS, ISANDO RSA**

Laboratory/Laboratorium: **BAYER AG, LEVERKUSEN GERMANY  
PHARMACEUTICAL CONTRACTORS, ISANDO RSA  
INSPECTORATE M & L, ORMONDE RSA  
SANOFI - SYNTHELABO, WOODMEAD RSA**

Shelf-life/Rakleefyd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie **30 Oktober 2000**

## MBR 15

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Registration number/Registrasiensnommer: **32/21.2/0026**

Name of medicine/Naam van medisyne: **LIMARCAN 100**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:  
**EACH TABLET CONTAINS/ELKE TABLET BEVAT:**  
**MIGLITOL 100,0 mg**

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

Applicant/Applikant: **SANOFI - SYNTHELABO (PTY) LTD**

Manufacturer/Vervaardiger: **BAYER AG, LEVERKUSEN GERMANY**

Packer/Verpakker: **DIVPHARM MANUFACTURING AND PACKAGING  
LONGDALE RSA  
PHARMACEUTICAL CONTRACTORS, ISANDO RS**

Laboratory/Laboratorium: **BAYER AG, LEVERKUSEN GERMANY  
PHARMACEUTICAL CONTRACTORS, ISANDO RS  
INSPECTORATE M & L, ORMONDE RSA  
SANOFI - SYNTHELABO, WOODMEAD RSA**

Shelf-life/Rakleef tyd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

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## MBR 15

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Registration number/Registrasiensnommer: **32/20.2.8/0378**

Name of medicine/Naam van medisyne: **VYROHEXAL 200**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:  
**EACH TABLET CONTAINS/ELKE TABLET BEVAT:**  
**ACICLOVIR ...200,0 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: **DIVPHARM MANUFACTURING AND  
PACKAGING, LONGDALE RSA  
KLOCKE VERPACKUNGS-SERVICE,  
WEINGARTEN GERMANY**

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

Shelf-life/Rakleef tyd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

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**MBR 15**

Registration number/Registrasiënommer: **30/20.1.2/0463**

Name of medicine/Naam van medisyne: **PYCIN 2 g**

Dosage form/Doseringsvorm: **INJECTION/INSPUITING**

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

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

Applicant/Applikant: **PHARMACARE LIMITED**

Manufacturer/Vervaardiger: **ACS DOBFAR SpA, MILAN ITALY**

Packer/Verpakker: **C T LABORATORIA FARMACEUTICO,  
SANREMO ITALY**

Laboratory/Laboratorium: **C T LABORATORIA FARMACEUTICO,  
SANREMO ITALY  
INTRAMED, PORT ELIZABETH RSA**

Shelf-life/Rakleef tyd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

**MBR 15**

Registration number/Registrasiënommer: **30/20.1.2/0464**

Name of medicine/Naam van medisyne: **PYCIN 4 g**

Dosage form/Doseringsvorm: **INJECTION/INSPUITING**

Active ingredients/Aktiewe bestanddele:  
**EACH VIAL CONTAINS/ELKE FLESSIE BEVAT :**  
**PIPERACILLIN SODIUM EQUIVALENT TO PIPERACILLIN ...4,0 g**

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

Applicant/Applikant: **PHARMACARE LIMITED**

Manufacturer/Vervaardiger: **ACS DOBFAR SpA, MILAN ITALY**

Packer/Verpakker: **C T LABORATORIA FARMACEUTICO,  
SANREMO ITALY**

Laboratory/Laboratorium: **C T LABORATORIA FARMACEUTICO,  
SANREMO ITALY  
INTRAMED, PORT ELIZABETH RSA**

Shelf-life/Rakleef tyd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

Registration number/Registrasienommer: 33/10.2.2/0431

Name of medicine/Naam van medisyne: **ADCO-KETOTIFEN ALCOHOL AND SUGAR FREE**

Dosage form/Doseringsvorm: **SYRUP/STROOP**

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

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

Applicant/Applikant: **ADCOCK INGRAM LTD**

Manufacturer/Vervaardiger: **ADCOCK INGRAM LTD, WADEVILLE RSA**

Packer/Verpakker: **ADCOCK INGRAM LTD, WADEVILLE RSA**

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

Shelf-life/Rakleefityd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

Registration number/Registrasienommer: 33/13.4.1/0303

Name of medicine/Naam van medisyne: **MAXADERM**

Dosage form/Doseringsvorm: **CREAM/ROOM**

Active ingredients/Aktiewe bestanddele:  
**EACH 1,0 g CREAM CONTAINS/ELKE 1,0 g ROOM BEVAT:**  
**DIFLUCORTOLONE VALERATE/DIFLUKORTELOONVALERAAT 1,0 mg**  
**ISOCONAZOLE NITRATE/ISOKONASOOLNITRAAT ... 10,0 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/Rakleefityd: **24 months/maande**

Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

MBR 15

Registration number/Registrasienommer: **33/13.1/0382**  
Name of medicine/Naam van medisyne: **STERIDINE ANTISEPTIC OINTMENT**  
Dosage form/Doseringsvorm: **OINTMENT/SALF**

Active ingredients/Aktiewe bestanddele:  
**EACH 1,0 g OINTMENT CONTAINS/ELKE 1,0 g SALF BEVAT:**  
**POVIDONE-IODINE ... 100,0 mg**

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: **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/Rakleefityd: **24 months/maande**  
Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

MBR 15

Registration number/Registrasienommer: **31/18.3/0283**  
Name of medicine/Naam van medisyne: **ALKAFIZZ SOLUBLE TABLETS**  
Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:  
**EACH TABLET CONTAINS/ELKE TABLET BEVAT:**  
**CITRIC ACID/SITROENSUUR 0,700 g**  
**SODIUM BICARBONATE/**  
**NATRIUMBIKARBONAAT 1,362 g**  
**SODIUM CITRATE/NATRIUMSITRAAT 0,615 g**  
**TARTARIC ACID/ WYNSTEENSUUR ... 0,860 g**

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Aplikant: **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/Rakleefityd: **24 months/maande**  
Date of registration: **30 October 2000**  
Datum van registrasie: **30 Oktober 2000**

## MBR 15

Registration number/Registrasiënommer: 33/20.2.2/0309

Name of medicine/Naam van medisyne: KETAZOL TABLET

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
KETOCONAZOLE...200,0 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/Rakleef tyd: 24 months/maande

Date of registration: 01 November 2000

Datum van registrasie: 01 November 2000

## MBR 15

Registration number/Registrasiënommer: 33/21.8.2/0053

Name of medicine/Naam van medisyne: LOETTE TABLET-21

Dosage form/Doseringsvorm: TABLET

Active ingredients/Aktiewe bestanddele:

EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
ETHINYLESTRADIOL ... 0,02 mg  
LEVONORGESTREL ...0,10 mg

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: PHARMACARE LIMITED

Manufacturer/Vervaardiger: WYETH PHARMACEUTICALS CO,  
GUAYAMA PUERTO RICO

Packer/Verpakker: WYETH PHARMACEUTICALS CO,  
GUAYAMA PUERTO RICO  
AKROMED PRODUCTS, CLAYVILLE RSA

Laboratory/Laboratorium: WYETH PHARMACEUTICALS CO,  
GUAYAMA PUERTO RICO  
AKROMED PRODUCTS, CLAYVILLE RSA

Shelf-life/Rakleef tyd: 24 months/maande

Date of registration: 07 November 2000

Datum van registrasie: 07 November 2000

**MBR 15**

Registration number/Registrasiënommer: **33/21.8.2/0054**

Name of medicine/Naam van medisyn: **LOETTE TABLET-28**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:

**21 PINK TABLETS EACH CONTAINS/21 LIGROOS TABLETTE ELKEEN BEVAT:**

**LEVONORGESTREL ... 0,10 mg**

**ETHINYLESTRADIOL ...0,02 mg**

**7 GREEN PLACEBO TABLETS/7 GROEN PLASEBO TABLETTE:**

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: **PHARMACARE LIMITED**

Manufacturer/Vervaardiger: **WYETH PHARMACEUTICALS CO,  
GUAYAMA PUERTO RICO**

Packer/Verpakker: **WYETH PHARMACEUTICALS CO,  
GUAYAMA PUERTO RICO  
AKROMED PRODUCTS, CLAYVILLE RSA**

Laboratory/Laboratorium: **WYETH PHARMACEUTICALS CO,  
GUAYAMA PUERTO RICO  
AKROMED PRODUCTS, CLAYVILLE RSA**

Shelf-life/Rakleefyd: **24 months/maande**

Date of registration: **07 November 2000**

Datum van registrasie: **07 November 2000**

**MBR 15**

Registration number/Registrasiënommer: **31/21.8.2/0343**

Name of medicine/Naam van medisyn: **MEGACE 160**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:

**EACH TABLET CONTAINS/ELKE TABLET BEVAT**

**MEGESTROL ACETATE...160,0 mg**

Conditions of registration/Voorwaardes vir registrasie:

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

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

Manufacturer/Vervaardiger: **BRISTOL-MYERS SQUIBB, REGENSBURG GERMANY**

Packer/Verpakker: **BRISTOL-MYERS SQUIBB, WADEVILLE RSA**

Laboratory/Laboratorium: **BRISTOL-MYERS SQUIBB, REGENSBURG GERMANY  
BRISTOL-MYERS SQUIBB, WADEVILLE RSA**

Shelf-life/Rakleefyd: **24 months/maande**

Date of registration: **09 November 2000**

Datum van registrasie: **09 November 2000**

**MBR 15**

Registration number/Registrasiënommer: **33/1.2/0439**

Name of medicine/Naam van medisyne: **RALITIN 5**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:

**EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
METHYLPHENIDATE HYDROCHLORIDE ... 5,0 mg**

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: **TRIOMED (PTY) LTD**

Manufacturer/Vervaardiger: **DANBURY PHARMACAL, CARMEL, NEW YORK USA**

Packer/Verpakker: **DANBURY PHARMACAL, CARMEL, NEW YORK USA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA**

Laboratory/Laboratorium: **DANBURY PHARMACAL, CARMEL, NEW YORK USA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON PRETORIA RSA  
TRIOMED, MONTAGUE GARDENS RSA**

Shelf-life/Rakleef tyd: **24 months/maande**

Date of registration: **09 November 2000**

Datum van registrasie: **09 November 2000**

**MBR 15**

Registration number/Registrasiënommer: **33/1.2/0440**

Name of medicine/Naam van medisyne: **RALITIN 10**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:

**EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
METHYLPHENIDATE HYDROCHLORIDE...10,0 mg**

Conditions of registration/Voorwaardes vir registrasie:

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

Applicant/Applikant: **TRIOMED (PTY) LTD**

Manufacturer/Vervaardiger: **DANBURY PHARMACAL, CARMEL, NEW YORK USA**

Packer/Verpakker: **DANBURY PHARMACAL, CARMEL, NEW YORK USA  
DIVPHARM MANUFACTURING AND PACKAGING,  
LONGDALE RSA**

Laboratory/Laboratorium: **DANBURY PHARMACAL, CARMEL, NEW YORK USA  
INSTITUTE FOR PHARM & CHEM SERVICE,  
TECHNIKON  
PRETORIA RSA  
TRIOMED, MONTAGUE GARDENS RSA**

Shelf-life/Rakleef tyd: **24 months/maande**

Date of registration: **09 November 2000**

Datum van registrasie: **09 November 2000**

**MBR 15**

Registration number/Registrasienommer: **33/23/0210**

Name of medicine/Naam van medisyne: **DIPEPTIVEN**

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

Active ingredients/Aktiewe bestanddele:  
**EACH 100,0 ml SOLUTION CONTAINS/ELKE 100,0 ml OPLOSSING BEVAT :  
L-ALANINE ...8,20 g  
LEVOGLUTAMIDE ...13,46 g**

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

Applicant/Applikant: **FRESENIUS KABI SA (PTY) LTD**

Manufacturer/Vervaardiger: **FRESENIUS PHARMA, GRAZ, AUSTRIA**

Packer/Verpakker: **FRESENIUS PHARMA, GRAZ, AUSTRIA**

Laboratory/Laboratorium: **FRESENIUS PHARMA, GRAZ, AUSTRIA  
FRESENIUS AG, INDUSTRIESTRASSE GERMANY  
KHULULEKANI LABORATORY SERVICES,  
MIDRAND RSA  
SOUTH AFRICAN BUREAU OF STANDARDS,  
PRETORIA RSA  
FRESENIUS KABI, MIDRAND, RSA**

Shelf-life/Rakleef tyd: **36 months/maande**

Date of registration: **09 November 2000**  
Datum van registrasie: **09 November 2000**

**MBR 15**

Registration number/Registrasienommer: **32/20.2.8/0705**

Name of medicine/Naam van medisyne: **COMBIVIR**

Dosage form/Doseringsvorm: **TABLET**

Active ingredients/Aktiewe bestanddele:  
**EACH TABLET CONTAINS/ELKE TABLET BEVAT:  
LAMIVUDINE...150,0 mg  
ZIDOVUDINE...300,0 mg**

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

Applicant/Applikant: **GLAXO WELLCOME SA (PTY) LTD**

Manufacturer/Vervaardiger: **GLAXO WELLCOME, HERTFORDSHIRE UK**

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

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

Shelf-life/Rakleef tyd: **24 months/maande**

Date of registration: **10 November 2000**  
Datum van registrasie: **10 November 2000**

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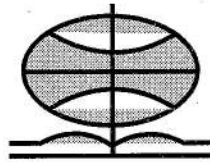


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Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001

Publications: Tel: (012) 334-4508, 334-4509, 334-4510

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