

MRF 15(MBR 15)

Registration number: 38/34/0226

Name of medicine: EBIXA 10MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
MEMANTINE HYDROCHLORIDE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: H. LUNDBECK (PTY) LTD

Manufacturer: ROTTENDOW PHARMA GmbH, ENNIGERLOH,
GERMANY

Packer: MERZ + CO. GmbH & CO., REINHEIM, GERMANY

Laboratory: **FPRC:** MERZ + **CO.** GmbH & **CO.**, REINHEIM, GERMANY
H. LUNDBECK A/S, COPENHAGEN, DENMARK
FPRR: H. LUNDBECK, NORTH **RIDING**, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/3.1/0390
Name of medicine:	DISFLAM (DISPERSIBLE TABLET)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: DICLOFENAC 46,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA, EAST LONDON
Packer:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA , EAST LONDON
Laboratory:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH SAD SELF MEDICATION, WILSONIA , EAST LONDON SOUTH AFRICAN BUREAU OF STANDARDS , GROENKLOOF , PRETORIA, RSA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM PHARMACARE LTD, WOODMEAD, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0395
Name of medicine:	TERBINISIL 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH , BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL , TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory: FPRC:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY IL SAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA
FPRR:	HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0396
Name of medicine:	TERBINISIL 125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLOFUDE EQUIVALENT TO TERBINAFINE 125,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY ILSAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0397
Name of medicine:	TERBANE 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLORIDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	HEXAL PHARMA (S.A.) (PTY) LTD
Manufacturer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY IL SAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY
Packer:	GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY IL SAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY DIVPHARM MANUFACTURING & PACKAGING, LONGDALE, RSA
Laboratory:	FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE, DENMARK SALUTAS PHARMA GmbH, BARLEBEN, GERMANY IL SAN ILAC VE HAMMADDELERI SANAYI, ISTANBUL, TURKEY CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA ANALYTICON, KEMPTON PARK, RSA FPRR: HEXAL PHARMA, WESTMEAD, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/20.2.2/0399

Name of medicine: TERBANE 125

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
TERBINAFINE HYDROCHLORIDE EQUIVALENT TO
TERBINAFINE 125,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **HEXAL PHARMA (S.A.) (PTY) LTD**

Manufacturer: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
İLSAN İLAÇ VE HAMMADDELERİ SANAYİ,
İSTANBUL, TURKEY

Packer: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
İLSAN İLAÇ VE HAMMADDELERİ SANAYİ,
İSTANBUL, TURKEY
DIVPHARM MANUFACTURING & PACKAGING,
LONGDALE, RSA

Laboratory: FPRC: GEA FARMACEUTISK FABRIK, HVIDOVRE,
DENMARK
SALUTAS PHARMA GmbH, BARLEBEN, GERMANY
İLSAN İLAÇ VE HAMMADDELERİ SANAYİ,
İSTANBUL, **TURKEY**
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRR: **HEXAL PHARMA, WESTMEAD, RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.1.2/0462
Name of medicine:	MYMOX 250
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: AMOXICILLIN TRIHYDRATE EQUIVALENT TO AMOXICILLIN 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UNICHEM S.A. (PTY) LTD
Manufacturer:	UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, BADDI, SOLAN , INDIA
Laboratory: FPRC:	UMCHEM LABORATORIES LTD, BADDI, SOLAN, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY , POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET , BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, BARDENE, BOKSBURG, RSA ALLIANCE PHARMA , VILLAGE MAIN, JOHANNESBURG, RSA
FPRR:	UNICHEM, VAN DER HOFF PARK , POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.1.2/0463
Name of medicine:	MYMOX 500
Dosage form:	CAPSULE
Active ingredients:	EACH CAPSULE CONTAINS: AMOXYCILLIN TRIHYDRATE EQUIVALENT TO AMOXYCILLIN 500,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	UMCHEM S.A.(PTY) LTD
Manufacturer:	UMCHEM LABORATORIES LTD, BADDI, SOLAN, INDIA
Packer:	UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA
Laboratory: FPRC:	UNICHEM LABORATORIES LTD, BADDI, SOLAN, INDIA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA INSTITUTE FOR PHARMACEUTICAL & CHEMICAL SERVICES, BARDENE, BOKSBURG, RSA ALLIANCE PHARMA , VILLAGE MAIN, JOHANNESBURG, RSA FPRR: UNICHEM, VAN DER HOFF PARK, POTCHEFSTROOM, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.2.2/0484
Name of medicine:	TERBICIL
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: TERBINAFINE HYDROCHLOFUDE EQUIVALENT TO TERBINAFINE 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH GENERIC [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: GENPHARM PHARMACEUTICALS, ONTARIO, CANADA LENNON LTD, KORSTEN, PORT ELIZABETH GENERIC [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM FPRR: PHARMACARE, KORSTEN , PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: A38/7.1.3/0509

Name of medicine: RILACE 1,25 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 1,25 **MG**

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK **INGRAM** HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: **24** months

Date of registration: **25** NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/05 10

Name of medicine: RILACE 2,5 TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK **INGRAM** LIMITED

Manufacturer: DELTA LTD, HAFNARFJORDUR, ICELAND

Packer: DELTA LTD, HAFNARFJORDUR, ICELAND
ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK INGRAM HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Laboratory: FPRC: DELTA LTD, HAFNARFJORDUR, ICELAND
FPRC/FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,
GERMISTON, RSA
ADCOCK **INGRAM** HEALTHCARE, CLAYVILLE,
OLIFANTSFONTEIN, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration **number:** **A38/7.1.3/0514**

Name of medicine: **XIXIPRIL 1,25**

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 MG

Conditions of registration: **1,2, 3, 4, 5, 6, 7**

Applicant: XIXIA PHARMACEUTICALS (PTY) **LTD**

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, **GERMISTON**, RSA

Laboratory: FPRC: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, **GERMISTON**, RSA
RESEARCH **INSTITUTE** FOR INDUSTRIAL
PHARMACY, UNIVERSITY, **POTCHEFSTROOM**, RSA
FPRR: **XIXIA** PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: **24** months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A38/7.1.3/0515**

Name of medicine: **XIXIPRIL 2,5**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:
RAMIPRIL 2,5 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **XIXIA PHARMACEUTICALS (PTY) LTD**

Manufacturer: **GENPHARM INC., ETOBICOKE, CANADA**

Packer: **GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA**

Laboratory: **FPRC:** **GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA**
FPRR: **XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/7.1.3/05 **16**

Name of medicine: XIXIPRIL 5

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: XIXIA PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: **FPRC:** GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
FPRR: RESEARCH INSTITUTE **FOR** INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, **RSA**
XIXIA PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/7.1.3/05 17

Name of medicine: **XIXIPRIL** 10

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
~~RAMPRI~~ 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ~~XIXIA~~ PHARMACEUTICALS (PTY) LTD

Manufacturer: GENPHARM INC., ETOBICOKE, CANADA

Packer: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: GENPHARM INC., ETOBICOKE, CANADA
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE **FOR** INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: ~~XIXIA~~ PHARMACEUTICALS, MODDERFONTEIN,
RSA

Shelf-life: 24 months

Date of registration: **25** NOVEMBER 2005

MRF 15(MBR 15)

Registration number: A38/1.2/0520

Name of medicine: STRATTERA 10MG

Dosage *form*: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:**
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 10,0 mg

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.)(PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO **RICO**

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO **RICO**
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA, RSA**
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/1.2/0521

Name of medicine: **STRATTERA 18 MG**

Dosage form: **CAPSULE**

Active ingredients: EACH CAPSULE **CONTAINS:**
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 18,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.)(PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO **RICO**

Packer: ELI LILLY & **CO** LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL **CARIBE**, CAROLINA, PUERTO **RICO**
BRECON **PHARMACEUTICALS**, HAY-ON-WYE,
HEREFORD, UK.

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE,U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO **RICO**
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 3 JUNE 2005

MRF 15(MBR 15)

Registration number: A38/1.2/0522

Name of medicine: STRATTERA 25 MG

Dosage form: **CAPSULE**

Active ingredients: EACH CAPSULE **CONTAINS:**
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 25,0 mg

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO RICO

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, **PUERTO RICO**
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, **UK**

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO RICO
SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROENKLOOF, **PRETORIA**, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 Months

Date of registration: 3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/1.2/0523

Name of medicine: **STRATTERA 40 MG**

Dosage form: **CAPSULE**

Active ingredients: EACH CAPSULE CONTAINS:
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO **ATOMOXETINE** 40,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **ELI LILLY (S.A.)(PTY) LTD**

Manufacturer: **ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO RICO
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK**

Packer: **ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, PUERTO **RICO****

Laboratory: **ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, **CAROLINA**, PUERTO RICO
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA**, RSA
ELI LILLY, BRYANSTON, GAUTENG, RSA**

Shelf-life: 36 months

Date of registration: 3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/1.2/0524

Name of medicine: STRATTERA 60 MG

Dosage form: CAPSULE

Active ingredients: EACH **CAPSULE** CONTAINS:
ATOMOXETINE HYDROCHLORIDE EQUIVALENT
TO ATOMOXETINE 60,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ELI LILLY (S.A.) (PTY) LTD

Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, **PUERTO RICO**

Packer: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL CARIBE, CAROLINA, **PUERTO RICO**
BRECON PHARMACEUTICALS, HAY-ON-WYE,
HEREFORD, UK

Laboratory: ELI LILLY & CO LTD, BASINGSTOKE,
HAMPSHIRE, U.K.
LILLY DEL **CARIBE, CAROLINA, PUERTO RICO**
SOUTH AFRICAN BUREAU OF **STANDARDS,**
GROENKLOOF, **PRETORIA, RSA**
ELI LILLY, BRYANSTON, GAUTENG, RSA

Shelf-life: 36 months

Date of registration: 3 JUNE 2005

MRF 15 (MBR 15)

Registration number: A38/26/0528

Name of medicine: METVIX CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g CREAM CONTAINS:
METHYL AMINOLEVULINATE HYDROCHLORIDE
EQUIVALENT TO METHYL AMINOLEVULINATE
160,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: GALDERMA LABORATORIES S.A.(PTY) LTD

Manufacturer: PENN PHARMACEUTICAL SERVICES LTD,
TREDEGAR, GWENT, U.K.

Packer: PENN PHARMACEUTICAL SERVICES LTD,
TREDEGAR, GWENT, U.R.

Laboratory: FPRC: COSI PHARMACEUTICALS, INDUSTRIA,
JOHANNESBURG, RSA
FPRR: GALDERMA LABORATORIES, BRYANSTON,
JOHANNESBURG, RSA

Shelf-life: 12 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/2.5/0567**

Name of **medicine**: **CIPLA – LAMOTRIGINE 25**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 M G**

Conditions of **registration**: **1, 2, 3, 4, 5, 6, 7**

Applicant: **CPLA LEE SCIENCES (PTY) LTD**

Manufacturer: **CPLA LTD, RAIGAD, MAHARASHTRA, INDIA**

Packer: **CPLA LTD, RAIGAD, MAHARASHTRA, INDIA**

Laboratory: **FPRC:** **CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA**
FPRR: **CIPLA LIFE SCIENCES, ROSENPARK, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/2.5/0568

Name of medicine: CIPLA – LAMOTRIGINE 50

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: **FPRC:** CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0569

Name of medicine: CIPLA – LAMOTRIGINE 100

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE **SCIENCES**(PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, **MAHARASHTRA**, INDIA

Laboratory: **FPRC:** CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE **SCIENCES**, ROSENPARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/2.5/0570**

Name of medicine: **CPLA – LAMOTRIGINE 200**

Dosage form: **TABLET**

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: **CIPLA LTD**, RAIGAD, MAHARASHTRA, **INDIA**

Laboratory: FPRC: CPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, RSA

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/21.1/0578

Name of medicine: APEX-METFORMIN 500 MG **TABLETS**

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS:**
METFORMIN HYDROCHLORIDE 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH **STERILAB** LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH **STERILAB LTD, VIRGONAGAR,**
BANGALORE, **INDIA**

Laboratory: FPRC: **MEDREICH **STERILAB** LTD, VIRGONAGAR,**
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, **RSA**
INSTITUTE FOR PHARMACEUTICAL **SERVICES,**
BARDENE, **BOKSBURG, RSA**
INSPECTORATE M&L, ORMONDE, **JOHANNESBURG**
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A3812 1.110579**

Name of **medicine**: **APEX-METFORMINFORTE 850 MG TABLETS**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:**
METFORMIN HYDROCHLORIDE 850,0 MG

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: **MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA**

Packer: **MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA**

Laboratory: FPRC: **MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA**
**SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA**
**INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA**
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/10.2.2/0584

Name of medicine: SINGULAIR SPRINKLES

Dosage form: GRANULES

Active ingredients: EACH PACKET CONTAINS:
MONTELUKAST SODIUM EQUIVALENT TO
MONTELUKAST 4,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MSD (PTY) LTD

Manufacturer: MERCK MANUFACTURING DIVISION, WEST POINT,
PA, USA

Packer: ANDERSON PACKAGING, ROCKFORD, IL, USA
MMD-HAARLEM, HAARLEM, THE NETHERLANDS
MSD, HALFWAY HOUSE, RSA

Laboratory: FPRC: MERCK MANUFACTURING DIVISION, WEST POINT,
PA, USA
FPRC/FPRR: MSD, HALFWAY HOUSE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0585

Name of medicine: ASPEN LAMOTRIGINE 25 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 25,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.5/0586

Name of medicine: ASPEN LAMOTRIGINE 50 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS INC, **ONTARIO, CANADA**
LENNON LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM PHARMACEUTICALS INC, **ONTARIO, CANADA**
LENNON **LTD**, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS **INC, ONTARIO, CANADA**
LENNON LTD, KORSTEN, **PORT ELIZABETH**
SOUTH **AFRICAN** BUREAU OF **STANDARDS**,
GROENKLOOF, PRETORIA, **RSA**
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, **UNIVERSITY**, POTCHEFSTROOM
FPRR: PHARMACARE LTD, **KORSTEN**, PORT ELIZABETH

Shelf-life: **24 months**

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A38/2.5/0587**

Name of medicine: **ASPEN LAMOTRIGINE 100MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Packer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Laboratory: FPRC: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROEMCLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRR: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH****

Shelf life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A3812.510588**

Name of medicine: **ASPEN LAMOTRIGINE 200 MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LAMOTRIGINE 200,0 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Packer: **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH**

Laboratory: **F'PRC:** **GENPHARM PHARMACEUTICALS INC, ONTARIO,
CANADA
LENNON LTD, KORSTEN, PORT ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRR:** **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/15.4/0592

Name of medicine: **REFRESH LIQUIGEL**

Dosage form: EYE DROPS

Active ingredients: EACH **1,0** ml SOLUTION **CONTAINS:**
CARBOXYMETHYLCELLULOSE SODIUM 10,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ALLERGAN PHARMACEUTICALS (PTY) LTD

Manufacturer: ALLERGAN INC., WACO, TEXAS

Packer: ALLERGAN INC., WACO, TEXAS

Laboratory: FPRC: ALLERGAN INC., WACO, TEXAS
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: ALLERGAN PHARMACEUTICALS,
HALFWAY HOUSE, RSA

Shelf-life: 18 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: **A38/2.6.5/0595**

Name of medicine: **ABILIFY 10MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
ARIPRAZOLE 10,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

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

Manufacturer: **BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO**

Packer: **BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA**

Laboratory: FPRC: **BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO
BRISTOLMYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE **PARK**, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL, MANUFACTURER,
WADEVILLE, GERMISTON, **RSA**
FPRR: **BRISTOLMYERS SQUIBB, BEDFORDVIEW, **RSA******

Shelf life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number:	A38/2.6.5/0596
Name of medicine:	ABILIFY 15 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: ARIPRAZOLE 15,0 MG
Conditions of registration:	1,2,3,4,5,6,7
Applicant:	BRISTOL-MYERS SQUIBB (PTY) LTD
Manufacturer:	BRISTOL-MYERS SQUIBB MANUFACTURING CO, MAYAGUEZ, PUERTO RICO
Packer:	BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD, NOBLE PARK , VICTORIA, AUSTRALIA
Laboratory:	FPRC: BRISTOL-MYERS SQUIBB MANUFACTURING CO, MAYAGUEZ, PUERTO RICO BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD, NOBLE PARK, VICTORIA, AUSTRALIA CONSULTING CHEMICAL LABORATORIES, STAR STREET, BOKSBURG, RSA MERCK PHARMACEUTICAL MANUFACTURER, WADEVILLE, GERMISTON, RSA FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A38/2.6.5/0598

Name of medicine: ABILIFY 30 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ARIPRAZOLE 30,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO

Packer: BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE PARK, VICTORIA, AUSTRALIA

Laboratory: **FPRC:** BRISTOL-MYERS **SQUIBB** MANUFACTURING CO,
MAYAGUEZ, PUERTO RICO
BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD,
NOBLE **PARK**, VICTORIA, AUSTRALIA
CONSULTING CHEMICAL **LABORATORIES**,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, **RSA**
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, **RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A38/20.1.1/0632**

Name of medicine: **REZIDIME 1000 INJECTION**

Dosage form: **INJECTION**

Active ingredients: **EACH VIAL CONTAINS:
CEFTAZIDIME PENTAHYDRATE EQUIVALENT TO
CEFTAZIDIME 1,0 G**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **RESMED HEALTHCARE**

Manufacturer: **ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA**

Packer: **ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA**

Laboratory: FPRC: **ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA**
FPRR: **RESMED HEALTHCARE, SPRINGFIELD PARK,
DURBAN, RSA**

Shelf-life: **36 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/20.1.1/0634

Name of medicine: ~~REZIDIME~~ 2000 INJECTION

Dosage **form**: **INJECTION**

Active ingredients: EACH VIAL CONTAINS;
~~CEFTAZIDIME~~ PENTAHYDRATE EQVALENT **TO**
~~CEFTAZIDIME~~ **2,0 G**

Conditions of registration: I, 2, 3, 4, 5, 6, 7

Applicant: RESMED **HEALTHCARE**

Manufacturer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, **INDIA**

Packer: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, **INDIA**

Laboratory: FPRC: ASTRAL PHARMACEUTICAL INDUSTRIES,
GUJARAT, INDIA
FPRR: RESMED HEALTHCARE, SPRINGFIELD **PARK**,
DURBAN, RSA

Shelf-life: 36 ~~months~~

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A38/13.4.1/0668

Name of medicine: ASPEN MOMETASONE CREAM

Dosage form: CREAM

Active ingredients: EACH 1,0 g *CREAM CONTAINS:*
MOMETASONE FUROATE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: **FPRC:** SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number :	A38/20.1.1/0692
Name of medicine:	ZITHROGEN 250
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN MONOHYDRATE HEMIETHANOLATE EQUIVALENT TO AZITHROMYCIN 250,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GERARD LABORATORIES, DUBLIN, IRELAND
Packer:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GEWSTON, RSA
Laboratory:	FPRC: GERARD LABORATORIES , DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GEWSTON, RSA SOUTH AFRICAN BUREAU OF STANDARDS , GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY , UNIVERSITY, POTCHEFSTROOM, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A38/20.1.1/0693
Name of medicine:	ZITHROGEN 500
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN MONOHYDRATE HEMIETHANOLATE EQUIVALENT TO AZITHROMYCIN 500,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	GERARD LABORATORIES, DUBLIN, IRELAND
Packer:	GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON , RSA SOUTH AFRICAN BUREAU OF STANDARDS , GROENKLOOF , PRETORIA, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY , POTCHEFSTROOM, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration **number**: **A38/20.1.1/0715**

Name of medicine: CIPRODAC 500

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**
CIPROFLOXACIN HYDROCHLORIDE EQUIVALENT
TO CIPROFLOXACIN 500,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **BE-TABS** PHARMACEUTICALS (PTY) LTD

Manufacturer: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, **INDIA**

Packer: **CADILA** PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, **INDIA**

Laboratory: FPRC: CADILA PHARMACEUTICALS LTD, AHMEDABAD,
GUJARAT, **INDIA**
FPRR: BE-TABS PHARMACEUTICALS, ROODEPOORT, **RSA**

Shelf-life: 36 months

Date **of** registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/2.5/0002
Name of medicine:	ASPEN LAMOTRIGINE 25 MG DISPERSIBLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 25,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY , POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0003

Name of medicine: ASPEN LAMOTRIGINE 50 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET **CONTAINS:**
LAMOTRIGINE 50,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Laboratory: FPRC: GENPHARM PHARMACEUTICALS Inc, ONTARIO,
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.5/0004

Name of medicine: ASPEN LAMOTRIGINE 100 MG DISPERSIBLE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LAMOTRIGINE 100,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM PHARMACEUTICALS Inc, **ONTARIO,**
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH

Packer: GENPHARM PHARMACEUTICALS Inc, **ONTARIO,**
CANADA
ASPEN PHARMACARE LTD, **KORSTEN, PORT**
ELIZABETH

Laboratory: **FPRC:** GENPHARM PHARMACEUTICALS Inc, **ONTARIO,**
CANADA
ASPEN PHARMACARE LTD, KORSTEN, PORT
ELIZABETH
SOUTH AFRICAN BUREAU OF **STANDARDS,**
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number:	A39/2.5/0006
Name of medicine:	ASPEN LAMOTRIGINE 5 MG DISPERSIBLE
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 5,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number:	A39/2,5/0007
Name of medicine:	ASPEN LAMOTRIGINE 200 MG DISPERSIBLE
Dosage form :	TABLET
Active ingredients:	EACH TABLET CONTAINS: LAMOTRIGINE 200,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	PHARMACARE LIMITED
Manufacturer:	GENPHARM PHARMACEUTICALS Inc, ONTARIO , CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Packer:	GENPHARM PHARMACEUTICALS Inc , ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS Inc, ONTARIO, CANADA ASPEN PHARMACARE LTD, KORSTEN, PORT ELIZABETH SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA RESEARCH INSTITUTE FOR PHARMACEUTICAL SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR:	PHARMACARE LTR, KORSTEN, PORT ELIZABETH
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR15)

Registration number :	A39/35/0016
Name of medicine:	ZEVALIN
Dosage form:	INFUSION
Active ingredients:	EACH 1,0ml SOLUTION CONTAINS: IBRITUMOMAB TIUXETAN 1,6 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SCHEIUNG (PTY) LTD
Manufacturer:	IDEC PHARMACEUTICALS, SAN DIEGO, CA, USA BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA
Packer:	BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, INDIANA, USA SCHERING AG, BERLIN, GERMANY
Laboratory:	FPRC: SCHERING AG, BERLIN, GERMANY SOUTH AFRICAN BUREAU OF STANDARDS , GROENKLOOF, PRETORIA FPRR: SCHERING, MIDRAND, RSA
Shelf-life:	12 months for BULK SOLUTIONS 24 months for KIT SOLUTIONS
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/20.1.1/0020
Name of medicine:	MACROZIT 500 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: AZITHROMYCIN 500,0 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	CAMOX PHARMACEUTICALS (PTY) LTD
Manufacturer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Packer:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA
Laboratory:	INTAS PHARMACEUTICALS LTD, MATODA, GUJARAT, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE, BOKSBURG, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG, RSA CAMOX PHARMACEUTICALS, ROSEBANK, RSA
Shelf-life:	24 months
Date of registration:	23 SEPTEMBER 2005

MRF 15 (MBR 15)

Registration number: **A39/5.1010062**

Name of medicine: **ASPEN ONDANSETRON 4MG/2 ML**

Dosage form: **INJECTION**

Active ingredients: **EACH 1,0 ml LIQUID CONTAINS:**
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 2,0 mg

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Packer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Laboratory: **FPRC:** **STRIDES ARCOLAB LTD, BANGALORE, INDIA**
FPRR: **LENNON LTD, KORSTEN, PORT ELIZABETH**
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A39/5.10/0063**

Name of medicine: **ASPEN ONDANSETRON 8 MG/4 ML**

Dosage **form**: **INJECTION**

Active ingredients: EACH 1,0 m LIQUID CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON **2,0 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Packer: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**

Laboratory: FPRC: **STRIDES ARCOLAB LTD, BANGALORE, INDIA**
LENNON LTD, KORSTEN, PORT ELIZABETH
FPRR: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15

Registration number: A39/20.2.8/0088

Name of medicine: REYATAZ **150** MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE EQUIVALENT TO
ATAZANAVIR 150,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BRISTOL-MYERS SQUIBB (PTY) LTD

Manufacturer: BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA

Packer: BRISTOL-MYERS SQUIBB CO, **EVANSVILLE**,
INDIANA, USA
BRISTOL LABORATORIES **INTERNATIONAL**,
EDIFICIO, PANAMA
BRISTOL-MYERS SQUIBB, MEYMAC, FRANCE

Laboratory: FPRC: BRISTOL-MYERS SQUIBB CO, **EVANSVILLE**,
INDIANA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR **STREET**, BOKSBURG, **RSA**
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA
FPRR: BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA

Shelf-life: **24** months

Date *of* registration: **25 NOVEMBER 2005**

MRF 15

Registration number: **A39/20.2.8/0089**

Name of medicine: **REYATAZ 200 MG**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:
ATAZANAVIR SULPHATE EQUIVALENT TO
ATAZANAVIR 200,0 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

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

Manufacturer: **BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA**

Packer: **BRISTOL-MYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
BRISTOL LABORATORIES INTERNATIONAL,
EDIFICIO, PANAMA
BRISTOL-MYERS SQUIBB, MEYMAC, FRANCE**

Laboratory: FPRC: **BRISTOLMYERS SQUIBB CO, EVANSVILLE,
INDIANA, USA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
MERCK PHARMACEUTICAL MANUFACTURER,
WADEVILLE, GERMISTON, RSA**
FPRR: **BRISTOL-MYERS SQUIBB, BEDFORDVIEW, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0 108
Name of medicine:	LISOZIDE 10 (TABLETS)
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: LISINOPRIL DIHYDRATE EQUIVALENT TO LISINOPRIL 10,0 mg HYDROCHLOROTHIAZIDE 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	AUSTELL LABORATORIES (PTY) LTD
Manufacturer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Packer:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA
Laboratory:	IPCA LABORATORIES LTD, DADRA & NAGAR HAVELI, INDIA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA INSPECTORATE M&L, ORMONDE, JOHANNESBURG INSTITUTE FOR PHARMACEUTICAL SERVICES, BARDENE , BOKSBURG, RSA AUSTELL LABORATORIES, SAXONWOLD, RSA
Shelf-life:	24 months
Date of registration:	29 JULY 2005

MRF 15 (MBR 15)

Registration number: **A39/7.1.3/0 109**

Name of medicine: **LISOZIDE 20 (TABLETS)**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
LISINOPRIL DIHYDRATE EQUIVALENT TO
LISINOPRIL 20,0 mg
HYDROCHLOROTHIAZIDE 12,5 mg**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **AUSTELL LABORATORIES (PTY) LTD**

Manufacturer: **IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA**

Packer: **IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA**

Laboratory: **IPCA LABORATORIES LTD, DADRA & NAGAR
HAVELI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
AUSTELL LABORATORIES, SAXONWOLD, RSA**

Shelf-life: **24 months**

Date *of* registration: **29 JULY 2005**

MRF 15 (MBR 15)

Registration **number** : A39/7.1.3/0141

Name of medicine: **RAMPIL 1,25 MG**

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 **MG**

Conditions **of** registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM **INC**, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM INC, ETOBICOKE, **ONTARIO**, CANADA
MERCK FARMA y **QUIMICA**, BARCELONA, SPAIN
PHARMACARE LTD, **KORSTEN**, **PORT** ELIZABETH

Laboratory: **F'PRC:** GENPHARM **INC**, ETOBICOKE, **ONTARIO**, CANADA
MERCK FARMA y **QUIMICA**, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF
STANDARDS, GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, **PRETORIA**, RSA
FPRC/FPRR: PHARMACARE LTD, RORSTEN, PORT ELIZABETH

Shelf-life: 24 ~~months~~

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A39/7.1.3/0142**

Name of medicine: **RAMPIL 2,5 MG**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:**
RAMPIL 2,5 MG

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA**
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA**
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: **FPRC** **GENPHARM INC, ETOBICOKE, ONTARIO, CANADA**
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration number: A39/7.1.3/0143

Name of medicine: **RAMPIL 5 MG**

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM **INC**, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, SPAIN
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, BARCELONA, **SPAIN**
PHARMACARE LTD, **KORSTEN**, PORT ELIZABETH

Laboratory: FPRC: GENPHARM INC, ETOBICOKE, ONTARIO, CANADA
MERCK FARMA y QUIMICA, **BARCELONA**, SPAIN
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA**
RESEARCH **INSTITUTE** FOR PHARMACEUTICAL
SERVICES, **UNIVERSITY**, PRETORIA, RSA
FPRC/FPRR: **PHARMACARE LTD, KORSTEN**, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0144

Name of medicine: RAMPIL 10 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE **CONTAINS:**
RAMIPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: GENPHARM INC, ETOBICOKE, ONTARIO, **CANADA**
MERCK FARMA y QUIMICA, BARCELONA, **SPAIN**
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Packer: GENPHARM **INC**, ETOBICOKE, ONTARIO, **CANADA**
MERCK FARMA y QUIMICA, BARCELONA, **SPAIN**
PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Laboratory: FPRC: GENPHARM **INC**, ETOBICOKE, **ONTARIO**, **CANADA**
MERCK FARMA y QUIMICA, BARCELONA, **SPAIN**
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA**
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, PRETORIA, RSA
FPRC/FPRR: PHARMACARE **LTD**, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0145
Name of medicine:	MERCK-CARVEDILOL 3,125
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 3,125 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN , IRELAND GENEFUCS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECFAR S.A., ATHENS , GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN , IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY , POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0146
Name of medicine:	MERCK-CARVEDILOL 6,25
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 6,25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0147
Name of medicine:	MERCK-CARVEDILOL 12,5
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: CARVEDILOL 12,5 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENEFUCS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA
	FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0148
Name of medicine:	MERCK-CARVEDILOL 25
Dosage form:	TABLET
Active ingredients :	EACH TABLET CONTAINS: CARVEDILOL 25 mg
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	XIXIA PHARMACEUTICALS (PTY) LTD
Manufacturer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY, IRELAND
Packer:	SPECIFAR S.A., ATHENS, GREECE CHANELLE MEDICAL LTD, GALWAY , IRELAND Mc DERMOTT LABORATORIES, DUBLIN, IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA
Laboratory:	FPRC: SPECIFAR S.A., ATHENS , GREECE CHANELLE MEDICAL LTD, GALWAY , IRELAND Mc DERMOTT LABORATORIES , DUBLIN, IRELAND GENERICUS UK LTD, POTTERS BAR, HERTFORDSHIRE, UK MERCK PHARMACEUTICAL MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY , POTCHEFSTROOM, RSA SOUTH AFRICAN BUREAU OF STANDARDS, GROENKLOOF, PRETORIA, RSA FPRR: XIXIA PHARMACEUTICALS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: A3913410162

Name of medicine: SABAX LOW GLUCOSE ACID **DIASOL**

Dosage form: **SOLUTION**

Active ingredients: EACH 1000,0 ml SOLUTION **CONTAINS:**

SODIUM CHLORIDE	214,8 G
GLACIAL ACETIC ACID	6,310 G
POTASSIUM CHLORIDE	3,920 G
CALCIUM CHLORIDE DIHYDRATE	7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE	2,135 G
GLUCOSE MONOHYDRATE	38,50 G

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: ADCOCK **INGRAM** CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: **FPRC:** WICKHAM **LABORATORIES**, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**

Shelf-life: **24** months

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration number: A3913410163

Name of medicine: SABAX LOW MAGNESIUM ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 214,8 G
GLACIAL ACETIC ACID 6,310 G
POTASSIUM CHLORIDE 3,920 G
CALCIUM CHLORIDE **DIHYDRATE** 7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE 2,135 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL **CARE**, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0164

Name of medicine: **SABAX** LIQUID BICARBONATE
CONCENTRATE 8,4 %

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM BICARBONATE 84,0 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: **FPRC:** WICKHAM LABORATORIES, WICKHAM,
FPRR; HAMPSHIRE, U.K.
ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A3913410165

Name of medicine: SABAX STANDARD CHRONIC **ACID** DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:

SODIUM CHLORIDE	214,8 G
GLACIAL ACETIC ACID	6,310 G
POTASSIUM CHLORIDE	3,920 G
CALCIUM CHLORIDE DIHYDRATE	7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE	5,340 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK **INGRAM** CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM **LABORATORIES**, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK **INGRAM CRITICAL** CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0 168

Name of medicine: SABAX STANDARD ACUTE ACID DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:

SODIUM CHLORIDE	198,40 G
GLACIAL, ACETIC ACID	6,310 G
POTASSIUM CHLORIDE	3,920 G
CALCIUM CHLORIDE DIHYDRATE	7,720 G
MAGNESIUM CHLORIDE HEXAHYDRATE	5,340 G
GLUCOSE MONOHYDRATE	154,00 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL **CARE**, AEROTON, JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM, HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON, JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0 169

Name of medicine: SABAX HIGH **POTASSIUM ACID** DIASOL

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 198,40 G
GLACIAL ACETIC ACID 6,310 G
POTASSIUM CHLORIDE 9,130 G
CALCIUM CHLORIDE DIHYDRATE **7,720 G**
MAGNESIUM CHLORIDE HEXAHYDRATE 5,340 G
GLUCOSE MONOHYDRATE 154,00 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: **ADCOCK** INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK **INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRR: **ADCOCK INGRAM** CRITICAL CARE, AEROTON,
JOHANNESBURG, **RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/2.2/0184

Name of medicine: **MIDAZOLAM-CP 5 MG/5 ML**

Dosage form: INJECTION

Active ingredients: **EACH 5,0 ml AMPOULE CONTAINS:**
MIDAZOLAM 5,0 MG

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Packer: **LABORATORIOS** REIG JOFRE, BARCELONA, **SPAIN**

Laboratory: FPRC: LABORATORIOS **REIG** JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR **STREET**, BOKSBURG, **RSA**
FPRR: PHARMAPLAN, MIDRAND, **RSA**

Shelf-life: **24** months

Date *of* registration: **25** NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.2/0185

Name of medicine: MIDAZOLAM-CP 15 MG/3 ML

Dosage form: INJECTION

Active ingredients: EACH 3,0 ml AMPOULE **CONTAINS:**
MIDAZOLAM 15,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Packer: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN

Laboratory: FPRC: LABORATORIOS REIG JOFRE, BARCELONA, SPAIN
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A3 912210186**

Name of medicine: **MIDAZOLAM-CP 50 MG/10 ML**

Dosage form: **INJECTION**

Active ingredients: **EACH 10,0 ml AMPOULE CONTAINS:**
MIDAZOLAM 50,0 MG

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMAPLAN (PTY) LTD**

Manufacturer: **LABORATORIOS REIG JOFRE, BARCELONA, SPAIN**

Backer: **LABORATORIOS REIG JOFRE, BARCELONA, SPAIN**

Laboratory: **FPRC:** **LABORATORIOS REIG JOFRE, BARCELONA, SPAIN**
COMBINO PHARM S.L., BARCELONA, SPAIN
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: **PHARMAPLAN, MIDRAND, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: **A39/1.2/02 16**

Name of medicine: **XET 20 TABLETS**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:
PAROXETINE HYDROCHLORIDE EQUIVALENT TO
PAROXETINE 20,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **ZYDUS HEALTHCARE S.A.(PTY) LTD**

Manufacturer: **CADILA HEALTHCARE, SANAND, AHMEDABAD,
INDIA**

Packer: **CADILA HEALTHCARE, SANAND, AHMEDABAD,
INDIA**

Laboratory: **F'PRC: CADILA HEALTHCARE, SANAND, AHMEDABAD,
INDIA
RESEARCH INSTITUTE FOR INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, PRETORIA, RSA
FPRR: ZYDUS HEALTHCARE, POTCHEFSTROOM, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A3912.810228

Name of medicine: IBUMOL BANANA

Dosage form: SUSPENSION

Active ingredients: EACH 10,0 ml SUSPENSION CONTAINS:
PARACETAMOL **250,0** mg
IBUPROFEN 200,0 mg

Conditions of registration: **1,2, 3, 4, 5, 6, 7**

Applicant: PHARMACARE LIMITED

Manufacturer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, **WILSONIA**, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, **WILSONIA**, EAST LONDON

Laboratory: FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN **PHARMACARE**, **WILSONIA**, EAST LONDON
FPRC: SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA**, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA

Shelf-life: **24** months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration **number:** A39/2.8/0229

Name of medicine: IBUMOL GRAPE

Dosage form: SUSPENSION

Active ingredients: EACH 10,0 ml SUSPENSION CONTAINS :
PARACETAMOL 250,0 mg
IBUPROFEN 200,0 mg

Conditions of registration: 1,2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: **PHARMACARE LTD**, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: **FPRC:** ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
RESEARCH INSTITUTE **FOR** PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM, RSA
FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0231
Name of medicine:	PREXUM 2,5 MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 2,5 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	BIOGARAN SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY , FRANCE SERVER INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVIER INDUSTRIE, GIDY , FRANCE SERVER INDUSTRIES LTD, ARKLOW, IRELAND TECHNIKON LABORATORIES, ROBERTVILLE, RSA
Laboratory:	FPRC: LES LABORATOIRES SERVIER INDUSTRE, GIDY , FRANCE SERVER INDUSTRIES LTD, ARKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG FPRR: BIOGARAN S.A., RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0232

Name of medicine: **PREXUM 5 MG**

Dosage form: **TABLET**

Active ingredients: **EACH TABLET CONTAINS:**
PERINDOPRIL ARGININE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: **LES LABORATOIRES SERVIER INDUSTRIE, GIDY,**
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: **LES LABORATOIRES SERVIER INDUSTRIE?, GIDY,**
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: **FPRC:** **LES LABORATOIRES SERVIER INDUSTRIE, GIDY,**
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
FPRR: **BIOGARAN S.A., RIVONIA, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration **number** : A39/7.1.3/0233

Name of medicine: PREXUM 10 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BIOGARAN SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVER **INDUSTRIE, GIDY,**
FRANCE
SERVIER **INDUSTRIES** LTD, **ARKLOW,** IRELAND

Packer: LES LABORATOIRES SERVIER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, **IRELAND**
TECHNIKON LABORATORIES, ROBERTVILLE, **RSA**

Laboratory: FPRC: LES LABORATOIRES SERVER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
INSPECTORATE **M&L,** ORMONDE, JOHANNESBURG
FPRR: BIOGARAN S.A., RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR15)

Registration number: A39/7.1.3/0234

Name of medicine: **COVERSYL 2,5 MG**

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**
PERINDOPRIL ARGININE 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SERVIER **LABORATORIES** SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVIER INDUSTRIE, **GIDY**,
FRANCE
SERVIER INDUSTRIES LTD, **ARKLOW**, IRELAND

Packer: LES **LABOMTOIRES** SERVIER INDUSTRIE, **GIDY**,
FRANCE
SERVIER INDUSTRIES LTD, **ARKLOW**, IRELAND
TECHNIKON LABORATORZES, ROBERTVILLE, RSA

Laboratory: FPRC: LES **LABORATOIRES** SERVIER INDUSTRIE, **GIDY**,
FRANCE
SERVIER INDUSTRIES LTD, **ARKLOW**, IRELAND
FPRR: **INSPECTORATE M&L, ORMONDE**, JOHANNESBURG
SERVIER LABORATORIES, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0235

Name of medicine: COVERSYL 5 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
PERINDOPRIL ARGININE 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SERVER LABORATORIES SOUTH AFRICA (PTY) LTD

Manufacturer: LES LABORATOIRES SERVER INDUSTRIE, GIDY,
FRANCE
SERVIER INDUSTRIES LTD, ARKLOW, IRELAND

Packer: LES LABOMTOIRES SERVER INDUSTRIE, GIDY,
FRANCE
SERVER INDUSTRIES LTD, ARKLOW, IRELAND
TECHNIKON LABORATORIES, ROBERTVILLE, RSA

Laboratory: FPRC: LES **LABORATOIRES** SERVER **INDUSTRIE, GIDY,**
FRANCE
SERVER **INDUSTRIES** LTD, ARKLOW, IRELAND
INSPECTORATE M&L, **ORMONDE, JOHANNESBURG**
FPRR: SERVER LABORATORIES, RIVONIA, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number :	A39/7.1.3/0236
Name of medicine:	COVERSYL 10MG
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: PERINDOPRIL ARGININE 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	SERVER LABORATORIES SOUTH AFRICA (PTY) LTD
Manufacturer:	LES LABORATOIRES SERVER INDUSTRIE, GIDY , FRANCE SERVIER INDUSTRIES LTD, ARKLOW, IRELAND
Packer:	LES LABORATOIRES SERVER INDUSTRIE, GIDY , FRANCE SERVER INDUSTRIES LTD, ARKLOW, IRELAND TECHNIKON LABORATORIES , ROBERTVILLE, RSA
Laboratory:	FPRC: LES LABORATOIRES SERVER INDUSTRIE, <i>GIDY</i> , FRANCE SERVIER INDUSTRIES LTD, ARKLOW, IRELAND INSPECTORATE M&L, ORMONDE, JOHANNESBURG FPRR: SERVIER LABORATORIES, RIVONIA, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: **A39/20.2.8/0249**

Name of medicine: **ASPEN ZIDOVUDINE 100MG**

Dosage form: **CAPSULE**

Active ingredients: **EACH CAPSULE CONTAINS:
ZIDOVUDINE 100,0 MG**

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: **PHARMACARE LIMITED**

Manufacturer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON**

Packer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH
ASPEN PHARMACARE, WILSONIA, EAST LONDON**

Laboratory: FPRC: **ASPEN PHARMACARE, WILSONIA, EAST LONDON
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENIUOOF, PRETORIA, RSA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration number: A39/20.2.8/0250

Name of medicine: **ASPEN ZIDOVUDINE 250 MG**

Dosage form: **CAPSULE**

Active ingredients: EACH **CAPSULE** CONTAINS:
ZIDOVUDINE 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMACARE LIMITED

Manufacturer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Packer: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**
ASPEN PHARMACARE, WILSONIA, EAST LONDON

Laboratory: FPRC: **ASPEN PHARMACARE, WILSONIA, EAST LONDON**
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA
RESEARCH INSTITUTE FOR PHARMACEUTICAL
SERVICES, UNIVERSITY, POTCHEFSTROOM
FPRC/FPRR: **PHARMACARE LTD, KORSTEN, PORT ELIZABETH**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0255

Name of **medicine**: **APEX-RANITIDINE 150MG**

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 150,0 MG

Conditions of registration: **1, 2, 3, 4, 5, 6, 7**

Applicant: CAMOX **PHARMACEUTICALS**(PTY) LTD

Manufacturer: **MEDREICH STERILAB LTD, VIRGONAGAR,**
BANGALORE, INDIA

Packer: **MEDREICH STERILAB LTD, VIRGONAGAR,**
BANGALORE, INDIA

Laboratory: FPRC: **MEDREICH STERILAB LTD, VIRGONAGAR,**
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: **INSPECTORATE M&L, ORMONDE, JOHANNESBURG**
CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0256

Name of medicine: APEX-RANITIDINE 300 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 300,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: **FPRC:** MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0276

Name of medicine: CAMOX-RANITIDINE 150MG

Dosage form: TABLET

Active ingredients: **EACH** TABLET CONTAINS:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 150,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS(PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Laboratory: FPRC: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL **SERVICES,**
BARDENE, BOKSBURG, RSA
FPRR: INSPECTORATE M&L, ORMONDE, **JOHANNESBURG**
CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 ~~months~~

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.4.3/0277

Name of medicine: CAMOX-RANITIDINE:300 MG

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
RANITIDINE HYDROCHLORIDE EQUIVALENT TO
RANITIDINE 300,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA

Packer: MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, **INDIA**

Laboratory: **FPRC:** MEDREICH STERILAB LTD, VIRGONAGAR,
BANGALORE, INDIA
SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROENKLOOF, PRETORIA, RSA
INSTITUTE FOR PHARMACEUTICAL SERVICES,
BARDENE, BOKSBURG, RSA
FPRR: INSPECTORATE M&L, ORMONDE, JOHANNESBURG
CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number : A39/20.1.1/0292

Name of medicine: SANDOZ CLARITHROMYCIN 125 P

Dosage form: **SUSPENSION**

Active ingredients: EACH 5,0 ml **SUSPENSION** CONTAINS:
CLARITHROMYCIN 125,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: **LEK** d.d., LJUBLJANA, SLOVENIA
KERN PHARMA S.A., VENUS, TERRASSA, SPAIN

Packer: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/20.1.110293

Name of medicine: SANDOZ CLARITHROMYCIN 250 P

Dosage form: SUSPENSION

Active ingredients: EACH 5,0 ml SUSPENSION CONTAINS:
CLARITHROMYCIN 250,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: LEK d.d., LJUBLJANA, SLOVENIA
KERN PHARMA S.A., VENUS, TERRASSA, SPAIN

Packer: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
NOVARTIS, SPARTAN, KEMPTON PARK, RSA

Laboratory: FPRC: KERN PHARMA S.A., VENUS, TERRASSA, SPAIN
FPRC/FPRR: NOVARTIS, SPARTAN, KEMPTON PARK, RSA
FPRR: SANDOZ, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration number: A39/7.1.3/0304

Name of medicine: APEX – RAMIPRIL 1,25 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 1,25 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, **INDIA**

Packer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, **INDIA**

Laboratory: FPRC: IPCA LABORATORIES LTD, **DADRA &**
NAGAR HAVELI, **INDIA**
SOUTH AFRICAN BUREAU OF STANDARDS,
GROEMCLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0305

Name of medicine: **APEX – RAMIPRIL 2,5 MG**

Dosage form: CAPSULE

Active ingredients: EACH **CAPSULE** CONTAINS;
RAMIPRIL 2,5 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Packer: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA

Laboratory: FPRC: IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA, RSA**
INSPECTORATE M&L, ORMONDE, **JOHANNESBURG**
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15(MBR 15)

Registration number: A39/7.1.3/0306

Name of medicine: APEX – RAMIPRIL 5 MG

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 5,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CAMOX PHARMACEUTICALS (PTY) LTD

Manufacturer: IPCA LABORATORIES LTD, DADRA &
NAGAR **HAVELI**, INDIA

Packer: IPCA LABORATORIES LTD, **DADRA &**
NAGAR HAVELI, INDIA

Laboratory: FPRC IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, **INDIA**
SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROEMKLOOF, PRETORIA, RSA
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, **RSA**
FPRR: CAMOX PHARMACEUTICALS, ROSEBANK, RSA

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/7.1.3/0307

Name of medicine: APEX – RAMIPRIL 10 **MG**

Dosage form: CAPSULE

Active ingredients: EACH CAPSULE CONTAINS:
RAMIPRIL 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **CAMOX PHARMACEUTICALS (PTY) LTD**

Manufacturer: **IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA**

Packer: **IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA**

Laboratory: **FPRC:** **IPCA LABORATORIES LTD, DADRA &
NAGAR HAVELI, INDIA**
**SOUTH AFRICAN BUREAU OF STANDARDS,
GROEMKLOOF, PRETORIA, RSA**
INSPECTORATE M&L, ORMONDE, JOHANNESBURG
**INSTITUTE FOR PHARMACEUTICAL SERVICES,
SILVERTONDALE, RSA**
FPRR: **CAMOX PHARMACEUTICALS, ROSEBANK, RSA**

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/2.2/0348

Name of medicine: MERCK-ZOLPIDEM

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**
ZOLPIDEM TARTRATE 10,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, **GERMISTON, RSA**
MERCK FARMA y QUIMICA SA, BARCELONA,
SPAIN

Packer: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GEWSTON, **RSA**
MERCK FARMA y QUIMICA SA, BARCELONA,
SPAIN
GERARD **LABORATORIES, DUBLIN, IRELAND**
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK

Laboratory: FPRC: MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, **GERMISTON, RSA**
MERCK FARMA y QUIMICA SA, BARCELONA,
SPAIN
GERARD **LABORATORIES, DUBLIN, IRELAND**
GENERICS UK LTD, POTTERS BAR,
HERTFORDSHIRE, UK
RESEARCH INSTITUTE FOR **INDUSTRIAL**
PHARMACY, UNIVERSITY, POTCHEFSTROOM, **RSA**
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, **PRETORIA, RSA**

FPRR: MERCK GENERICS RSA, MODDERFONTEIN, **RSA**

Shelf-life: **24 months**

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0349
Name of medicine:	MERCK-FOSINOPRIL 20
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FOSINOPRIL SODIUM 20,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO , CANADA GENERICS [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory: FPRC:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA GENERICS [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY , POTCHEFSTROOM
FPRR:	MERCK GENERICS , MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/34/0400

Name of medicine: SABAX **LOW** CALCIUM **ACID** DIASOL (1,25 mmol/l)

Dosage form: SOLUTION

Active ingredients: EACH 1000,0 ml SOLUTION CONTAINS:
SODIUM CHLORIDE 214,8 G
GLACIAL, ACETIC ACID 6,310 G
POTASSIUM CHLORIDE 3,920 G
CALCIUM CHLORIDE DIHYDRATE 6,430 G
MAGNESIUM CHLORIDE HEXAHYDRATE 2,135 G

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD

Manufacturer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Packer: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Laboratory: FPRC: WICKHAM LABORATORIES, WICKHAM,
HAMPSHIRE, U.K.
FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE, AEROTON,
JOHANNESBURG, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.9/0406

Name of medicine: LOPIDUM

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOPERAMIDE HYDROCHLORIDE 2,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA MEDPRO (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, **RAIGAD**, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA MEDPRO, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/11.9/0407

Name of medicine: CIPLA-LOPERAMIDE

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
LOPERAMIDE HYDROCHLORIDE 2,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: CIPLA LIFE SCIENCES (PTY) LTD

Manufacturer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Packer: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA

Laboratory: FPRC: CIPLA LTD, RAIGAD, MAHARASHTRA, INDIA
FPRR: CIPLA LIFE SCIENCES, ROSENPARK, BELLVILLE, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR15)

Registration number: A39/5.10/0413

Name of medicine: ODARON 4MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON **HYDROCHLORIDE** EQUIVALENT
TO ONDANSETRON 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Packer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Laboratory: **FPRC:** M J PHARMACEUTICALS LTD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15(MBR 15)

Registration **number**: A39/5.10/0414

Name of medicine: ODARON 8 MG TABLETS

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
ONDANSETRON HYDROCHLORIDE EQUIVALENT
TO ONDANSETRON 8,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Packer: M J PHARMACEUTICALS LTD, GUJARAT, INDIA

Laboratory: FPRC: M J PHARMACEUTICALS LTD, GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES, STAR
STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number:	A39/7.1.3/0441
Name of medicine:	MERCK-FOSINOPRIL 10
Dosage form:	TABLET
Active ingredients:	EACH TABLET CONTAINS: FOSINOPRIL SODIUM 10,0 MG
Conditions of registration:	1, 2, 3, 4, 5, 6, 7
Applicant:	MERCK GENERICS RSA (PTY) LTD
Manufacturer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA
Packer:	GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA GENERICS [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND
Laboratory:	FPRC: GENPHARM PHARMACEUTICALS INC, ONTARIO, CANADA GENERICS [UK] LTD, POTTERS BAR, HERTFORDSHIRE, U.K. GERARD LABORATORIES, DUBLIN, IRELAND MERCK PHARMACEUTICALS MANUFACTURING, WADEVILLE, GERMISTON, RSA RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, UNIVERSITY, POTCHEFSTROOM FPRR: MERCK GENERICS, MODDERFONTEIN, RSA
Shelf-life:	24 months
Date of registration:	25 NOVEMBER 2005

MRF 15 (MBR 15)

Registration number: A39/5.10/0448

Name of medicine: ODARON 4 MG INJECTION

Dosage form: INJECTION

Active *ingredients*: EACH 1,0ml SOLUTION CONTAINS:
ONDASETRON HYDROCHLORIDE EQUIVALENT TO
ONDANSETRON 2,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: PHARMAPLAN (PTY) LTD

Manufacturer: M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA

Packer: M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA

Laboratory: FPRC: M J PHARMACEUTICALS LTD, PANCHMAHAL,
GUJARAT, INDIA
CONSULTING CHEMICAL LABORATORIES,
STAR STREET, BOKSBURG, RSA
FPRR: PHARMAPLAN, MIDRAND, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: A39/5.10/0509

Name of medicine: MERCK-ONDANSETRON 4 MG/2 ML

Dosage form: INJECTION

Active ingredients: EACH 2,0 ml AMPOULE CONTAINS:
ONDANSETRON HYDROCHLORIDE
EQUIVALENT TO ONDANSETRON 4,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, **DUBLIN**, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH **INSTITUTE FOR** INDUSTRIAL
PHARMACY, UNIVERSITY, POTCHEFSTROOM
SOUTH AFRICAN BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: **24** months

Date of registration: 25 NOVEMBER 2005

MRF 15

Registration number: A39/5.10/0510

Name of medicine: MERCK-ONDANSETRON 8 MG/4 ML

Dosage form: INJECTION

Active ingredients: EACH 4,0 ml **AMPOULE** CONTAINS:
ONDANSETRON HYDROCHLORIDE
EQUIVALENT TO ONDANSETRON 8,0 MG

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: MERCK GENERICS RSA (PTY) LTD

Manufacturer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE

Packer: PHARMATHEN PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA

Laboratory: FPRC: **PHARMATHEN** PHARMACEUTICAL INDUSTRY,
ATHENS, GREECE
GERARD LABORATORIES, DUBLIN, IRELAND
GENERICS, POTTERS BAR, HERTFORDSHIRE,
UK
MERCK PHARMACEUTICAL MANUFACTURING,
WADEVILLE, GERMISTON, RSA
RESEARCH INSTITUTE FOR **INDUSTRIAL**
PHARMACY, **UNIVERSITY**, POTCHEFSTROOM
SOUTH **AFRICAN** BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
FPRR: MERCK GENERICS, MODDERFONTEIN, RSA

Shelf-life: **24** months

Date of registration: **25** NOVEMBER 2005

MRF 15(MBR 15)

Registration number: A40/21.2/0006

Name of medicine: DIAGLIM 1

Dosage form: TABLET

Active ingredients: EACH TABLET CONTAINS:
GLIMEPIRIDE 1,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **SANDOZ** (PTY) LTD

Manufacturer: NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA

Packer: NOVARTIS S.A., **SPARTAN**, KEMPTON PARK, RSA

Laboratory: FPRC: SOUTH **AFRICAN** BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS **S.A.**, SPARTAN, KEMPTON PARK, RSA
FPRR: **SANDOZ**, SPARTAN, KEMPTON PARK, RSA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER **2005**

MRF 15 (MBR 15)

Registration number: **A40/21.2/0007**

Name of medicine: **DIAGLIM 2**

Dosage form: **TABLET**

Active ingredients: EACH TABLET CONTAINS:
GLIMEPIRIDE 2,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: SANDOZ (PTY) LTD

Manufacturer: **NOVARTIS S.A., SPARTAN, KEMPTON PARK, RSA**

Packer: NOVARTIS S.A., **SPARTAN**, KEMPTON PARK, RSA

Laboratory: **FPRC:** SOUTH **AFRICAN** BUREAU OF **STANDARDS**,
GROENKLOOF, PRETORIA, RSA
ANALYTICON, KEMPTON PARK, RSA
FPRC/FPRR: NOVARTIS S.A., SPARTAN, KEMPTON **PARK**, RSA
FPRR: SANDOZ, **SPARTAN**, KEMPTON PARK

Shelf-life: 24 months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A40/21.2/0008

Name of medicine: **DIAGLIM 4**

Dosage form: TABLET

Active ingredients: **EACH TABLET CONTAINS:**
GLIMEPIRIDE 4,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: **SANDOZ (PTY) LTD**

Manufacturer: NOVARTIS **S.A.**, SPARTAN, KEMPTON PARK, **RSA**

Packer: NOVARTIS **S.A.**, SPARTAN, KEMPTON **PARK**, **RSA**

Laboratory: **FPRC:** SOUTH **AFRICAN** BUREAU OF STANDARDS,
GROENKLOOF, PRETORIA, **RSA**
ANALYTICON, KEMPTON PARK, **RSA**
FPRC/FPRR: NOVARTIS **S.A.**, **SPARTAN**, KEMPTON PARK, **RSA**
FPRR: **SANDOZ**, SPARTAN, KEMPTON **PARK**

Shelf-life: **24** months

Date of registration: **25 NOVEMBER 2005**

MRF 15 (MBR 15)

Registration number: A40/2.7/0255

Name of medicine: **BARRS PARACETAMOL SYRUP**

Dosage form: SYRUP

Active ingredients: EACH 5,0 ml SYRUP CONTAINS:
PARACETAMOL 120,0 ml

Conditions of registration: 1, 2, 3, 4, 5, 6, 7

Applicant: BARRS PHARMACEUTICAL INDUSTRIES CC

Manufacturer: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN

Packer: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN

Laboratory: FPRC/FPRR: BARRS PHARMACEUTICAL INDUSTRIES,
OBSERVATORY, CAPE TOWN
FPRC: SOUTH AFRICAN BUREAU OF **STANDARDS**,
GROENKLOOF, PRETORIA

Shelf-life: 24 months

Date of registration: 25 NOVEMBER 2005
