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## GENERAL NOTICE ALGEMENE KENNISGEWING

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### NOTICE 1341 OF 2009

#### MEDICINES CONTROL COUNCIL

#### CONDITIONS OF REGISTRATION OF A MEDICINE IN TERMS OF THE PROVISIONS OF SECTION 15(7) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of the current Good Manufacturing Practices as determined by Council
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the package insert shall be updated on a regular basis to conform to the package insert recently approved by Council.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
5. The registration of this medicine shall be subject to review at intervals as determined by Council regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues Council may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.
8. The provisional shelf-life allocated must be confirmed with stability data over the full shelf-life period on the first two production batches (well-known API) or first three production batches (NCE) in accordance with the Stability Guideline. Stability testing submitted on any pilot batches must also be completed and reported on. The stability report must be submitted within six months after completion of the stability trial. However, Council has to be informed immediately if any parameter shows a significant change or out-of-specification result during the stability trial.
9. A post-registration inspection must be conducted on the first production batch manufactured by each local manufacturer.
10. A post-registration inspection must be conducted on the first production batch of the imported product.
11. Marketing of the product may only commence following a satisfactory post-registration inspection report.
12. One sample of every batch, together with four copies of the protocol for testing of the bulk lot and filling lot, and six copies of the certificate of release issued by a competent authority in the country in which the product was manufactured, must be submitted to the Council for lot release purposes.
13. The expiry date allocated shall be modified by adding a statement that the virus strains are currently recommended for South African usage in the specific year.
14. The strains of the master seed viruses must be approved by the Department of Health for each year.

MRF 15

Registration number: 06/1.3/04  
Name of medicine: THIANIL/TREXONIL COMBIPACK  
Dosage form: INJECTION  
Active ingredients: EACH PACK CONTAINS:  
THIANIL VIAL CONTAINING:  
THIAFENTANIL OXALATE 10,0 mg/1,0 ml  
TREXONIL VIAL CONTAINING:  
NALTREXONE HYDROCHLORIDE 50,0 mg/1,0 ml  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: MC PHARMA (PTY) LTD  
Manufacturer: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
Packer: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
Laboratory: FPRC: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
FPRR: MC PHARMA, MNANDI, CENTURION  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 06/1.3/05  
Name of medicine: TREXONIL  
Dosage form: INJECTION  
Active ingredients: EACH VIAL CONTAINS:  
NALTREXONE HYDROCHLORIDE 50,0 mg/1,0 ml  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: MC PHARMA (PTY) LTD  
Manufacturer: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
Packer: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
Laboratory: FPRC: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
FPRR: MC PHARMA, MNANDI, CENTURION  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 06/1.3/06  
 Name of medicine: THIANIL  
 Dosage form: INJECTION  
 Active ingredients: EACH VIAL CONTAINS:  
 THIAFENTANIL OXALATE 10,0 mg/1,0 ml  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: MC PHARMA (PTY) LTD  
 Manufacturer: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
 Packer: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
 Laboratory: FPRC: PHARMA-Q, INDUSTRIA WEST, JOHANNESBURG  
 FPRR: MC PHARMA, MNANDI, CENTURION  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 34/21.5.1/0343  
 Name of medicine: ASMANEX TWISTHALER 200 ug  
 Dosage form: INHALER  
 Active ingredients: EACH INHALATION CONTAINS:  
 MOMETASONE FUROATE 200,0 ug  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: SCHERING-PLOUGH (PTY) LTD  
 Manufacturer: SCHERING-PLOUGH, TUAS STREET,  
 SINGAPORE  
 Packer: SCHERING-PLOUGH, TUAS STREET,  
 SINGAPORE  
 SCHERING-PLOUGH, HEIST-OP-DEN-BERG  
 SCHERING-PLOUGH, WOODMEAD,  
 SANDTON  
 Laboratory: FPRC: SCHERING-PLOUGH, TUAS STREET,  
 SINGAPORE  
 SCHERING-PLOUGH, HEIST-OP-DEN-BERG  
 FPRC/FPRR: SCHERING-PLOUGH, WOODMEAD,  
 SANDTON  
 Shelf-life: 18 months  
 Date of registration: 14 AUGUST 2009

**MRF 15**

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Registration number: 34/21.5.1/0344  
Name of medicine: ASMANEX TWISTHALER 400 ug  
Dosage form: INHALER  
Active ingredients: EACH INHALATION CONTAINS:  
MOMETASONE FUROATE 400,0 ug

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

Applicant: SCHERING-PLOUGH (PTY) LTD  
Manufacturer: SCHERING-PLOUGH, TUAS STREET, SINGAPORE  
Packer: SCHERING-PLOUGH, TUAS STREET, SINGAPORE  
SCHERING-PLOUGH, HEIST-OP-DEN-BERG  
SCHERING-PLOUGH, WOODMEAD, SANDTON

Laboratory: FPRC: SCHERING-PLOUGH, TUAS STREET, SINGAPORE  
SCHERING-PLOUGH, HEIST-OP-DEN-BERG

FPRC/FPRR: SCHERING-PLOUGH, WOODMEAD, SANDTON

Shelf-life: 18 months  
Date of registration: 14 AUGUST 2009

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**MRF 15**

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Registration number: 37/5.8/0139  
Name of medicine: SINUTAB SINUS PAIN EXTRA STRENGTH  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
PARACETAMOL 500,0 mg  
PSEUDOEPHEDRINE HYDROCHLORIDE 30,0 mg  
CHLORPHENIRAMINE MALEATE 2,0 mg  
CODEINE PHOSPHATE 10,0 mg

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

Applicant: JOHNSON & JOHNSON (PTY) LTD  
Manufacturer: GOEDECKE AG, FREIBURG, GERMANY  
Packer: GOEDECKE AG, FREIBURG, GERMANY  
JOHNSON & JOHNSON, RETREAT, RSA

Laboratory: FPRC: GOEDECKE AG, FREIBURG, GERMANY

FPRC/FPRR: JOHNSON & JOHNSON, RETREAT, RSA

Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

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**MRF 15**

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Registration number: 38/2.7/0261  
Name of medicine: ADVIL LIQUI-GELS 400  
Dosage form: CAPSULE  
Active ingredients: EACH CAPSULE CONTAINS:  
IBUPROFEN 400,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: WYETH S.A. (PTY) LTD  
Manufacturer: CARDINAL HEALTH LTD, BLAGROVE, SWINDON,  
WILTSHIRE, UK  
Packer: WYETH LEDERLE S.p.A., APRILIA, ITALY  
Laboratory: FPRC: CARDINAL HEALTH LTD, BLAGROVE, SWINDON,  
WILTSHIRE, UK  
WYETH LEDERLE S.p.A., APRILIA, ITALY  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG  
FPRR: WYETH S.A., VORNA VALLEY, MIDRAND  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

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**MRF 15**

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Registration number: 38/11.5/0166  
Name of medicine: AGAROL LACTULOSE  
Dosage form: SYRUP  
Active ingredients: EACH 5,0 ml SYRUP CONTAINS:  
LACTULOSE 3,3 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 8  
Applicant: PHARMACARE LIMITED  
Manufacturer: PHARMACARE LTD, KORSTEN, PORT  
ELIZABETH  
Packer: PHARMACARE LTD, KORSTEN, PORT  
ELIZABETH  
Laboratory: FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT  
ELIZABETH  
FPRR: PHARMACARE LTD, WOODMEAD,  
SANDTON  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

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## MRF 15

Registration number: A39/3.2/0352  
 Name of medicine: SUPLASYN  
 Dosage form: INJECTION  
 Active ingredients: EACH PRE-FILLED SYRINGE CONTAINS:  
 SODIUM HYALURONATE 20,0 mg  
  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: PHARMACO DISTRIBUTION (PTY) LTD  
  
 Manufacturer: BIONICHE INC, INVERIN, COUNTY GALWAY,  
 IRELAND  
 LIFECORE BIOMEDICAL INC, CHASKA,  
 MINNESOTA, USA  
  
 Packer: BIONICHE INC, INVERIN, COUNTY GALWAY,  
 IRELAND  
 LIFECORE BIOMEDICAL INC, CHASKA,  
 MINNESOTA, USA  
  
 Laboratory: FPRC: BIONICHE INC, INVERIN, COUNTY GALWAY,  
 IRELAND  
 LIFECORE BIOMEDICAL INC, CHASKA,  
 MINNESOTA, USA  
  
 FPRR PHARMACO DISTRIBUTION, SANDTON,  
 JOHANNESBURG  
  
 Shelf-life: 24 months (Provisional)  
  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: A39/30.3/0591  
 Name of medicine: RECOMBINATE 250 I.U.  
 Dosage form: INJECTION  
 Active ingredients: EACH 10,0 ml SOLUTION CONTAINS:  
 FACTOR VIII, OCTOCOG ALFA  
 250,0 I.U.  
  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ADCOCK INGRAM CRITICAL CARE (PTY)  
 LTD  
  
 Manufacturer: BAXTER HEALTHCARE CORPORATION,  
 THOUSAND OAKS, CALIFORNIA, USA  
 BAXTER S.A., LESSINES, BELGIUM  
 GENETIC INSTITUTE INC, ANDOVER,  
 MASSACHUSETTS, USA  
  
 Packer: BAXTER S.A., LESSINES, BELGIUM  
 ADCOCK INGRAM CRITICAL CARE,  
 AEROTON, JOHANNESBURG  
  
 Laboratory: FPRC: BAXTER S.A., LESSINES, BELGIUM  
  
 FPRC/FPRR: ADCOCK INGRAM CRITICAL CARE,  
 AEROTON, JOHANNESBURG  
  
 Shelf-life: 24 months  
  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: A39/30.3/0592  
 Name of medicine: RECOMBINATE 500 I.U.  
 Dosage form: INJECTION  
 Active ingredients: EACH 10,0 ml SOLUTION CONTAINS:  
 FACTOR VIII, OCTOCOG ALFA 500,0 I.U.  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD  
 Manufacturer: BAXTER HEALTHCARE CORPORATION,  
 THOUSAND OAKS, CALIFORNIA, USA  
 BAXTER S.A., LESSINES, BELGIUM  
 GENETIC INSTITUTE INC, ANDOVER,  
 MASSACHUSETTS, USA  
 Packer: BAXTER S.A., LESSINES, BELGIUM  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
 Laboratory: FPRC: BAXTER S.A., LESSINES, BELGIUM

FPRR ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG

Shelf-life: 24 months

Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: A39/30.3/0593  
 Name of medicine: RECOMBINATE 1 000 I.U.  
 Dosage form: INJECTION  
 Active ingredients: EACH 10,0 ml SOLUTION CONTAINS:  
 FACTOR VIII, OCTOCOG ALFA 1 000,0 I.U.  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ADCOCK INGRAM CRITICAL CARE (PTY) LTD  
 Manufacturer: BAXTER HEALTHCARE CORPORATION,  
 THOUSAND OAKS, CALIFORNIA, USA  
 BAXTER S.A., LESSINES, BELGIUM  
 GENETIC INSTITUTE INC, ANDOVER,  
 MASSACHUSETTS, USA  
 Packer: BAXTER S.A., LESSINES, BELGIUM  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
 Laboratory: FPRC BAXTER S.A., LESSINES, BELGIUM

FPRR ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG

Shelf-life: 24 months

Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: A39/34/0647  
 Name of medicine: PROGRAF 0,5 mg  
 Dosage form: CAPSULE  
 Active ingredients: EACH CAPSULE CONTAINS:  
 TACROLIMUS 0,5 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ASTELLAS PHARMA (PTY) LTD  
 Manufacturer: FUJISAWA IRELAND LTD, KILLORGLIN, Co. KERRY,  
 IRELAND  
 Packer: FUJISAWA IRELAND LTD, KILLORGLIN, Co. KERRY,  
 IRELAND  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
 DIVPHARM MANUFACTURING & PACKAGING,  
 LONGDALE, JOHANNESBURG  
 Laboratory: FPRC: FUJISAWA IRELAND LTD, KILLORGLIN, Co. KERRY,  
 IRELAND  
 FPRR: ASTELLAS PHARMA, BEDFORDVIEW, JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: A40/5.10/0323  
 Name of medicine: SABAX ONDANSETRON 2 mg/ml  
 Dosage form: INJECTION  
 Active ingredients: EACH 2,0 ml SOLUTION CONTAINS:  
 ONDANSETRON 4,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ADCOCK INGRAM LIMITED  
 Manufacturer: PHARMAMED PARENTERALS LTD, ZEJTUN,  
 MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
 Packer: PHARMAMED PARENTERALS LTD, ZEJTUN,  
 MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
 SYNTHON HISPANIA, BARCELONA, SPAIN  
 NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
 PHARMA-Q, INDUSTRIAL, JOHANNESBURG  
 Laboratory: FPRC: PHARMAMED PARENTERALS LTD, ZEJTUN,  
 MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
 SYNTHON HISPANIA, BARCELONA, SPAIN  
 SYNTHON BV, NIJMEGEN, THE NETHERLANDS  
 NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA  
 PHARMA-Q, INDUSTRIAL, JOHANNESBURG  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
 FPRR: ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
 GERMISTON  
 ADCOCK INGRAM LTD, ERAND GARDENS,  
 MIDRAND  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009



**MRF 15**

**Registration number:** A40/5.10/0324  
**Name of medicine:** COVAN ONDANSETRON 2 mg/ml  
**Dosage form:** INJECTION  
**Active ingredients:** EACH 2,0 ml SOLUTION CONTAINS:  
 ONDANSETRON 4,0 mg  
**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7  
**Applicant:** ADCOCK INGRAM LIMITED  
**Manufacturer:** PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
**Packer:** PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
 SYNTHON HISPANIA, BARCELONA, SPAIN  
 NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
 PHARMA-Q, INDUSTRIA, JOHANNESBURG  
**Laboratory:** **FPRC:** PHARMAMED PARENTERALS LTD, ZEJTUN, MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
 SYNTHON HISPANIA, BARCELONA, SPAIN  
 SYNTHON BV, NIJMEGEN, THE NETHERLANDS  
 NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA  
 PHARMA-Q, INDUSTRIA, JOHANNESBURG  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
**FPRR:** ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
 GERMISTON  
 ADCOCK INGRAM LTD, ERAND GARDENS, MIDRAND  
**Shelf-life:** 24 months  
**Date of registration:** 14 AUGUST 2009

**MRF 15**

**Registration number:** A40/5.10/0325  
**Name of medicine:** PROPAN ONDANSETRON 2 mg/ml  
**Dosage form:** INJECTION  
**Active ingredients:** EACH 2,0 ml SOLUTION CONTAINS:  
 ONDANSETRON 4,0 mg  
**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7  
**Applicant:** ADCOCK INGRAM LIMITED  
**Manufacturer:** PHARMAMED PARENTERALS LTD, ZEJTUN,  
 MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
**Packer:** PHARMAMED PARENTERALS LTD, ZEJTUN,  
 MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
 SYNTHON HISPANIA, BARCELONA, SPAIN  
 NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
 PHARMA-Q, INDUSTRIA, JOHANNESBURG  
**Laboratory:** **FPRC:** PHARMAMED PARENTERALS LTD, ZEJTUN,  
 MALTA  
 FAMAR S.A., P. FALIRO, GREECE  
 SYNTHON HISPANIA, BARCELONA, SPAIN  
 SYNTHON BV, NIJMEGEN, THE NETHERLANDS  
 NYCOMED AUSTRIA GmbH, LINZ, AUSTRIA  
 PHARMA-Q, INDUSTRIA, JOHANNESBURG  
 ADCOCK INGRAM CRITICAL CARE, AEROTON,  
 JOHANNESBURG  
**FPRR:** ADCOCK INGRAM HEALTHCARE, WADEVILLE,  
 GERMISTON  
 ADCOCK INGRAM LTD, ERAND GARDENS,  
 MIDRAND  
**Shelf-life:** 24 months  
**Date of registration:** 14 AUGUST 2009

**MRF 15**

**Registration number:** A40/2.6.5/0527  
**Name of medicine:** RESKIT 0,5  
**Dosage form:** TABLET  
**Active ingredients:** EACH TABLET CONTAINS:  
RISPERIDONE 0,5 mg  
**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7, 8  
**Applicant:** RANBAXY (S.A.) (PTY) LTD  
**Manufacturer:** RANBAXY LABORATORIES LTD, DEWAS,  
MADHYA PRADESH, INDIA  
**Packer:** RANBAXY LABORATORIES LTD, DEWAS,  
MADHYA PRADESH, INDIA  
**Laboratory:** FPRC: RANBAXY LABORATORIES LTD, DEWAS,  
MADHYA PRADESH, INDIA  
KHULULEKANI LABORATORY SERVICES,  
COVENTRY PARK, MIDRAND  
CENTRE FOR QUALITY ASSURANCE, NORTH-  
WEST UNIVERSITY, POTCHEFSTROOM  
FPRR: RANBAXY (S.A.), CENTURION, RSA  
**Shelf-life:** 24 months (Provisional)  
**Date of registration:** 14 AUGUST 2009

**MRF 15**

**Registration number:** A40/2.6.5/0528  
**Name of medicine:** RESKIT 1  
**Dosage form:** TABLET  
**Active ingredients:** EACH TABLET CONTAINS:  
RISPERIDONE 1,0 mg  
**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7, 8  
**Applicant:** RANBAXY (S.A.) (PTY) LTD  
**Manufacturer:** RANBAXY LABORATORIES LTD, DEWAS,  
MADHYA PRADESH, INDIA  
**Packer:** RANBAXY LABORATORIES LTD, DEWAS,  
MADHYA PRADESH, INDIA  
**Laboratory:** FPRC: RANBAXY LABORATORIES LTD, DEWAS,  
MADHYA PRADESH, INDIA  
KHULULEKANI LABORATORY SERVICES,  
COVENTRY PARK, MIDRAND  
CENTRE FOR QUALITY ASSURANCE,  
NORTH-WEST UNIVERSITY,  
POTCHEFSTROOM  
FPRR: RANBAXY (S.A.), CENTURION, RSA  
**Shelf-life:** 24 months (Provisional)  
**Date of registration:** 14 AUGUST 2009

MRF 15

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Registration number: A40/2.6.5/0529  
Name of medicine: RESKIT 2  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
RISPERIDONE 2,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: RANBAXY (S.A.) (PTY) LTD  
Manufacturer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA  
Packer: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA  
  
Laboratory: FPRC: RANBAXY LABORATORIES LTD, DEWAS, MADHYA PRADESH, INDIA  
KHULULEKANI LABORATORY SERVICES,  
COVENTRY PARK, MIDRAND  
CENTRE FOR QUALITY ASSURANCE, NORTH-WEST UNIVERSITY, POTCHEFSTROOM  
FPRR: RANBAXY (S.A.), CENTURION, RSA  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

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MRF 15

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Registration number: A40/26/0609  
Name of medicine: PCH-PACLITAXEL 30  
Dosage form: SOLUTION  
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:  
PACLITAXEL 6,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: PHARMACHEMIE (PTY) LTD  
Manufacturer: PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS  
Packer: PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG  
  
Laboratory: FPRC: PHARMACHEMIE B.V, HAARLEM, THE NETHERLANDS  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG  
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY,  
POTCHEFSTROOM  
FPRR: PHARMACHEMIE, RUIMSIG, ROODEPOORT  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

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**MRF 15**

Registration number: A40/26/0610  
Name of medicine: PCH-PACLITAXEL 100  
Dosage form: SOLUTION  
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:  
PACLITAXEL 6,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: PHARMACHEMIE (PTY) LTD  
Manufacturer: PHARMACHEMIE B.V, HAARLEM, THE  
NETHERLANDS  
Packer: PHARMACHEMIE B.V, HAARLEM, THE  
NETHERLANDS  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG  
Laboratory: FPRC: PHARMACHEMIE B.V, HAARLEM, THE  
NETHERLANDS  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, NORTH-WEST UNIVERSITY,  
POTCHEFSTROOM  
FPRR: PHARMACHEMIE, RUIMSIG, ROODEPOORT  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: A40/26/0611  
Name of medicine: PCH-PACLITAXEL 300  
Dosage form: SOLUTION  
Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:  
PACLITAXEL 6,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: PHARMACHEMIE (PTY) LTD  
Manufacturer: PHARMACHEMIE B.V, HAARLEM, THE  
NETHERLANDS  
Packer: PHARMACHEMIE B.V, HAARLEM, THE  
NETHERLANDS  
DIVPHARM MANUFACTURING &  
PACKAGING, LONGDALE, JOHANNESBURG  
Laboratory: FPRC: PHARMACHEMIE B.V, HAARLEM, THE  
NETHERLANDS  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, NORTH-WEST UNIVERSITY,  
POTCHEFSTROOM  
FPRR: PHARMACHEMIE, RUIMSIG, ROODEPOORT  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: A40/2.6.5/0674  
 Name of medicine: SANDOZ RISPERIDONE 1  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 RISPERIDONE 1,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: SANDOZ SA (PTY) LTD  
 Manufacturer: NOVARTIS (BANGLADESH) LTD, TONGI,  
 GAZIPUR, BANGLADESH, INDIA  
 Packer: NOVARTIS (BANGLADESH) LTD, TONGI,  
 GAZIPUR, BANGLADESH, INDIA  
 NOVARTIS SA, SPARTAN, KEMPTON PARK  
 Laboratory: FPRC: NOVARTIS (BANGLADESH) LTD, TONGI,  
 GAZIPUR, BANGLADESH, INDIA  
 NOVARTIS SA, SPARTAN, KEMPTON PARK  
 FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: A40/2.6.5/0675  
 Name of medicine: SANDOZ RISPERIDONE 2  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 RISPERIDONE 2,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: SANDOZ SA (PTY) LTD  
 Manufacturer: NOVARTIS (BANGLADESH) LTD, TONGI,  
 GAZIPUR, BANGLADESH, INDIA  
 Packer: NOVARTIS (BANGLADESH) LTD, TONGI,  
 GAZIPUR, BANGLADESH, INDIA  
 NOVARTIS SA, SPARTAN, KEMPTON PARK  
 Laboratory: FPRC: NOVARTIS (BANGLADESH) LTD, TONGI,  
 GAZIPUR, BANGLADESH, INDIA  
 NOVARTIS SA, SPARTAN, KEMPTON PARK  
 FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: A40/2.6.5/0676  
Name of medicine: SANDOZ RISPERIDONE 3  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
RISPERIDONE 3,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: SANDOZ SA (PTY) LTD  
Manufacturer: NOVARTIS (BANGLADESH) LTD, TONGI,  
GAZIPUR, BANGLADESH, INDIA  
Packer: NOVARTIS (BANGLADESH) LTD, TONGI,  
GAZIPUR, BANGLADESH, INDIA  
NOVARTIS SA, SPARTAN, KEMPTON PARK  
Laboratory: FPRC: NOVARTIS (BANGLADESH) LTD, TONGI,  
GAZIPUR, BANGLADESH, INDIA  
NOVARTIS SA, SPARTAN, KEMPTON PARK  
FPRC/FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: A40/2.6.5/0677  
Name of medicine: SANDOZ RISPERIDONE 4  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
RISPERIDONE 4,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: SANDOZ SA (PTY) LTD  
Manufacturer: NOVARTIS (BANGLADESH) LTD, TONGI,  
GAZIPUR, BANGLADESH, INDIA  
Packer: NOVARTIS (BANGLADESH) LTD, TONGI,  
GAZIPUR, BANGLADESH, INDIA  
NOVARTIS SA, SPARTAN, KEMPTON PARK  
Laboratory: FPRC: NOVARTIS (BANGLADESH) LTD, TONGI,  
GAZIPUR, BANGLADESH, INDIA  
NOVARTIS SA, SPARTAN, KEMPTON PARK  
FPRC/FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: A40/2.5/0768  
 Name of medicine: ZYDUS LAMOTRIGINE 50 mg TABLETS  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LAMOTRIGINE 50,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD  
 Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND,  
 AHMEDABAD, INDIA  
 Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND,  
 AHMEDABAD, INDIA  
 Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND,  
 AHMEDABAD, INDIA  
 RESEARCH INSTITUTE FOR INDUSTRIAL  
 PHARMACY, NORTH-WEST UNIVERSITY,  
 POTCHEFSTROOM  
 FPRR: ZYDUS HEALTHCARE S.A., VAN DER HOFF  
 PARK, POTCHEFSTROOM  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: A40/2.5/0769  
 Name of medicine: ZYDUS LAMOTRIGINE 100 mg TABLETS  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LAMOTRIGINE 100,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: ZYDUS HEALTHCARE S.A. (PTY) LTD  
 Manufacturer: ZYDUS CADILA HEALTHCARE LTD,  
 SANAND, AHMEDABAD, INDIA  
 Packer: ZYDUS CADILA HEALTHCARE LTD,  
 SANAND, AHMEDABAD, INDIA  
 Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD,  
 SANAND, AHMEDABAD, INDIA  
 RESEARCH INSTITUTE FOR INDUSTRIAL  
 PHARMACY, NORTH-WEST UNIVERSITY,  
 POTCHEFSTROOM  
 FPRR: ZYDUS HEALTHCARE S.A., VAN DER HOFF  
 PARK, POTCHEFSTROOM  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: A40/2.5/0770  
Name of medicine: ZYDUS LAMOTRIGINE 200 mg TABLETS

Dosage form: TABLET

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

Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8

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

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA  
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE S.A., VAN DER HOFF PARK, POTCHEFSTROOM

Shelf-life: 24 months (Provisional)

Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/7.1.3/0041  
Name of medicine: ZYDUS-LISINOPRIL/HYDROCHLOROTHIAZIDE 20/12,5 mg

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, 8

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

Manufacturer: ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA

Packer: ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA

Laboratory: FPRC: ZYDUS CADILA HEALTHCARE LTD, SANAND, AHMEDABAD, INDIA  
RESEARCH INSTITUTE FOR INDUSTRIAL PHARMACY, NORTH-WEST UNIVERSITY, POTCHEFSTROOM

FPRR: ZYDUS HEALTHCARE, VAN DER HOFF PARK, POTCHEFSTROOM

Shelf-life: 24 months (Provisional)

Date of registration: 14 AUGUST 2009



**MRF 15**

Registration number: 41/5.7.1/0119  
 Name of medicine: LORMEG 10  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LORATADINE 10,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: GULF DRUG COMPANY (PTY) LTD  
 Manufacturer: ALEMBIC LTD, TAL-HALOL, DISTRICT  
 PANCHMAHALS, GUJARAT, INDIA  
 Packer: ALEMBIC LTD, TAL-HALOL, DISTRICT  
 PANCHMAHALS, GUJARAT, INDIA  
 Laboratory: FPRC: ALEMBIC LTD, TAL-HALOL, DISTRICT  
 PANCHMAHALS, GUJARAT, INDIA  
 M&L LABORATORY SERVICES, ORMONDE,  
 JOHANNESBURG  
 CONSULTING CHEMICAL LABORATORIES  
 ATLASVILLE, BOKSBURG  
 PHARMA-Q, INDUSTRIA-WEST, JOHANNESBURG  
 CONSULTING MICROBIOLOGICAL LABORATORY,  
 MOREWILL, BEYERSPARK  
 FPRR: GULF DRUG COMPANY, MOUNT EDGECOMBE, KZN  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/26/0160  
 Name of medicine: CIPLA-CISPLATIN 10  
 Dosage form: INJECTION  
 Active ingredients: EACH 20,0 ml VIAL CONTAINS:  
 CISPLATIN 10,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: CIPLA LIFE SCIENCES (PTY) LTD  
 Manufacturer: CIPLA LTD, UNIT V, VERNA, SALCETTE,  
 GOA, INDIA  
 Packer: CIPLA LTD, UNIT V, VERNA, SALCETTE,  
 GOA, INDIA  
 Laboratory: FPRC: CIPLA LTD, UNIT V, VERNA, SALCETTE,  
 GOA, INDIA  
 FPRR: CIPLA LIFE SCIENCES, ROSENPAK,  
 BELLVILLE  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/26/0161  
Name of medicine: CIPLA-CISPLATIN 50  
Dosage form: INJECTION  
Active ingredients: EACH 50,0 ml VIAL CONTAINS:  
CISPLATIN 50,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: CIPLA LIFE SCIENCES (PTY) LTD  
Manufacturer: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA  
Packer: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA  
Laboratory: FPRC: CIPLA LTD, UNIT V, VERNA, SALCETTE, GOA, INDIA  
FPRR: CIPLA LIFE SCIENCES, ROSENPAK, BELLVILLE  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/21.5.1/0243  
Name of medicine: REDIPRED  
Dosage form: LIQUID  
Active ingredients: EACH 5,0 ml LIQUID CONTAINS:  
PREDNISOLONE SODIUM PHOSPHATE  
EQUIVALENT TO PREDNISOLONE 15,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: PHARMACARE LIMITED  
Manufacturer: SPECPHARM HOLDINGS, HALFWAY HOUSE,  
MIDRAND  
GLAXOSMITHKLINE, EPPING, CAPE TOWN  
PHARMACARE LTD, KORSTEN, PORT  
ELIZABETH  
Packer: SPECPHARM HOLDINGS, HALFWAY HOUSE,  
MIDRAND  
GLAXOSMITHKLINE, EPPING, CAPE TOWN  
PHARMACARE LTD, KORSTEN, PORT  
ELIZABETH  
Laboratory: FPRC: SPECPHARM HOLDINGS, HALFWAY HOUSE,  
MIDRAND  
GLAXOSMITHKLINE, EPPING, CAPE TOWN  
M&L LABORATORY SERVICES, ORMONDE,  
JOHANNESBURG  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, NORTH-WEST UNIVERSITY,  
POTCHEFSTROOM  
PHARMACARE LTD, KORSTEN, PORT  
ELIZABETH  
FPRR: PHARMACARE LTD, WOODMEAD, SANDTON  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/7.1.3/0499  
 Name of medicine: AUSTOZAAR-25  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LOSARTAN POTASSIUM 25,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: AUSTELL LABORATORIES (PTY) LTD  
 Manufacturer: IPCA LABORATORIES LTD, SILVASSA, DADRA  
 & NAGAR HAVELI, INDIA  
 Packer: IPCA LABORATORIES LTD, SILVASSA, DADRA  
 & NAGAR HAVELI, INDIA  
 Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA  
 & NAGAR HAVELI, INDIA  
 M&L LABORATORY SERVICES, ORMONDE,  
 JOHANNESBURG  
 FPRR: AUSTELL LABORATORIES, SPRINGFIELD,  
 JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/7.1.3/0500  
 Name of medicine: AUSTOZAAR-50  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LOSARTAN POTASSIUM 50,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: AUSTELL LABORATORIES (PTY) LTD  
 Manufacturer: IPCA LABORATORIES LTD, SILVASSA,  
 DADRA & NAGAR HAVELI, INDIA  
 Packer: IPCA LABORATORIES LTD, SILVASSA,  
 DADRA & NAGAR HAVELI, INDIA  
 Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA,  
 DADRA & NAGAR HAVELI, INDIA  
 M&L LABORATORY SERVICES,  
 ORMONDE, JOHANNESBURG  
 FPRR: AUSTELL LABORATORIES,  
 SPRINGFIELD, JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

**MRF 15**

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Registration number: 41/7.1.3/0501  
Name of medicine: AUSTOZAAR-100  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
LOSARTAN POTASSIUM 100,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: AUSTELL LABORATORIES (PTY) LTD  
Manufacturer: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
Packer: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
M&L LABORATORY SERVICES, ORMONDE,  
JOHANNESBURG  
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,  
JOHANNESBURG  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

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**MRF 15**

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Registration number: 41/7.1.3/0502  
Name of medicine: LORTELL-25  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
LOSARTAN POTASSIUM 25,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: AUSTELL LABORATORIES (PTY) LTD  
Manufacturer: IPCA LABORATORIES LTD, SILVASSA,  
DADRA & NAGAR HAVELI, INDIA  
Packer: IPCA LABORATORIES LTD, SILVASSA,  
DADRA & NAGAR HAVELI, INDIA  
Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA,  
DADRA & NAGAR HAVELI, INDIA  
M&L LABORATORY SERVICES, ORMONDE,  
JOHANNESBURG  
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,  
JOHANNESBURG  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

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**MRF 15**

Registration number: 41/7.1.3/0503  
 Name of medicine: LORTELL-50  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LOSARTAN POTASSIUM 50,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: AUSTELL LABORATORIES (PTY) LTD  
 Manufacturer: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
 NAGAR HAVELI, INDIA  
 Packer: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
 NAGAR HAVELI, INDIA  
 Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
 NAGAR HAVELI, INDIA  
 M&L LABORATORY SERVICES, ORMONDE,  
 JOHANNESBURG  
 FPRR: AUSTELL LABORATORIES, SPRINGFIELD,  
 JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/7.1.3/0517  
 Name of medicine: LORTELL-100  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LOSARTAN POTASSIUM 100,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: AUSTELL LABORATORIES (PTY) LTD  
 Manufacturer: IPCA LABORATORIES LTD, SILVASSA,  
 DADRA & NAGAR HAVELI, INDIA  
 Packer: IPCA LABORATORIES LTD, SILVASSA,  
 DADRA & NAGAR HAVELI, INDIA  
 Laboratory: FPRC: IPCA LABORATORIES LTD, SILVASSA,  
 DADRA & NAGAR HAVELI, INDIA  
 M&L LABORATORY SERVICES, ORMONDE,  
 JOHANNESBURG  
 FPRR: AUSTELL LABORATORIES, SPRINGFIELD,  
 JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/7.1.5/0644  
Name of medicine: CIALIS 5  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
TADALAFIL 5,0 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, UK  
LILLY DEL CARIBE INC, CAROLINA, PUERTO RICO  
Packer: ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK  
BRECON PHARMACEUTICALS LTD, HAY-ON-WYE, HEREFORD, UK  
CARDINAL HEALTH UK, CORBY, NORTH HAMPTONSHIRE, UK  
LILLY S.A., ALCOBENDAS, MADRID, SPAIN  
Laboratory: FPRC: ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK  
LILLY S.A., ALCOBENDAS, MADRID, SPAIN  
FPRR: ELI LILLY (S.A.), BRYANSTON, JOHANNESBURG  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/7.1.5/0645  
Name of medicine: CIALIS 2,5  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
TADALAFIL 2,5mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: ELI LILLY (S.A.) (PTY) LTD  
Manufacturer: ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK  
LILLY DEL CARIBE INC, CAROLINA, PUERTO RICO  
Packer: ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK  
BRECON PHARMACEUTICALS LTD, HAY-ON-WYE, HEREFORD, UK  
CARDINAL HEALTH UK, CORBY, NORTH HAMPTONSHIRE, UK  
LILLY S.A., ALCOBENDAS, MADRID, SPAIN  
Laboratory: FPRC: ELI LILLY & CO LTD, BASINGSTOKE, HAMPSHIRE, UK  
LILLY S.A., ALCOBENDAS, MADRID, SPAIN  
FPRR: ELI LILLY (S.A.), BRYANSTON, JOHANNESBURG  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 41/7.1/0659  
 Name of medicine: AMTAS 5  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 AMLODIPINE BESYLATE EQUIVALENT TO  
 AMLODIPINE 5,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ACCORD HEALTHCARE (PTY) LTD  
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA,  
 SANAND, AHMEDABAD, INDIA  
 Packer: INTAS PHARMACEUTICALS LTD, MATODA,  
 SANAND, AHMEDABAD, INDIA  
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA,  
 SANAND, AHMEDABAD, INDIA  
 CONSULTING CHEMICAL LABORATORIES,  
 ATLASVILLE, BOKSBURG  
 FPRR: ACCORD HEALTHCARE, RIVONIA,  
 JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 41/7.1/0660  
 Name of medicine: AMTAS 10  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 AMLODIPINE BESYLATE EQUIVALENT TO  
 AMLODIPINE 10,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ACCORD HEALTHCARE (PTY) LTD  
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND,  
 AHMEDABAD, INDIA  
 Packer: INTAS PHARMACEUTICALS LTD, MATODA, SANAND,  
 AHMEDABAD, INDIA  
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA, SANAND,  
 AHMEDABAD, INDIA  
 CONSULTING CHEMICAL LABORATORIES,  
 ATLASVILLE, BOKSBURG  
 FPRC/FPRR: ACCORD HEALTHCARE, RIVONIA, JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/20.2.8/0808  
Name of medicine: AURO-STAVUDINE CAPSULES 15 mg  
Dosage form: CAPSULE  
Active ingredients: EACH CAPSULE CONTAINS:  
STAVUDINE 15,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: AUROBINDO PHARMA (PTY) LTD  
Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR  
MANDAL, RANGA REDDY DISTRICT, ANDHRA  
PRADESH, INDIA  
Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR  
MANDAL, RANGA REDDY DISTRICT, ANDHRA  
PRADESH, INDIA  
Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR  
MANDAL, RANGA REDDY DISTRICT, ANDHRA  
PRADESH, INDIA  
FPRR AUROBINDO PHARMA, MEYERSDAL,  
JOHANNESBURG  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/20.2.8/0809  
Name of medicine: AURO-STAVUDINE CAPSULES 20 mg  
Dosage form: CAPSULE  
Active ingredients: EACH CAPSULE CONTAINS:  
STAVUDINE 20,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: AUROBINDO PHARMA (PTY) LTD  
Manufacturer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR  
MANDAL, RANGA REDDY DISTRICT, ANDHRA  
PRADESH, INDIA  
Packer: AUROBINDO PHARMA LTD, QUTHUBULLAPUR  
MANDAL, RANGA REDDY DISTRICT, ANDHRA  
PRADESH, INDIA  
Laboratory: FPRC: AUROBINDO PHARMA LTD, QUTHUBULLAPUR  
MANDAL, RANGA REDDY DISTRICT, ANDHRA  
PRADESH, INDIA  
FPRR: AUROBINDO PHARMA, MEYERSDAL,  
JOHANNESBURG  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009



## MRF 15

Registration number: 41/30.2/0883  
 Name of medicine: ERBITUX 5 mg/ml  
 Dosage form: INFUSION  
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:  
 CETUXIMAB 5,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: MERCK (PTY) LTD  
 Manufacturer: BOEHRINGER INGELHEIM PHARMA GmbH,  
 BIBERACH AN DER RISS, GERMANY  
 Packer: MERCK KgaA, DARMSTADT, GERMANY  
 Laboratory: FPRC: BOEHRINGER INGELHEIM PHARMA GmbH,  
 BIBERACH AN DER RISS, GERMANY  
 MERCK KgaA, DARMSTADT, GERMANY  
 FPRR: MERCK, MODDERFONTEIN, RSA  
 Shelf-life: 24 months (provisional)  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 41/26/1002  
 Name of medicine: ACCORD VINCRISTINE 1 mg/ml INJECTION  
 Dosage form: INJECTION  
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:  
 VINCRISTINE SULPHATE 1,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: ACCORD HEALTHCARE (PTY) LTD  
 Manufacturer: INTAS PHARMACEUTICALS LTD, MATODA,  
 SANAND, AHMEDABAD, INDIA  
 Packer: INTAS PHARMACEUTICALS LTD, MATODA,  
 SANAND, AHMEDABAD, INDIA  
 Laboratory: FPRC: INTAS PHARMACEUTICALS LTD, MATODA,  
 SANAND, AHMEDABAD, INDIA  
 CONSULTING CHEMICAL LABORATORIES,  
 ATLASVILLE, BOKSBURG  
 FPRR: ACCORD HEALTHCARE, RIVONIA,  
 JOHANNESBURG  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

**MRF 15**

**Registration number:** 41/20.1.1/1018  
**Name of medicine:** AUSTELL LEVOFLOXACIN 250 mg  
**Dosage form:** TABLET  
**Active ingredients:** EACH TABLET CONTAINS:  
LEVOFLOXACIN HEMIHYDRATE EQUIVALENT  
TO LEVOFLOXACIN 250,0 mg  
**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7, 8  
**Applicant:** AUSTELL LABORATORIES (PTY) LTD  
**Manufacturer:** IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
**Packer:** IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
**Laboratory:** FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
M&L LABORATORY SERVICES, ORMONDE,  
JOHANNESBURG  
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,  
JOHANNESBURG  
**Shelf-life:** 24 months (Provisional)  
**Date of registration:** 14 AUGUST 2009

**MRF 15**

**Registration number:** 41/20.1.1/1019  
**Name of medicine:** AUSTELL LEVOFLOXACIN 500 mg  
**Dosage form:** TABLET  
**Active ingredients:** EACH TABLET CONTAINS:  
LEVOFLOXACIN HEMIHYDRATE EQUIVALENT TO  
LEVOFLOXACIN 500,0 mg  
**Conditions of registration:** 1, 2, 3, 4, 5, 6, 7, 8  
**Applicant:** AUSTELL LABORATORIES (PTY) LTD  
**Manufacturer:** IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
**Packer:** IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
**Laboratory:** FPRC: IPCA LABORATORIES LTD, SILVASSA, DADRA &  
NAGAR HAVELI, INDIA  
M&L LABORATORY SERVICES, ORMONDE,  
JOHANNESBURG  
FPRR: AUSTELL LABORATORIES, SPRINGFIELD,  
JOHANNESBURG  
**Shelf-life:** 24 months (Provisional)  
**Date of registration:** 14 AUGUST 2009

**MRF 15**

Registration number: 41/7.1.3/1074  
 Name of medicine: SPEC LOSARTAN 25  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LOSARTAN POTASSIUM 25,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: SPECPHARM (PTY) LTD  
 Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE  
 Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE  
 SPECPHARM HOLDINGS, HALFWAY HOUSE,  
 MIDRAND  
 DIVPHARM MANUFACTURING & PACKAGING,  
 LONGDALE, JOHANNESBURG  
 Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE  
 FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/7.1.3/1075  
 Name of medicine: SPEC LOSARTAN 100  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 LOSARTAN POTASSIUM 100,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: SPECPHARM (PTY) LTD  
 Manufacturer: SPECIFAR S.A., VARVARA, ATHENS,  
 GREECE  
 Packer: SPECIFAR S.A., VARVARA, ATHENS,  
 GREECE  
 SPECPHARM HOLDINGS, HALFWAY  
 HOUSE, MIDRAND  
 DIVPHARM MANUFACTURING &  
 PACKAGING, LONGDALE, JOHANNESBURG  
 Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS,  
 GREECE  
 FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/7.1.3/1076  
Name of medicine: SPEC LOSARTAN 50  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
LOSARTAN POTASSIUM 50,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: SPECPHARM (PTY) LTD  
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS, GREECE  
Packer: SPECIFAR S.A., VARVARA, ATHENS, GREECE  
SPECPHARM HOLDINGS, HALFWAY HOUSE,  
MIDRAND  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG  
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS, GREECE  
FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 41/7.1.3/1077  
Name of medicine: SPEC LOSARTAN 12,5  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
LOSARTAN POTASSIUM 12,5 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: SPECPHARM (PTY) LTD  
Manufacturer: SPECIFAR S.A., VARVARA, ATHENS,  
GREECE  
Packer: SPECIFAR S.A., VARVARA, ATHENS,  
GREECE  
SPECPHARM HOLDINGS, HALFWAY  
HOUSE, MIDRAND  
DIVPHARM MANUFACTURING &  
PACKAGING, LONGDALE, JOHANNESBURG  
Laboratory: FPRC: SPECIFAR S.A., VARVARA, ATHENS,  
GREECE  
FPRR: SPECPHARM, HALFWAY HOUSE, MIDRAND  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 41/26/1095  
 Name of medicine: LOXAT 30  
 Dosage form: INFUSION  
 Active ingredients: EACH VIAL CONTAINS:  
 PACLITAXEL 30,0  
 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: SANDOZ S.A.(PTY) LTD  
 Manufacturer: HAUPT PHARMA WOLFRATSHAUSEN  
 GmbH, WOLFRATSHAUSEN, GERMANY  
 Packer: HAUPT PHARMA WOLFRATSHAUSEN  
 GmbH, WOLFRATSHAUSEN, GERMANY  
 Laboratory: FPRC: HAUPT PHARMA WOLFRATSHAUSEN  
 GmbH, WOLFRATSHAUSEN, GERMANY  
  
 FPRC/FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 41/26/1096  
 Name of medicine: LOXAT 100  
 Dosage form: INFUSION  
 Active ingredients: EACH VIAL CONTAINS:  
 PACLITAXEL 100,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: SANDOZ S.A.(PTY) LTD  
 Manufacturer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,  
 WOLFRATSHAUSEN, GERMANY  
 Packer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,  
 WOLFRATSHAUSEN, GERMANY  
 Laboratory: FPRC: HAUPT PHARMA WOLFRATSHAUSEN GmbH,  
 WOLFRATSHAUSEN, GERMANY  
  
 FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/26/1097  
Name of medicine: LOXAT 300  
Dosage form: INFUSION  
Active ingredients: EACH VIAL CONTAINS:  
PACLITAXEL 300,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
Applicant: SANDOZ S.A.(PTY) LTD  
Manufacturer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,  
WOLFRATSHAUSEN, GERMANY  
Packer: HAUPT PHARMA WOLFRATSHAUSEN GmbH,  
WOLFRATSHAUSEN, GERMANY  
Laboratory: FPRC: HAUPT PHARMA WOLFRATSHAUSEN GmbH,  
WOLFRATSHAUSEN, GERMANY  
FPRR: SANDOZ S.A., SPARTAN, KEMPTON PARK  
Shelf-life: 24 months (Provisional)  
Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 41/2.9/1103  
Name of medicine: OXYNORM 5 mg CAPSULES  
Dosage form: CAPSULE  
Active ingredients: EACH CAPSULE CONTAINS:  
OXYCODONE HYDROCHLORIDE 5,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: MEDWICH PHARMA (PTY) LTD  
Manufacturer: BARD PHARMACEUTICALS LTD,  
CAMBRIDGE, UK  
Packer: BARD PHARMACEUTICALS LTD,  
CAMBRIDGE, UK  
Laboratory: FPRC: BARD PHARMACEUTICALS LTD,  
CAMBRIDGE, UK  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVULLE, BOKSBURG  
FPRR: MEDWICH PHARMA, LYNNWOOD GLEN,  
PRETORIA  
Shelf-life: 36 months  
Date of registration: 14 AUGUST 2009

## MRF 15

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Registration number: 41/2.9/1103  
Name of medicine: OXYNORM 5 mg CAPSULES  
Dosage form: CAPSULE  
Active ingredients: EACH CAPSULE CONTAINS:  
OXYCODONE HYDROCHLORIDE 5,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: MEDWICH PHARMA (PTY) LTD  
Manufacturer: BARD PHARMACEUTICALS LTD, CAMBRIDGE,  
UK  
Packer: BARD PHARMACEUTICALS LTD, CAMBRIDGE,  
UK  
Laboratory: FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE,  
UK  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG  
FPRR: MEDWICH PHARMA, LYNNWOOD GLEN,  
PRETORIA  
Shelf-life: 36 months  
Date of registration: 14 AUGUST 2009

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## MRF 15

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Registration number: 41/2.9/1104  
Name of medicine: OXYNORM 10 mg CAPSULES  
Dosage form: CAPSULE  
Active ingredients: EACH CAPSULE CONTAINS:  
OXYCODONE HYDROCHLORIDE 10,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: MEDWICH PHARMA (PTY) LTD  
Manufacturer: BARD PHARMACEUTICALS LTD,  
CAMBRIDGE, UK  
Packer: BARD PHARMACEUTICALS LTD,  
CAMBRIDGE, UK  
Laboratory: FPRC: BARD PHARMACEUTICALS LTD,  
CAMBRIDGE, UK  
CONSULTING CHEMICAL  
LABORATORIES, ATLASVILLE,  
BOKSBURG  
FPRC/FPRR: MEDWICH PHARMA, LYNNWOOD GLEN,  
PRETORIA  
Shelf-life: 36 months  
Date of registration: 14 AUGUST 2009

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**MRF 15**

Registration number: 41/2.9/1105  
Name of medicine: OXYNORM 20 mg CAPSULES  
Dosage form: CAPSULE  
Active ingredients: EACH CAPSULE CONTAINS:  
OXYCODONE HYDROCHLORIDE 20,0 mg

Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: MEDWICH PHARMA (PTY) LTD  
Manufacturer: BARD PHARMACEUTICALS LTD, CAMBRIDGE,  
UK  
Packer: BARD PHARMACEUTICALS LTD, CAMBRIDGE,  
UK  
Laboratory: FPRC: BARD PHARMACEUTICALS LTD, CAMBRIDGE,  
UK  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG

FPRC/FPRR: MEDWICH PHARMA, LYNNWOOD GLEN,  
PRETORIA

Shelf-life: 36 months  
Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 42/30.1/0118  
Name of medicine: ADACEL QUADRA  
Dosage form: SUSPENSION  
Active ingredients: EACH 0,5 ml DOSE CONTAINS:  
DIPHTHERIA TOXOID 2,0 Lf  
PERTUSSIS TOXOID 2,5 ug  
FILAMENTOUS HAEMAGGLUTININ 5,0 ug  
FIMBRIAE TYPE 2+3 5,0 ug  
PERTACTIN 3,0 ug  
TETANUS TOXOID 5,0 Lf  
POLIOMYELITIS VIRUS TYPE 1 40 D-antigen units  
POLIOMYELITIS VIRUS TYPE 2 8 D-antigen units  
POLIOMYELITIS VIRUS TYPE 3 32 D-antigen units

Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: SANOFI-AVENTIS SOUTH AFRICA (PTY) LTD  
Manufacturer: AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA  
AVENTIS PASTEUR SA, MARCY L'ETOILE, FRANCE  
AVENTIS PASTEUR SA, VAL DE REUIL, FRANCE  
Packer: AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA  
AVENTIS PASTEUR SA, MARCY L'ETOILE, FRANCE  
AVENTIS PASTEUR SA, VAL DE REUIL, FRANCE  
Laboratory: FPRC: AVENTIS PASTEUR LTD, TORONTO, ONTARIO, CANADA  
AVENTIS PASTEUR SA, MARCY L'ETOILE, FRANCE  
AVENTIS PASTEUR SA, VAL DE REUIL, FRANCE

FPRR: SANOFI-AVENTIS S.A., MIDRAND, RSA

Shelf-life: 36 months  
Date of registration: 14 AUGUST 2009



MRF 15

Registration number: 42/26/0132  
 Name of medicine: SANDOZ VINORELBINE 10 mg/1 ml  
 Dosage form: INJECTION  
 Active ingredients: EACH VIAL CONTAINS:  
 VINORELBINE TARTRATE EQUIVALENT TO  
 VINORELBINE 10,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: SANDOZ SA (PTY) LTD  
 Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
 Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
 TECHNIKON LABORATORIES, ROBERTVILLE,  
 FLORIDA  
 DIVPHARM MANUFACTURING & PACKAGING,  
 LONGDALE, JOHANNESBURG  
 SANDOZ SA, SPARTAN, KEMPTON PARK  
 Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
 CONSULTING CHEMICAL LABORATORIES,  
 ATLASVILLE, BOKSBURG  
 FPRC/FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

MRF 15

Registration number: 42/26/0133  
 Name of medicine: SANDOZ VINORELBINE 50 mg/5 ml  
 Dosage form: INJECTION  
 Active ingredients: EACH VIAL CONTAINS:  
 VINORELBINE TARTRATE EQUIVALENT TO  
 VINORELBINE 50,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: SANDOZ SA (PTY) LTD  
 Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
 Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
 TECHNIKON LABORATORIES, ROBERTVILLE,  
 FLORIDA  
 DIVPHARM MANUFACTURING & PACKAGING,  
 LONGDALE, JOHANNESBURG  
 SANDOZ SA, SPARTAN, KEMPTON PARK  
 Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
 CONSULTING CHEMICAL LABORATORIES,  
 ATLASVILLE, BOKSBURG  
 FPRC/FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
 Shelf-life: 24 months  
 Date of registration: 14 AUGUST 2009

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MRF 15

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Registration number: 42/26/0134  
Name of medicine: NEUVEL 10 mg/1 ml  
Dosage form: INJECTION  
Active ingredients: EACH VIAL CONTAINS:  
VINORELBINE TARTRATE EQUIVALENT TO  
VINORELBINE 10,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: SANDOZ SA (PTY) LTD  
Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
TECHNIKON LABORATORIES, ROBERTVILLE,  
FLORIDA  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG  
SANDOZ SA, SPARTAN, KEMPTON PARK  
Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG  
FPRC/FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

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MRF 15

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Registration number: 42/26/0135  
Name of medicine: SANDOZ VINORELBINE 50 mg/5 ml  
Dosage form: INJECTION  
Active ingredients: EACH VIAL CONTAINS:  
VINORELBINE TARTRATE EQUIVALENT TO  
VINORELBINE 50,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: SANDOZ SA (PTY) LTD  
Manufacturer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
Packer: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
TECHNIKON LABORATORIES, ROBERTVILLE,  
FLORIDA  
DIVPHARM MANUFACTURING & PACKAGING,  
LONGDALE, JOHANNESBURG  
SANDOZ SA, SPARTAN, KEMPTON PARK  
Laboratory: FPRC: SANDOZ S.A., BUENOS AIRES, ARGENTINA  
CONSULTING CHEMICAL LABORATORIES,  
ATLASVILLE, BOKSBURG  
FPRC/FPRR: SANDOZ SA, SPARTAN, KEMPTON PARK  
Shelf-life: 24 months  
Date of registration: 14 AUGUST 2009

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## MRF 15

Registration number: 42/5.7.1/0143  
 Name of medicine: ASPEN CETIRIZINE 1 mg/ml  
 Dosage form: SOLUTION  
 Active ingredients: EACH 1,0 ml SOLUTION CONTAINS:  
 CETIRIZINE DIHYDROCHLORIDE 1,0 mg  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7, 8  
 Applicant: PHARMACARE LIMITED  
 Manufacturer: PHARMACARE LTD, KORSTEN, PORT  
 ELIZABETH  
 Packer: PHARMACARE LTD, KORSTEN, PORT  
 ELIZABETH  
 Laboratory: FPRC: M&L LABORATORY SERVICES, ORMONDE,  
 JOHANNESBURG  
 RESEARCH INSTITUTE FOR INDUSTRIAL  
 PHARMACY, NORTH-WEST UNIVERSITY,  
 POTCHEFSTROOM  
 FPRC/FPRR: PHARMACARE LTD, KORSTEN, PORT  
 ELIZABETH  
 FPRR: PHARMACARE LTD, WOODMEAD, SANDTON  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 42/20.2.2/0446  
 Name of medicine: GLENMARK TERBINAFINE 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, 8  
 Applicant: GLENMARK PHARMACEUTICALS SOUTH  
 AFRICA (PTY) LTD  
 Manufacturer: GLENMARK PHARMACEUTICALS LTD,  
 BARDEZ, GOA, INDIA  
 Packer: GLENMARK PHARMACEUTICALS LTD,  
 BARDEZ, GOA, INDIA  
 Laboratory: FPRC: GLENMARK PHARMACEUTICALS LTD,  
 BARDEZ, GOA, INDIA  
 FPRR: GLENMARK PHARMACEUTICALS, VORNA  
 VALLEY, MIDRAND  
 Shelf-life: 24 months (Provisional)  
 Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 42/20.1.1/0592  
Name of medicine: MOXIBAY IV  
Dosage form: INFUSION  
Active ingredients: EACH 250,0 ml SOLUTION CONTAINS:  
MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT  
TO MOXIFLOXACIN 400,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: BAYER (PTY) LTD  
Manufacturer: BAYER HEALTHCARE AG, LEVERKUSEN,  
GERMANY  
Packer: BAYER HEALTHCARE AG, LEVERKUSEN,  
GERMANY  
BAYER, WILLOWTON, PIETERMARITZBURG  
Laboratory: FPRC: BAYER HEALTHCARE AG, LEVERKUSEN,  
GERMANY  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, NORTH-WEST UNIVERSITY,  
POTCHEFSTROOM  
FPRR: BAYER, ISANDO, KEMPTON PARK  
Shelf-life: 60 months  
Date of registration: 14 AUGUST 2009

**MRF 15**

Registration number: 42/20.1.1/0593  
Name of medicine: MOXIBAY TABLETS  
Dosage form: TABLET  
Active ingredients: EACH TABLET CONTAINS:  
MOXIFLOXACIN HYDROCHLORIDE  
EQUIVALENT TO MOXIFLOXACIN 400,0 mg  
Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
Applicant: BAYER (PTY) LTD  
Manufacturer: BAYER HEALTHCARE AG, LEVERKUSEN,  
GERMANY  
Packer: BAYER HEALTHCARE AG, LEVERKUSEN,  
GERMANY  
BAYER, WILLOWTON, PIETERMARITZBURG  
Laboratory: FPRC: BAYER HEALTHCARE AG, LEVERKUSEN,  
GERMANY  
RESEARCH INSTITUTE FOR INDUSTRIAL  
PHARMACY, NORTH-WEST UNIVERSITY,  
POTCHEFSTROOM  
FPRR: BAYER, ISANDO, KEMPTON PARK  
Shelf-life: 60 months  
Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 42/20.1.1/0594  
 Name of medicine: BAYQUIN TABLETS  
 Dosage form: TABLET  
 Active ingredients: EACH TABLET CONTAINS:  
 MOXIFLOXACIN HYDROCHLORIDE EQUIVALENT  
 TO MOXIFLOXACIN 400,0 mg  
  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: BAYER (PTY) LTD  
 Manufacturer: BAYER HEALTHCARE AG, LEVERKUSEN,  
 GERMANY  
 Packer: BAYER HEALTHCARE AG, LEVERKUSEN,  
 GERMANY  
 BAYER, WILLOWTON, PIETERMARITZBURG  
 Laboratory: FPRC: BAYER HEALTHCARE AG, LEVERKUSEN,  
 GERMANY  
 RESEARCH INSTITUTE FOR INDUSTRIAL  
 PHARMACY, NORTH-WEST UNIVERSITY,  
 POTCHEFSTROOM  
  
 FPRR: BAYER, ISANDO, KEMPTON PARK  
 Shelf-life: 60 months  
 Date of registration: 14 AUGUST 2009

## MRF 15

Registration number: 42/20.1.1/0595  
 Name of medicine: BAYQUIN IV  
 Dosage form: INFUSION  
 Active ingredients: EACH 250,0 ml SOLUTION CONTAINS:  
 MOXIFLOXACIN HYDROCHLORIDE  
 EQUIVALENT TO MOXIFLOXACIN  
 400,0 mg  
  
 Conditions of registration: 1, 2, 3, 4, 5, 6, 7  
 Applicant: BAYER (PTY) LTD  
 Manufacturer: BAYER HEALTHCARE AG, LEVERKUSEN,  
 GERMANY  
 Packer: BAYER HEALTHCARE AG, LEVERKUSEN,  
 GERMANY  
 BAYER, WILLOWTON, PIETERMARITZBURG  
 Laboratory: FPRC: BAYER HEALTHCARE AG, LEVERKUSEN,  
 GERMANY  
 RESEARCH INSTITUTE FOR INDUSTRIAL  
 PHARMACY, NORTH-WEST UNIVERSITY,  
 POTCHEFSTROOM  
  
 FPRR: BAYER, ISANDO, KEMPTON PARK  
 Shelf-life: 60 months  
 Date of registration: 14 AUGUST 2009