



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N\$3.20

WINDHOEK - 7 October 2010

No. 4577

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 225 2010

REGISTRATION OF CERTAIN MEDICINES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

In terms of section 23 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) I make known that the medicines set out Part I of the Schedule have been registered -

- (a) in terms of that Act; and
- (b) subject to the conditions set out in Part II of the Schedule.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 24 September 2010

SCHEDULE

PART I

| S/N | APPLICANT | PROPRIETARY NAME | APPROVED NAME OF ACTIVE(S) | DOSAGE FORM | STRENGTH/DOSE UNIT | REGIST. NO. NAMIBIA | REGISTRATION DATE | SCHED. STATUS |
|-----|------------------------------|--------------------------------------------------|----------------------------|---------------------------------------|---------------------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 1 | Ferring (Pty) Ltd | DDAVP 0,2 mg tablets | Desmopressin acetate | tablet | Each tablet contains Desmopressin Acetate 0,2 mg | 10/18.2/0424 | 6/10/2010 | NS2 |
| 2 | Ferring (Pty) Ltd | Tractocile Solution for Injection | Atosiban Acetate | solution for injection | Each one ml solution contains Atosiban Acetate equiv. to Atosiban free base 7,5 mg | 10/18.9/0425 | 6/10/2010 | NS2 |
| 3 | Ferring (Pty) Ltd | Tractocile Concentrate for Solution for Infusion | Atosiban Acetate | concentrate for solution for infusion | Each one ml solution contains Atosiban Acetate equiv. to Atosiban free base 7,5 mg | 10/18.9/0426 | 6/10/2010 | NS2 |
| 4 | Ranbaxy (S.A) (Pty) Ltd | Efegen XR 75 | Venlafaxine HCl | capsule | Each extended release capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 75 mg | 10/1.2/0427 | 6/10/2010 | NS3 |
| 5 | Ranbaxy (S.A) (Pty) Ltd | Efegen XR 150 | Venlafaxine HCl | extended release capsule | Each extended release capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 150 mg | 10/1.2/0428 | 6/10/2010 | NS3 |
| 6 | Aurobindo Pharma (Pty) Ltd | Auropidone 0,5 mg | Risperidone | tablet | Each tablet contains Risperidone 0,5 mg | 10/2.6.5/0429 | 6/10/2010 | NS3 |
| 7 | Aurobindo Pharma (Pty) Ltd | Auropidone 1 mg | Risperidone | tablet | Each tablet contains Risperidone 1,0 mg | 10/2.6.5/0430 | 6/10/2010 | NS3 |
| 8 | Aurobindo Pharma (Pty) Ltd | Auropidone 2 mg | Risperidone | tablet | Each tablet contains Risperidone 2 mg | 10/2.6.5/0431 | 6/10/2010 | NS3 |
| 9 | Aurobindo Pharma (Pty) Ltd | Auropidone Solution 1 mg/ml | Risperidone | solution | Each 1,0 ml solution contains Risperidone 1,0 mg | 10/2.6.5/0432 | 6/10/2010 | NS3 |
| 10 | Sanofi-Aventis S.A (Pty) Ltd | Rhinathiol 2% Sugar Free Children and Infants | Carbocysteine | syrup | Each 100ml syrup contains Carbocysteine 2,0 g | 10/10.1/0433 | 6/10/2010 | NS1 |
| 11 | Sanofi-Aventis S.A (Pty) Ltd | Rhinathiol 5% Sugar Free Expectoant for Adults | Carbocysteine | syrup | Each 5ml syrup contains Carbocysteine 250 mg | 10/10.1/0434 | 6/10/2010 | NS1 |

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|-----|---------------------------------------|--------------------------------------------------|----------------------------|---------------------------------------|---------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 12 | Adcock Ingram Critical Care (Pty) Ltd | Sabax Midazolam Injection 5 mg/5 ml | Midazolam | injection | Each 5,0 ml solution contains Midazolam 5,0 mg | 10/2.2/0435 | 6/10/2010 | NS3 |
| 13 | Aurobindo Pharma (Pty) Ltd | Auro-Cefalexin Tablets 250 mg | Cefalexin Monohydrate | tablet | Each tablet contains Cefalexin Monohydrate equivalent to Cefalexin 250,0 mg | 10/20.1.1/0436 | 6/10/2010 | NS2 |
| 14 | Aurobindo Pharma (Pty) Ltd | Auro-Cefalexin Tablets 500 mg | Cefalexin Monohydrate | tablet | Each tablet contains Cefalexin Monohydrate equivalent to Cefalexin 500,0 mg | 10/20.1.1/0437 | 6/10/2010 | NS2 |
| 15 | Aurobindo Pharma (Pty) Ltd | Auro-Cefalexin Tablets 1000 mg | Cefalexin Monohydrate | tablet | Each tablet contains Cefalexin Monohydrate equivalent to Cefalexin 1000,0 mg | 10/20.1.1/0438 | 6/10/2010 | NS2 |
| 16 | Solvay Pharma (Pty) Ltd | Cynt 0,2 | Moxonidine | tablet | Each film-coated tablet contains Moxonidine 0,2 mg | 10/7.1.3/0439 | 6/10/2010 | NS2 |
| 17 | Solvay Pharma (Pty) Ltd | Cynt 0,3 | Moxonidine | tablet | Each film-coated tablet contains Moxonidine 0,3mg | 10/7.1.3/0440 | 6/10/2010 | NS2 |
| 18 | Solvay Pharma (Pty) Ltd | Cynt 0,4 | Moxonidine | tablet | Each film-coated tablet contains Moxonidine 0,4 mg | 10/7.1.3/0441 | 6/10/2010 | NS2 |
| 19 | Cipla Medpro (Pty) Ltd | Ciclovent 80 | Ciclesonide | Metered Dose Inhaler | Each actuation delivers Ciclesonide 80 µg | 10/21.5.1/0442 | 6/10/2010 | NS2 |
| 20 | Cipla Medpro (Pty) Ltd | Ciclovent 160 | Ciclesonide | Metered Dose Inhaler | Each actuation delivers Ciclesonide 160 µg | 10/21.5.1/0443 | 6/10/2010 | NS2 |
| 21 | Cipla Medpro (Pty) Ltd | Oncogem 1000 | Gemcitabine Hydrochloride | Injection | Each 50 ml vial contains Gemcitabine Hydrochloride equivalent to Gemcitabine 1000 mg | 10/26/0444 | 6/10/2010 | NS2 |
| 22 | Cipla Medpro (Pty) Ltd | Oncogem 200 | Gemcitabine Hydrochloride | Injection | Each 10 ml vial contains Gemcitabine Hydrochloride equivalent to Gemcitabine 200,0 mg | 10/26/0445 | 6/10/2010 | NS2 |
| 23 | Specpharm (Pty) Ltd | Spec-Perindopril 2 | Perindopril terbutylamine | tablet | Each tablet contains Perindopril terbutylamine 2,0 mg | 10/7.1.3/0446 | 6/10/2010 | NS2 |
| 3 | Ferring (Pty) Ltd | Tractocile Concentrate for Solution for Infusion | Atosiban Acetate | concentrate for solution for infusion | Each one ml solution contains Atosiban Acetate equiv. to Atosiban free base 7,5 mg | 10/18.9/0426 | 6/10/2010 | NS2 |

| S/N | APPLICANT | PROPRIETARY NAME | APPROVED NAME OF ACTIVE(S) | DOSAGE FORM | STRENGTH/DOSE UNIT | REGIST. NO. NAMIBIA | REGISTRATION DATE | SCHED. STATUS |
|-----|-------------------------|-------------------------|-----------------------------------------|-------------|------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 24 | Specpharm (Pty) Ltd | Spec-Perindopril 4 | Perindopril tert-butylamine | tablet | Each tablet contains Perindopril tert-butylamine 4,0 mg | 10/7.1.3/0447 | 6/10/2010 | NS2 |
| 25 | Specpharm (Pty) Ltd | Spec-Perindopril 8 | Perindopril tert-butylamine | tablet | Each tablet contains Perindopril tert-butylamine 8,0 mg | 10/7.1.3/0448 | 6/10/2010 | NS2 |
| 26 | Specpharm (Pty) Ltd | Spec-Perindopril Plus 2 | Perindopril tert-butylamine; Indapamide | tablet | Each tablet contains Perindopril tert-butylamine 2,0 mg and Indapamide 0,625 mg | 10/7.1.3/0449 | 6/10/2010 | NS2 |
| 27 | Specpharm (Pty) Ltd | Spec-Perindopril Plus 4 | Perindopril tert-butylamine; Indapamide | tablet | Each tablet contains Perindopril tert-butylamine 4,0 mg and Indapamide 1,25 mg | 10/7.1.3/0450 | 6/10/2010 | NS2 |
| 28 | Ranbaxy (S.A) (Pty) Ltd | Seran 25 | Quetiapine Fumarate | tablet | Each tablet contains Quetiapine Fumarate equivalent to Quetiapine Free Base 25 mg | 10/2.6.5/0451 | 6/10/2010 | NS3 |
| 29 | Ranbaxy (S.A) (Pty) Ltd | Seran 100 | Quetiapine Fumarate | tablet | Each tablet contains Quetiapine Fumarate equivalent to Quetiapine Free Base 100 mg | 10/2.6.5/0452 | 6/10/2010 | NS3 |
| 30 | Ranbaxy (S.A) (Pty) Ltd | Seran 200 | Quetiapine Fumarate | tablet | Each tablet contains Quetiapine Fumarate equivalent to Quetiapine Free Base 200 mg | 10/2.6.5/0453 | 6/10/2010 | NS3 |
| 31 | Ranbaxy (S.A) (Pty) Ltd | Seran 300 | Quetiapine Fumarate | tablet | Each tablet contains Quetiapine Fumarate equivalent to Quetiapine Free Base 300 mg | 10/2.6.5/0454 | 6/10/2010 | NS3 |
| 32 | Ranbaxy (S.A) (Pty) Ltd | Zypene 2,5 | Olanzapine | tablet | Each tablet contains Olanzapine 2,5 mg | 10/2.6.5/0455 | 6/10/2010 | NS3 |
| 33 | Ranbaxy (S.A) (Pty) Ltd | Zypene S | Olanzapine | tablet | Each tablet contains Olanzapine 5 mg | 10/2.6.5/0456 | 6/10/2010 | NS3 |
| 34 | Ranbaxy (S.A) (Pty) Ltd | Zypene 10 | Olanzapine | tablet | Each tablet contains Olanzapine 10 mg | 10/2.6.5/0457 | 6/10/2010 | NS3 |
| 35 | Ranbaxy (S.A) (Pty) Ltd | Candagen 8 | Candesartan Cilixetil | tablet | Each tablet contains Candesartan Cilixetil 8 mg | 10/7.1.3/0458 | 6/10/2010 | NS2 |
| 36 | Ranbaxy (S.A) (Pty) Ltd | Candagen 16 | Candesartan Cilixetil | tablet | Each tablet contains Candesartan Cilixetil 16 mg | 10/7.1.3/0459 | 6/10/2010 | NS2 |

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|-----|---------------------------|-----------------------|-----------------------------|----------------------|----------------------------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 37 | Ranbaxy (S.A) (Pty) Ltd | Setigo 24 | Betahistine Dihydrochloride | tablet | Each tablet contains Betahistine Dihydrochloride 24 mg | 10/5.6/0460 | 6/10/2010 | NS2 |
| 38 | Ranbaxy (S. A) (Pty) Ltd | Mercide 500 | Meropenem | powder for injection | Each vial contains Meropenem (sterile) equivalent to anhydrous Meropenem 500,0 mg | 10/20.1.1/0461 | 6/10/2010 | NS2 |
| 39 | Ranbaxy (S.A) (Pty) Ltd | Mercide 1G | Meropenem | powder for injection | Each vial contains Meropenem (sterile) equivalent to anhydrous Meropenem 1G | 10/20.1.1/0462 | 6/10/2010 | NS2 |
| 40 | Bayer (Pty) Ltd | Xarelto 10 | Rivaroxaban | tablet | Each film-coated tablet contains Rivaroxaban 10,0 mg | 10/8.2/0463 | 6/10/2010 | NS2 |
| 41 | Astellas Pharma (Pty) Ltd | Denol Swallow Tablets | Tripotassium Bismuthate III | tablet | Each tablet contains Tripotassium Dicitrato Bismuthate III, 300 mg equivalent to Bismuth Trioxide 120 mg | 10/11,10/0464 | 6/10/2010 | NS1 |
| 42 | Astellas Pharma (Pty) Ltd | Progaf 0,5mg | Tacrolimus | capsule | Each capsule contains Tacrolimus 0,5 mg | 10/34/0465 | 6/10/2010 | NS2 |
| 43 | Astellas Pharma (Pty) Ltd | Vesicare 10 mg | Solifenacin Succinate | tablet | Each tablet contains Solifenacin Succinate 10,0 mg | 10/5.4/0466 | 6/10/2010 | NS2 |
| 44 | Tema Medical (Pty) Ltd | Pedea | Ibuprofen | injection | Each 2 ml ampoule contains Ibuprofen 10,0 mg | 10/3.1/0467 | 6/10/2010 | NS2 |
| 45 | Specpharm (Pty) Ltd | Spec-Clopidogrel 75 | Clopidogrel Besylate | film-coated tablet | Each film-coated tablet contains Clopidogrel Besylate equivalent to Clopidogrel base 75 mg | 10/8.2/0468 | 6/10/2010 | NS2 |

PART II

The Medicines set out in Part I of the Schedule have been registered subject to the following conditions:

1. The manufacture and control of the medicines must -
 - (a) comply with the requirements of the Current Good Manufacturing Practices;
 - (b) regularly be inspected and investigated by the inspectors authorised under section 35 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003).
2. The information in the package insert must be -
 - (a) updated regularly;
 - (b) approved by the Namibia Medicines Regulatory Council.
3. The Namibia Medicines Regulatory Council may as it deem fit review the registration dossier.
4. The first two production batches of the medicines must comply with the Validation Protocol which was submitted at the time of the application for the registration of the medicine and the report of validation which is in conformity with the Validation Protocol must be submitted to the Namibia Medicines Regulatory Council within one month starting from the date of the completion of the validation.

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 226

2010

**REGISTRATION OF CERTAIN MEDICINES: MEDICINES AND RELATED
SUBSTANCES CONTROL ACT, 2003**

In terms of section 23 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) I give notice that the medicines set out in the Schedule have been registered in terms of that Act, subject to the following conditions -

- (a) the manufacture and control of the medicines must be in accordance with the existing current Good Manufacturing Practices as required by the World Health Organization;
- (b) in order to assess compliance with paragraph (a), inspections and investigations may be carried out regularly by inspectors authorized in terms of sections 35 of the Act;
- (c) the information in the package insert must regularly be updated to conform with the package insert approved by the Council;
- (d) the holder of the certificate of registration, referred to in section 19(7) of the Act, must comply with the Act;
- (e) the registration of medicine is subject to regular review regarding its quality, safety and efficacy, and the Council may, as it considers necessary, vary the registration of the medicine;

- (f) the first two production batches must be validated in accordance with the detailed process validation protocol which was submitted at the time of the application for registration;
- (g) a validation report must be submitted to the Council within one month from the date of completion of the validation referred to in paragraph (f); and
- (h) the Council may review the registration dossier at such intervals as the Council may determine.

J. GAESEB
REGISTRAR OF MEDICINES

28 September 2010

SCHEDULE

| S/N | APPLICANT | PROPRIETARY NAME | APPROVED NAME OF ACTIVE(S) | DOSAGE FORM | STRENGTH/DOSE UNIT | REGIST. NO. NAMIBIA | REGISTRATION DATE | SCHED. STATUS |
|-----|-----------------------------------------|------------------|-------------------------------------------------------------------------------------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 1 | Eli Lilly (Pty) Ltd | Cialis 5 | Tadalafil | tablet | Each tablet contains Tadalafil 5,0 mg | 10/7.1.5/0469 | 2010/08/12 | NS2 |
| 2 | Glaxo SmithKline South Africa (Pty) Ltd | Synflorix | Pneumococcal polysaccharide and non-Typeable Haemophilus Influenzae protein D conjugate vaccine | suspension for injection | Each 0.5 ml dose contains 1 µg of Pneumococcal polysaccharide for serotypes 1, 5, 6B, 7V, 9V, 14 and 23F and 3 µg of serotypes 4, 18CV and 19F and non-Typeable Haemophilus Influenzae protein D | 10/30.1/0470 | 2010/08/12 | NS1 |
| 3 | Cipla Medpro (Pty) Ltd | Didivir | Emtricitabine and Tenofovir disonroxil | tablet | Each film-coated tablet contains Emtricitabine 200 mg mg Tenofovir disonroxil fumarate 300 mg | 10/20.2.8/0471 | 2010/08/12 | NS2 |
| 4 | Inova Pharmaceuticals (Pty) Ltd | Metrogel V | Metronidazole | vaginal gel | Each 5g dose contains Metronidazole 37,5 mg | 10/20.2.6/0472 | 2010/08/12 | NS1 |
| 5 | Pharma Dynamics (Pty) Ltd | Peploc 20 mg | Pantoprazole Sodium sesquihydrate | tablet | Each tablet contains Pantoprazole Sodium sesquihydrate equivalent to Pantoprazole 20,0 mg | 10/11.4.3/0473 | 2010/08/12 | NS2 |
| 6 | Pharma Dynamics (Pty) Ltd | Peploc 40 mg | Pantoprazole Sodium sesquihydrate | tablet | Each tablet contains Pantoprazole Sodium sesquihydrate equivalent to Pantoprazole 40,0 mg | 10/11.4.3/0474 | 2010/08/12 | NS2 |
| 7 | Pharma Dynamics (Pty) Ltd | Pearinda 2 | Perindopril tert-butylamine | tablet | Each tablet contains Perindopril tert-butylamine 2,0 mg | 10/7.1.3/0475 | 2010/08/12 | NS2 |
| 8 | Pharma Dynamics (Pty) Ltd | Pearinda 4 | Perindopril tert-butylamine | tablet | Each tablet contains Perindopril tert-butylamine 4,0 mg | 10/7.1.3/0476 | 2010/08/12 | NS2 |
| 9 | Pharma Dynamics (Pty) Ltd | Pearinda 8 | Perindopril tert-butylamine | tablet | Each tablet contains Perindopril tert-butylamine 8,0 mg | 10/7.1.3/0477 | 2010/08/12 | NS2 |
| 10 | Pharma Dynamics (Pty) Ltd | Zytomil 10 mg | Escitalopram Oxalate | tablet | Each tablet contains Escitalopram oxalate equivalent to Escitalopram 10,0 mg | 10/1.2/0478 | 2010/08/12 | NS3 |
| 11 | Pharma Dynamics (Pty) Ltd | Zytomil 5 mg | Escitalopram Oxalate | tablet | Each tablet contains Escitalopram Oxalate equivalent to Escitalopram 5,0 mg | 10/1.2/0479 | 2010/08/12 | NS3 |
| 12 | Pharma Dynamics (Pty) Ltd | Zytomil 15 mg | Escitalopram Oxalate | tablet | Each tablet contains Escitalopram Oxalate equivalent to Escitalopram 15,0 mg | 10/1.2/0480 | 2010/08/12 | NS3 |
| 13 | Pharma Dynamics (Pty) Ltd | Zytomil 20 mg | Escitalopram Oxalate | tablet | Each tablet contains Escitalopram Oxalate equivalent to Escitalopram 20,0 mg | 10/1.2/0481 | 2010/08/12 | NS3 |

| S/N | APPLICANT | PROPRIETARY NAME | APPROVED NAME OF ACTIVE(S) | DOSAGE FORM | STRENGTH/DOSE UNIT | REGIST. NO. NAMIBIA | REGISTRATION DATE | SCHED. STATUS |
|-----|---------------------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 14 | Cipla Medpro (Pty) Ltd | Cipex Tablets | Mebendazole | tablet | Each tablet contains Mebendazole 100,0 mg | 10/12/0482 | 2010/08/12 | NS1 |
| 15 | Ferring (Pty) Ltd | Pentasa 1 g | Mesalazine | suppository | Each suppository contains Mesalazine 1,0 g | 10/11/0483 | 2010/08/12 | NS2 |
| 16 | Pharmaplan (Pty) Ltd | Paser Granules | 4-aminosalicylic acid | granules | Each packet contains of 4-Aminosalicylic Acid 4 g | 10/20.2.3/0484 | 2010/08/12 | NS2 |
| 17 | Adcock Ingram Critical Care (Pty) Ltd | Vitahes | Hydroxyethyl starch; Sodium chloride | infusion solution | Each 500 ml solution contains poly (0-2 Hydroxyethyl) Starch (HES) 30g and Sodium chloride 4,5 g | 10/8.4/0485 | 2010/08/12 | NS1 |
| 18 | Adcock Ingram Critical Care (Pty) Ltd | Vitafusal | Hydroxyethyl starch; Sodium chloride; Potassium chloride; Calcium chloride dihydrate; Magnesium | infusion solution | Each 1000ml contains Hydroxyethyl Starch 60g, Sodium Chloride 6g, Potassium Chloride 0.4g, Calcium Chloride dihydrate 0.134g, Magnesium Chloride hexahydrate 0.2g and Sodium Acetate trihydrate 3.7g | 10/8.4/0486 | 2010/08/12 | NS1 |
| 19 | Adcock Ingram Limited | Adco-Sporozole | Itraconazole | capsule | Each capsule contains Itraconazole 100,0 mg | 10/20.2.2/0487 | 2010/08/12 | NS2 |
| 20 | Ingelheim Pharmaceuticals (Pty) Ltd | Spiriva Respimat | Tiotropium bromide | solution | Each puff delivers Tiotropium Monohydrate 3.124 µg equivalent to Tiotropium 2,5 µg | 10/10.2.1/0488 | 2010/08/12 | NS1 |
| 21 | Adcock Ingram Limited | Dovobet | Calcipotriol; Betamethasone | ointment | Each gram ointment contains Calcipotriol 50 µg (as hydrate 52,2 µg), Betamethasone 0,5 mg (as dipropionate 0,643 mg) | 10/13.9.1/0489 | 2010/08/12 | NS2 |
| 22 | Aurobindo Pharma (Pty) Ltd | Auropidone 3 mg | Risperidone | tablet | Each tablet contains Risperidone 3,0 mg | 10/2.6.5/0490 | 2010/08/12 | NS3 |
| 23 | Aurobindo Pharma (Pty) Ltd | Auropidone 4 mg | Risperidone | tablet | Each tablet contains Risperidone 4,0 mg | 10/2.6.5/0491 | 2010/08/12 | NS3 |
| 24 | Adcock Ingram Ltd | Adco-Zidovudine Syrup Alcohol and Sugar Free | Zidovudine | syrup | Each 5,0 ml syrup contains Zidovudine 50,0 mg | 10/20.2.8/0492 | 2010/08/12 | NS2 |
| 25 | Adcock Ingram Ltd | Adco-Lamivudine Solution Alcohol and Sugar Free | Lamivudine | solution | Each 1,0 ml solution contains Lamivudine 10,0 mg | 10/20.2.80493 | 2010/08/12 | NS2 |

| S/N | APPLICANT | PROPRIETARY NAME | APPROVED NAME OF ACTIVE(S) | DOSAGE FORM | STRENGTH/DOSE UNIT | REGIST. NO. NAMIBIA | REGISTRATION DATE | SCHED. STATUS |
|-----|-------------------------------------|--------------------|----------------------------------------------|-------------------------|---------------------------------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 26 | Ingelheim Pharmaceuticals (Pty) Ltd | Pradaxa 75 mg | Dabigantran Etexilate Mesilate | capsule | Each capsule contains Dabigantran Etexilate Mesilate equivalent to Dabigantran 75,0 mg | 10/8.2/0494 | 2010/08/12 | NS2 |
| 27 | Ingelheim Pharmaceuticals (Pty) Ltd | Pradaxa 110 mg | Dabigantran Etexilate Mesilate | capsule | Each capsule contains Dabigantran Etexilate Mesilate equivalent to Dabigantran 110,0 mg | 10/8.2/0495 | 2010/08/12 | NS2 |
| 28 | Pharmacare Limited | Rampil 1,25 mg | Ramipril | capsule | Each capsule contains Ramipril 1,25 mg | 10/7.1.3/0496 | 2010/08/12 | NS2 |
| 29 | Pharmacare Limited | Rampil 2,5 mg | Ramipril | capsule | Each capsule contains Ramipril 2,5 mg | 10/7.1.3/097 | 2010/08/12 | NS2 |
| 30 | Phannacare Limited | Rampil 5,0 mg | Ramipril | capsule | Each capsule contains Ramipril 5 mg | 10/7.1.3/0498 | 2010/08/12 | NS2 |
| 31 | Pharmacare Limited | Rampil 10,0 mg | Ramipril | capsule | Each capsule contains Ramipril 10 mg | 10/7.1.3/0499 | 2010/08/12 | NS2 |
| 32 | Janssen Pharmaceutica (Pty) Ltd | Concerta 27 mg | Methylphenidate hydrochloride | extended-release tablet | Each extended-release tablet contains Methylphenidate hydrochloride 27,0 mg | 10/1.2/0500 | 2010/08/12 | NS3 |
| 33 | Ranbaxy (SA) (Pty) Ltd | Actrise 5 | Risedronate sodium | tablet | Each tablet contains Risedronate Sodium 5,0 mg equivalent to Risedronic Acid 4,64 mg | 10/3.2/0501 | 2010/08/12 | NS2 |
| 34 | Ranbaxy (SA) (Pty) Ltd | Actrise 35 | Risedronate sodium | tablet | Each tablet contains Risedronate Sodium 35,0 mg equivalent to Risedronic Acid 32,5 mg | 10/3.2/0502 | 2010/08/12 | NS2 |
| 35 | Ranbaxy (SA) (Pty) Ltd | Epralife 10 | Escitalopram oxalate | tablet | Each tablet contains Escitalopram oxalate equivalent to Escitalopram 10 mg | 10/1.2/0503 | 2010/08/12 | NS3 |
| 36 | Ranbaxy (SA) (Pty) Ltd | Epralife 20 | Escitalopram oxalate | tablet | Each tablet contains Escitalopram oxalate equivalent to Escitalopram 20 mg | 10/1.2/0504 | 2010/08/12 | NS3 |
| 37 | Cipla Medpro (Pty) Ltd | Sereflo 25/125 HFA | Salmeterol Xinafoate; Fluticasone Propionate | metered dose inhaler | Each actuation delivers Salmeterol Xinafoate equivalent to Salmeterol 25 µg and Fluticasone Propionate 125 µg | 10/21.5.4/0505 | 2010/08/12 | NS2 |
| 38 | Cipla Medpro (Pty) Ltd | Sereflo 25/250 HFA | Salmeterol Xinafoate; Fluticasone Propionate | metered dose inhaler | Each actuation delivers Salmeterol Xinafoate equivalent to Salmeterol 25 µg and Fluticasone Propionate 250 µg | 10/21.5.4/0506 | 2010/08/12 | NS2 |
| 39 | Cipla Medpro (Pty) Ltd | Sereflo 25/50 HFA | Salmeterol Xinafoate; Fluticasone Propionate | metered dose inhaler | Each actuation delivers Salmeterol Xinafoate equivalent to Salmeterol 25 µg and Fluticasone Propionate 50 µg | 10/21.5.4/0507 | 2010/08/12 | NS2 |

| S/N | APPLICANT | PROPRIETARY NAME | APPROVED NAME OF ACTIVE(S) | DOSAGE FORM | STRENGTH/DOSE UNIT | REGIST. NO. NAMIBIA | REGISTRATION DATE | SCHED. STATUS |
|-----|---------------------------------|-------------------------|------------------------------|-----------------------|-----------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 40 | Cipla Medpro (Pty) Ltd | Cipla-Vinorelbine 10 | Vinorelbine tartrate | intravenous injection | Each 1 ml solution contains Vinorelbine tartrate equivalent to Vinorelbine base 10,0 mg | 10/26/0508 | 2010/08/12 | NS2 |
| 41 | Novartis South Africa (Pty) Ltd | Otrivin Paed | Xylometazoline hydrochloride | drops | Each 1 ml contains Xylometazoline Hydrochloride 0,5 mg | 10/16.1/0509 | 2010/08/12 | NS1 |
| 42 | Novartis South Africa (Pty) Ltd | Otrivin Adult | Xylometazoline hydrochloride | drops | Each 1 ml contains Xylometazoline Hydrochloride 1,0 mg | 10/16.1/0510 | 2010/08/12 | NS1 |
| 43 | Novartis South Africa (Pty) Ltd | Otrivin Menthol | Xylometazoline hydrochloride | nasal spray | Each 1 ml contains Xylometazoline Hydrochloride 1,0 mg | 10/16.1/0511 | 2010/08/12 | NS1 |
| 44 | Novartis South Africa (Pty) Ltd | Fenivir Cold Sore Cream | Penciclovir | cream | Each 100 g cream contains Penciclovir 1 g | 10/20.2.8/0512 | 2010/08/12 | NS1 |
| 45 | Novartis South Africa (Pty) Ltd | Zymafluor Drops | Sodium Fluoride | drops | Each 4 drops contains Sodium Fluoride equivalent to Fluoride 0,25 mg | 10/24/0513 | 2010/08/12 | NS1 |
| 46 | Cipla Medpro (Pty) Ltd | Oncogem 1000 | Gemcitabine hydrochloride | Injection | Each 50 ml vial contains Gemcitabine hydrochloride equivalent to Gemcitabine 1000 mg | 10/26/0514 | 2010/08/12 | NS2 |
| 47 | Cipla Medpro (Pty) Ltd | Oncogem 200 | Gemcitabine hydrochloride | Injection | Each 10 ml vial contains Gemcitabine hydrochloride equivalent to Gemcitabine 200,0 mg | 10/26/0515 | 2010/08/12 | NS2 |
| 48 | Ranbaxy (S.A.) (Pty) Ltd | Flucoric Infusion | Fluconazole | Injection | Each vial contains Fluconazole 2 mg/ml | 10/20.2.2/0516 | 2010/08/12 | NS2 |
| 49 | Cipla-Medpro (Pty) Ltd | Cipex Tablets | Mebendazole | tablet | Each tablet contains Mebendazole 100,0 mg | 10/12/0517 | 2010/08/12 | NS1 |
| 50 | Cipla-Medpro (Pty) Ltd | Cipla-Loperamide | Loperamide Hydrochloride | tablet | Each tablet contains Loperamide Hydrochloride 2,0 mg | 10/11.9.2/0518 | 2010/08/12 | NS1 |
| 51 | Cipla Medpro (Pty) Ltd | Nexonase | Mometasone Furoate | nasal spray | Each metered spray delivers Mometasone Furoate | 10/14.4.1/0519 | 2010/08/12 | NS2 |
| 52 | Pharmacare Limited | Aspen Mirtazapine 15 mg | Mirtazapine | tablet | Each tablet contains Mirtazapine 15,0 mg | 10/1.2/0520 | 2010/08/12 | NS3 |
| 53 | Pharmacare Limited | Aspen Mirtazapine 30 mg | Mirtazapine | tablet | Each tablet contains Mirtazapine 30,0 mg | 10/1.2/0521 | 2010/08/12 | NS3 |

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|-----|--------------------|-----------------------------|-----------------------------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------|---------------|
| 54 | Pharmacare Limited | Aspen Midazolam 50 mg/10 ml | Midazolam Hydrochloride | Injection | Each 10,0 ml solution contains Midazolam Hydrochloride equivalent to Midazolam 50,0 mg | 10/2.2/0522 | 2010/08/12 | NS3 |
| 55 | Pharmacare Limited | Aspen Fluconazole 50 mg | Fluconazole | capsule | Each capsule contains Fluconazole 50,0 mg | 10/20.2.2/0523 | 2010/08/12 | NS2 |
| 56 | Pharmacare Limited | Aspen Fluconazole 150 mg | Fluconazole | capsule | Each capsule contains Fluconazole 150,0 mg | 10/20.2.2/0524 | 2010/08/12 | NS2 |
| 57 | Pharmacare Limited | Aspen Fluconazole 200 mg | Fluconazole | capsule | Each capsule contains Fluconazole 200,0 mg | 10/20.2.2/0525 | 2010/08/12 | NS2 |
| 58 | Pharmacare Limited | Amiotach | Amiodarone Hydrochloride | Injection | Each 3,0 ml solution contains Amiodarone Hydrochloride 150,0 mg | 10/6.2/0526 | 2010/08/12 | NS2 |
| 59 | Pharmacare Limited | Almadin 10 | Amlodipine Besylate | tablet | Each tablet contains Amlodipine Besylate equivalent to Amlodipine 10,0 mg | 10/7.1/0527 | 2010/08/12 | NS2 |
| 60 | Pharmacare Limited | Equinorm 10 mg Tablets | Clomipramine Hydrochloride | tablet | Each tablet contains Clomipramine Hydrochloride 10 mg | 10/1.2/0528 | 2010/08/12 | NS3 |
| 61 | Pharmacare Limited | Equinorm 25 mg Tablets | Clomipramine Hydrochloride | tablet | Each tablet contains Clomipramine Hydrochloride 25 mg | 10/1.2/0529 | 2010/08/12 | NS3 |
| 62 | Pharmacare Limited | Augmaxcil SF | Amoxicillin Trihydrate; Potassium Clavulanate | suspension | Each 5,0 ml suspension contains Amoxicillin Trihydrate equivalent to Amoxicillin 250,0 mg and Potassium Clavulanate equivalent to Clavulanic Acid 62,5 mg | 10/20.1.2/0530 | 2010/08/12 | NS2 |
| 63 | Pharmacare Limited | Augmaxcil S | Amoxicillin Trihydrate; Potassium Clavulanate | suspension | Each 5,0 ml suspension contains Amoxicillin Trihydrate equivalent to Amoxicillin 125,0 mg and Potassium Clavulanate equivalent to Clavulanic Acid 31,25 mg | 10/20.1.2/0531 | 2010/08/12 | NS2 |
| 64 | Pharmacare Limited | Augmaxcil 375 | Amoxicillin Trihydrate; Potassium Clavulanate | tablet | Each tablet contains Amoxicillin Trihydrate equivalent to Amoxicillin 250,0 mg and Potassium Clavulanate equivalent to Clavulanic Acid 125,0 mg | 10/20.1.2/0532 | 2010/08/12 | NS2 |
| 65 | Pharmacare Limited | Bezachole SR | Bezafibrate | tablet | Each tablet contains Bezafibrate 400,0 mg | 10/7.5/0533 | 2010/08/12 | NS2 |
| 66 | Pharmacare Limited | Aspen Simvastatin 10mg | Simvastatin | tablet | Each tablet contains Simvastatin 10,0 mg | 10/7.5/0534 | 2010/08/12 | NS2 |

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| 67 | Pharmacare Limited | Aspen Risperidone 0,5 mg | Risperidone | tablet | Each tablet contains Risperidone 0,5 mg | 10/2.6.5/0535 | 2010/08/12 | NS3 |
| 68 | Pharmacare Limited | Aspen Risperidone 1 mg | Risperidone | tablet | Each tablet contains Risperidone 1,0 mg | 10/2.6.5/0536 | 2010/08/12 | NS3 |
| 69 | Pharmacare Limited | Aspen Risperidone 2 mg | Risperidone | tablet | Each tablet contains Risperidone 2,0 mg | 10/2.6.5/0537 | 2010/08/12 | NS3 |
| 70 | Pharmacare Limited | Aspen Risperidone 3 mg | Risperidone | tablet | Each tablet contains Risperidone 3,0 mg | 10/2.6.5/0538 | 2010/08/12 | NS3 |
| 71 | Pharmacare Limited | Aspen Risperidone 4 mg | Risperidone | tablet | Each tablet contains Risperidone 4,0 mg | 10/2.6.5/0539 | 2010/08/12 | NS3 |
| 72 | Pharmacare Limited | Dilatam 60 mg | Diltiazem hydrochloride | tablet | Each tablet contains Diltiazem Hydrochloride 60 mg | 10/7.1/0540 | 2010/08/12 | NS2 |
| 73 | Pharmacare Limited | Azor - 0,25 | Alprazolam | tablet | Each tablet contains Alprazolam 0,25 mg | 10//2.6/0541 | 2010/08/12 | NS3 |
| 74 | Pharmacare Limited | Aspen Pentoxifylline 400 SR | Pentoxifylline | tablet | Each tablet contains Pentoxifylline 400,0 mg | 10/8/0542 | 2010/08/12 | NS1 |
| 75 | Pharmacare Limited | Aspen Lansoprazole 30 | Lansoprazole | capsule | Each capsule contains Lansoprazole 30,0 mg | 10/11.4.3/0543 | 2010/08/12 | NS2 |
| 76 | Pharmacare Limited | Aspen Ondansetron 4mg/2ml | Ondansetron hydrochloride | Injection | Each 1,0 ml liquid contains Ondansetron Hydrochloride equivalent to Ondansetron 2,0 mg | 10/5.10/0544 | 2010/08/12 | NS2 |
| 77 | Pharmacare Limited | Aspen Ondansetron 8mg/4ml | Ondansetron hydrochloride | Injection | Each 1,0 ml liquid contains Ondansetron Hydrochloride equivalent to Ondansetron 2,0 mg | 10/5.10/0545 | 2010/08/12 | NS2 |
| 78 | Pharmacare Limited | Aspen Naproxen 275 mg | Naproxen Sodium | tablet | Each tablet contains Naproxen Sodium 275,0 mg | 10/3.1/0546 | 2010/08/12 | NS2 |
| 79 | Pharmacare Limited | Venteze CFC Free | Salbutamol Sulphate | metered dose inhaler | Each metered dose delivers Salbutamol Sulphate equivalent to Salbutamol 100,0 mcg | 10/10.2.1/0547 | 2010/08/12 | NS2 |
| 80 | Pharmacare Limited | Mybulen Capsules | Ibuprofen; Paracetamol; Codeine Phosphate | capsule | Each capsule contains Ibuprofen 200,0 mg, Paracetamol 250,0 mg and Codeine Phosphate 10,0 mg | 10/2.8/0548 | 2010/08/12 | NS1 |
| 81 | Pharmacare Limited | Triptam 50 mg | Sumatriptam | tablet | Each tablet contains Sumatriptam 50,0 mg | 10/7.3/0549 | 2010/08/12 | NS2 |

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| 82 | Pharmacare Limited | Redipred | Prednisolone Sodium Phosphate | liquid | Each 5,0 ml liquid contains Prednisolone Sodium Phosphate equivalent to Prednisolone 15,0 mg | 10/21.5.1/0550 | 2010/08/12 | NS2 |
| 83 | Pharmacare Limited | Hyospasmol Syrup | Hyoscine-N-Butyl | liquid | Each 5,0 ml liquid contains Hyoscine-N-Butyl | 10/11.2/0551 | 2010/08/12 | NS1 |
| 84 | Pharmacare Limited | Menograin Drops | Clonidine Hydrochloride | drops | Each 0,50 ml drops contains Clonidine Hydrochloride 25,0 mg | 10/7.3/0552 | 2010/08/12 | NS1 |
| 85 | Pharmacare Limited | Glyceron | Gliclazide | tablet | Each tablet contains Gliclazide 80,0 mg | 10/21.2/0553 | 2010/08/12 | NS2 |
| 86 | Pharmacare Limited | Orpic 2 mg/ml IV | Ciprofloxacin Lactate | Injection | Each 1,0 ml solution contains Ciprofloxacin Lactate equivalent to Ciprofloxacin 2,0 mg | 10/20.1.1/0554 | 2010/08/12 | NS2 |
| 87 | Pharmacare Limited | Oculerge | Antazoline Hydrochloride; Tetrahydrozoline Hydrochloride | eye drops | Each 1 ml liquid contains Antazoline Hydrochloride 0,5 mg and Tetrahydrozoline Hydrochloride 0,4 mg | 10115.410555 | 2010/08/12 | NS1 |
| 88 | Pharmacare Limited | Lovachol 20 mg | Lovastatin | tablet | Each tablet contains Lovastatin 20,0 mg | 10/7.5/0556 | 2010/08/12 | NS2 |
| 89 | Pharmacare Limited | Lovachol 40 mg | Lovastatin | tablet | Each tablet contains Lovastatin 40,0 mg | 10/7.5/0557 | 2010/08/12 | NS2 |
| 90 | Pharmacare Limited | Neophedan 10 | Tamoxifen Citrate | tablet | Each tablet contains Tamoxifen Citrate equivalent to Tamoxifen 10,0 mg | 10/26/0558 | 2010/08/12 | NS2 |
| 91 | Pharmacare Limited | Neophedan 20 | Tamoxifen Citrate | tablet | Each tablet contains Tamoxifen Citrate equivalent to Tamoxifen 20,0 mg | 10/26/00559 | 2010/08/12 | NS2 |
| 92 | Pharmacare Limited | Lenapain | Caffeine anhydrous; Codeine Phosphate; Doxylamine Succinate; Paracetamol | tablet | Each tablet contains Caffeine anhydrous 30 mg, Codeine Phosphate 10 mg, Doxylamine Succinate 5 mg and Paracetamol 450 mg | 10/2.9/0560 | 2010/08/12 | NS1 |
| 93 | Pharmacare Limited | Ketazol Cream | Ketoconazole | cream | Each 1,0 g cream contains Ketoconazole 20,0 mg | 10/20.2.2/0561 | 2010/08/12 | NS1 |
| 94 | Pharmacare Limited | Mybulen Suspension | Ibuprofen; Paracetamol; Codeine Phosphate | suspension | Each 10,0 ml suspension contains Ibuprofen 200,0 mg, Codeine Phosphate 10,0 mg and Paracetamol 250,0 mg | 10/2.8/0562 | 2010/08/12 | NS1 |
| 95 | Pharmacare Limited | Ibumol Grape | Paracetamol; Ibuprofen | suspension | Each 10,0 ml suspension contains Paracetamol 250,0 mg and Ibuprofen 200,0 mg | 10/2.8/0563 | 2010/08/12 | NS1 |
| 96 | Pharmacare Limited | Somnil Drops | Doxylamine Succinate | solution | Each 0,5 ml solution contains Doxylamine Succinate 25,0 mg | 10/2.2/0564 | 2010/08/12 | NS3 |

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| 97 | Pharmacare Limited | Stilpane | Caffeine; Codeine Phosphate; Meprobamate; Paracetamol | tablet | Each tablet contains Caffeine 32,0 mg, Codeine phosphate 8,0 mg, Meprobamate 150,0 mg and Paracetamol 320,0 mg | 10/2.9/0565 | 2010/08/12 | NS3 |
| 98 | Pharmacare Limited | Terbicil | Terbinafine Hydrochloride | tablet | Each tablet contains Terbinafine Hydrochloride equivalent to Terbinafine 250,0 mg | 10/20.2.2/0566 | 2010/08/12 | NS2 |
| 99 | Pharmacare Limited | Triptam 100 mg | Sumatriptam | tablet | Each tablet contains Sumatriptam 100,0 mg | 10/7.3/0567 | 2010/08/12 | NS2 |
| 100 | Pharmacare Limited | AP Methylpred | Methylprednisolone Sodium Succinate | Injection | Each 8,0 ml solution contains Methylprednisolone Sodium Succinate equivalent to | 10/21.5.1/0568 | 2010/08/12 | NS2 |
| 101 | Pharmacare Limited | Aspen Bromocriptine 2,5 mg | Bromocriptine Mesylate | tablet | Each tablet contains Bromocriptine Mesylate equivalent to Bromocriptine 2,5 mg | 10/21.12/0569 | 2010/08/12 | NS2 |
| 102 | Pharmacare Limited | AT Loratadine Syrup | Loratadine | syrup | Each 5,0 ml syrup contains Loratadine 5,0 mg | 10/5.7.1/0570 | 2010/08/12 | NS2 |
| 103 | Pharmacare Limited | Factive 320 mg | Gemifloxacin Mesylate | tablet | Each tablet contains Gemifloxacin Mesylate equivalent to Gemifloxacin 320,0 mg | 10/20.1.1/0571 | 2010/08/12 | NS2 |
| 104 | Pharmacare Limited | Throsyn 150 mg Tablet | Roxithromycin | tablet | Each tablet contains Roxithromycin 150,0 mg | 10/20.1.1/0572 | 2010/08/12 | NS2 |
| 105 | Cipla Medpro (Pty) Ltd | Ziamune Oral Solution | Abacavir Sulphate | solution | Each 1,0 ml solution contains Abacavir Sulphate equivalent to Abacavir 20,0 mg | 10/20.2.8/0573 | 2010/08/12 | NS2 |
| 106 | Cipla Medpro (Pty) Ltd | Tenvir 300 | Tenofovir Disoproxil Fumarate | tablet | Each tablet contains Tenofovir Disoproxil Fumarate 300,0 mg | 10/20.2.8/0574 | 2010/08/12 | NS2 |
| 107 | Cipla-Medpro (Pty) Ltd | Granitron 1 mg | Granisetron Hydrochloride | tablet | Each tablet contains Granisetron Hydrochloride equivalent to Granisetron 1,0 mg | 10/5.7.2/0575 | 2010/08/12 | NS2 |
| 108 | Cipla-Medpro (Pty) Ltd | Granitron 2 mg | Granisetron Hydrochloride | tablet | Each tablet contains Granisetron Hydrochloride equivalent to Granisetron 2,0 mg | 10/5.7.2/0576 | 2010/08/12 | NS2 |
| 109 | Cipla-Medpro (Pty) Ltd | Cipla-Actin | Cyproheptadine Hydrochloride | tablet | Each tablet contains Cyproheptadine Hydrochloride equivalent to Cyproheptadine 4,0 mg | 10/5.7.1/0577 | 2010/08/12 | NS2 |
| 110 | Cipla-Medpro (Pty) Ltd | Cipla Vinorelbine 50 | Vinorelbine Tartrate | Injection | Each 5,0 ml solution contains Vinorelbine Tartrate equivalent to Vinorelbine 50,0 mg | 10/26/0578 | 2010/08/12 | NS2 |

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| 111 | Cipla-Medpro (Pty) Ltd | Finpecia 1 mg | Finasteride | tablet | Each tablet contains Finasteride 1.0 mg | 10/21.12/0579 | 2010/08/12 | NS2 |
| 112 | Sanofi-Aventis South Africa (Pty) Ltd | Amaryl M 1/250 | Glimepiride; Metformin Hydrochloride | tablet | Each tablet contains Glimepiride 1 mg and Metformin Hydrochloride 250 mg | 10/21.2/0580 | 2010/08/12 | NS2 |
| 113 | Sanofi-Aventis South Africa (Pty) Ltd | Amaryl M 2/500 | Glimepiride; Metformin Hydrochloride | tablet | Each tablet contains Glimepiride 2 mg and Metformin Hydrochloride 500 mg | 10/21.2/0581 | 2010/08/12 | NS2 |