



GOVERNMENT GAZETTE

OF THE REPUBLIC OF NAMIBIA

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 90 2008

NOTIFICATION OF REGISTRATION OF CERTAIN MEDICINES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965

In terms of section 17 of the Medicine and Related Substances Control Act, 1965, (Act No. 101 of 1965), the Registrar of Medicines gives notice that the medicines set out in the Schedule have been registered in term of that Act, subject to the following conditions:

1. The manufacture and control of the medicines must be in accordance with the existing good manufacturing practices as required by the World Health Organization.
2. Inspection and investigations may be carried out, as the need arises, by inspectors authorized in terms of sections 26 of the Act in order to assess compliance with paragraph 1.
3. The information in the package insert must, as the need arises, be updated to conform with the package insert approved by the council.

4. The provisions of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), apply to each holder of a certificate of registration referred to section 15 (4) of that Act.
5. 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.
6. The first two production batches must be validated in accordance with the detailed process validation protocol submitted at the time of the application for registration.
7. A validation report must be submitted to the council within one month from the date of completion of the validation process referred to in paragraph 6.
8. The council may review the registration dossier at such intervals as the council may determine.

SCHEDULE

S/N	APPLICANT	REGISTERED NAME	APPROVED NAME OF ACTIVE(S)	DOSSAGE FORM	STRENGTH/DOSE UNIT	REGISTRATION NUMBER	REGISTRATION DATE
1	Pharmaplan (Pty) Ltd	Zanidip 20	Lercanidipine Hydrochloride	Tablets	Each tablet contains Lercanidipine Hydrochloride 20,0 mg	08/7.1/0001	2008/02/20
2	Pharmaplan (Pty) Ltd	Cardiect 250	Dobutamine Hydrochloride	Injection	Each vial contains Dobutamine Hydrochloride equivalent to Dobutamine 250,0 mg	08/6.1/0002	2008/02/20
3	Sandoz (Pty) Ltd	Sandoz Meloxicam 15 tablets	Meloxicam	Tablets	Each tablet contains Meloxicam 15,0 mg	08/3.1/0003	2008/02/20
4	Sandoz (Pty) Ltd	Sandoz Meloxicam 7,5 tablets	Meloxicam	Tablets	Each tablet contains Meloxicam 7,5 mg	08/3.1/0004	2008/02/20
5	Alcon Laboratories (SA) (Pty) Ltd	CiproBay HC Otic	Ciprofloxacin Hydrochloride, Hydrocortisone	Drops	Each 10 ml bottle contains Ciprofloxacin Hydrochloride equiv. to Ciprofloxacin 20,0 mg. Hydrocortisone 100,0 mg	08/16.2/0005	2008/02/20
6	UCB Pharma (SA) (Pty) Ltd	Cirrus Tablets	Cetirizine Dihydrochloride, Pseudoephedrine Hydrochloride	Tablets	Each tablet contains Cetirizine Dihydrochloride 5,0 mg, Pseudoephedrine Hydrochloride 120,0 mg	08/5.7.1/0006	2008/02/20
7	Hexal Pharma (SA) (Pty) Ltd	Hexal-Lisinopril Co 10 mg Tablets	Lisinopril, hydrochlorothiazide	Tablets	Each tablet contains Lisinopril 10,0 mg Hydrochlorothiazide 12,5 mg	08/7.1.3/0007	2008/02/20
8	Hexal Pharma (SA) (Pty) Ltd	Hexal-Lisinopril Co 20 mg Tablets	Lisinopril, hydrochlorothiazide	Tablets	Each tablet contains Lisinopril 20,0 mg Hydrochlorothiazide 12,5 mg	08/7.1.3/0008	2008/02/20
9	Hexal Pharma (SA) (Pty) Ltd	Pixicam 10	Piroxicam	Tablets	Each tablet contains: Piroxicam 10,0 mg	08/3.1/0009	2008/02/20
10	Hexal Pharma (SA) (Pty) Ltd	Allopurinol - Hexal 300	Allopurinol	Tablets	Each tablet contains Allopurinol 300,0 mg	08/3.3/0010	2008/02/20

11	Hexal Pharma (SA) (Pty) Ltd	Pharmaton	Combination	Capsules	Extract of Panax Ginseng root G115, 40 mg, others	08/22.1/0011	2008/02/20
12	Bayer (Pty) Ltd	Canesten Troche	Clotrimazole	Lozenge	Each lozenge contains Clotrimazole 10,0 mg	08/20.2/0012	2008/02/20
13	Aurobindo Pharma (Pty) Ltd	Auroxime Tablets 125 mg	Cefuroxime Axetil	Tablets	Each tablet contains Cefuroxime Axetil equiv. to Cefuroxime 125,0 mg	08/20.1.1/0013	2008/02/20
14	Aurobindo Pharma (Pty) Ltd	Auroxime Tablets 250 mg	Cefuroxime Axetil	Tablets	Each tablet contains Cefuroxime Axetil equiv. to Cefuroxime 250,0 mg	08/20.1.1/0014	2008/02/20
15	Aurobindo Pharma (Pty) Ltd	Auroxime Tablets 500 mg	Cefuroxime Axetil	Tablets	Each tablet contains Cefuroxime Axetil equiv. to Cefuroxime 500,0 mg	08/20.1.1/0015	2008/02/20
16	Janssen Pharmaceutica (Pty) Ltd	Durogesic (Matrix) 25 µg/h	Fentanyl	Trans. Patches	Each matrix patch contains 4,2 mg Fentanyl delivering Fentanyl 25 µg/h	08/2.9/0016	2008/02/20
17	Janssen Pharmaceutica (Pty) Ltd	Durogesic (Matrix) 50 µg/h	Fentanyl	Trans. Patches	Each matrix patch contains 8,4 mg Fentanyl delivering Fentanyl 50 µg/h	08/2.9/0017	2008/02/20
18	Janssen Pharmaceutica (Pty) Ltd	Durogesic (Matrix) 75 µg/h	Fentanyl	Trans. Patches	Each matrix patch contains Fentanyl 12,6 mg delivering Fentanyl 75 µg/h	08/2.9/0018	2008/02/20
19	Janssen Pharmaceutica (Pty) Ltd	Durogesic (Matrix) 100 µg/h	Fentanyl	Trans. Patches	Each matrix patch contains Fentanyl 16,8 mg delivering Fentanyl 100 µg/h	08/2.9/0019	2008/02/20
20	Ranbaxy (SA) (Pty) Ltd	Simayla Loratadine 10	Loratadine	Tablets	Each tablet contains Loratadine 10,0 mg	08/5.7.1/0020	2008/02/20
21	Ranbaxy (SA) (Pty) Ltd	Simayla Lisinopri 120	Lisinopril	Tablets	Each tablet contains Lisinopril Dihydrate equivalent to anhydrous Lisinopril 20,0 mg	08/7.1.3/0021	2008/02/20
22	Ranbaxy (SA) (Pty) Ltd	Simayla Ramipril 10	Ramipril	Capsules	Each capsule contains Ramipril 10,0 mg	08/7.1.3/0022	2008/02/20

23	Ranbaxy (SA) (Pty) Ltd	Simayla Clarithromycin Suspension 125 mg/5ml	Clarithromycin	Suspension	Each 5ml constituted suspension contains Clarithromycin 125,0 mg	08/20.1.1/0023	2008/02/20
24	Ranbaxy (SA) (Pty) Ltd	Simayla Lansoprazole 15	Lansoprazole	Capsules	Each capsule contains Lansoprazole 15,0 mg	08/11.4.3/0024	2008/02/20
25	Ranbaxy (SA) (Pty) Ltd	Simayla Ranitidine 75	Ranitidine Hydrochloride	Tablets	Each film coated tablet contains Ranitidine Hydrochloride equivalent to Ranitidine 75,0 mg	08/11.4.3/0025	2008/02/20
26	Ranbaxy (SA) (Pty) Ltd	Simayla Ciprofloxacin 250	Ciprofloxacin Hydrochloride	Tablets	Each tablet contains Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 250,0 mg	08/20.1.1/0026	2008/02/20
27	Ranbaxy (SA) (Pty) Ltd	Simayla Ciprofloxacin 750	Ciprofloxacin Hydrochloride	Tablets	Each tablet contains Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin 750,0 mg	08/20.1.1/0027	2008/02/20
28	Ranbaxy (SA) (Pty) Ltd	Simayla Ciprofloxacin 500	Ciprofloxacin Hydrochloride	Tablets	Each tablet contains Ciprofloxacin Hydrochloride equivalent to Ciprofloxacin 500,0 mg	08/20.1.1/0028	2008/02/20
29	Ranbaxy (SA) (Pty) Ltd	Simayla Ranitidine 150	Ranitidine Hydrochloride	Tablets	Each film coated contains Ranitidine Hydrochloride equivalent to Ranitidine 150,0 mg	08/11.4.3/0029	2008/02/20
30	Ranbaxy (SA) (Pty) Ltd	Simayla Ranitidine 300	Ranitidine Hydrochloride	Tablets	Each film coated tablet contains Ranitidine Hydrochloride equivalent to ranitidine 300,0 mg	08/11.4.3/0030	2008/02/20
31	Ranbaxy (SA) (Pty) Ltd	Simayla Simvastatin 20	Simvastatin	Tablets	Each tablet contains Simvastatin 20,0 mg	08/7.5/0031	2008/02/20
32	Ranbaxy (SA) (Pty) Ltd	Simayla Lansoprazole 30	Lanzoprazole 30	Capsules	Each capsule contains Lansoprazole 30,0 mg	08/11.4.3/0032	2008/02/20

33	Ranbaxy (SA) (Pty) Ltd	Simayla Cefpodoxime 100	Cefpodoxime Proxetil	Tablets	Each film coated tablet contains Cefpodoxime Proxetil equivalent to Cefpodoxime 100,0 mg	08/201.1/0033	2008/02/20
34	Ranbaxy (SA) (Pty) Ltd	Simayla Simvastatin 40	Simvastatin	Tablets	Each tablet contains Simvastatin (micronised) 40,0 mg	08/7.5/0034	2008/02/20
35	Ranbaxy (SA) (Pty) Ltd	Simayla Clarithromycin 500	Clarithromycin	Tablets	Each film-coated tablet contains Clarithromycin 500,0 mg	08/201.1/0035	2008/02/20
36	Ranbaxy (SA) (Pty) Ltd	Simayla Citalopram 20	Citalopram Hydrobromide	Tablets	Each tablet contains Citalopram Hydrobromide equiv. to Citalopram 20,0 mg	08/1.2/0036	2008/02/20
37	Ranbaxy (SA) (Pty) Ltd	Simayla Cefpodoxime 40 mg/5ml	Cefpodoxime Proxetil	Powder for oral suspension	Each 5ml constituted suspension contains Cefpodoxime Proxetil equiv. to Cefpodoxime 40,0 mg	08/201.1/0037	2008/02/20
38	Ranbaxy (SA) (Pty) Ltd	Simayla Simvastatin 10	Simvastatin	Tablets	Each tablet contains Simvastatin 10,0 mg	08/7.5/0038	2008/02/20
39	Ranbaxy (SA) (Pty) Ltd	Simayla Fluconazole 150	Fluconazole	Capsules	Each capsule contains Fluconazole 150,0 mg	08/202.2/0039	2008/02/20
40	Ranbaxy (SA) (Pty) Ltd	Simayla Fluconazole 200	Fluconazole	Capsules	Each capsule contains Fluconazole 200,0 mg	08/202.2/0040	2008/02/20
41	Ranbaxy (SA) (Pty) Ltd	Simayla Clarithromycin Suspension 250 mg/5ml	Clarithromycin	Powder for oral suspension	Each 5ml constituted suspension contains Clarithromycin 250,0 mg	08/201.1/0041	2008/02/20
42	Ranbaxy (SA) (Pty) Ltd	Simayla Lisinopril 5	Lisinopril Dihydrate	Tablets	Each tablet contains Lisinopril Dihydrate equiv. to anhydrous Lisinopril 5,0 mg	08/7.1/0042	2008/02/20
43	Ranbaxy (SA) (Pty) Ltd	Simayla Lisinopril 10	Lisinopril Dihydrate	Tablets	Each tablet contains Lisinopril Dihydrate equiv. to anhydrous Lisinopril 10,0 mg	08/7.1/0043	2008/02/20

44	Dr. Reddy's Laboratories (Pty) Ltd	Omez 40	Omeprazole	Capsules	Each capsule contains Omeprazole 40,0 mg	08/11.4.3/0044	2008/02/20
45	Dr. Reddy's Laboratories (Pty) Ltd	Amlate 5	Amlodipine Maleate	Tablets	Each tablet contains Amlodipine Maleate equiv. to Amlodipine 5,0mg	08/7.1/0045	2008/02/20
46	Dr. Reddy's Laboratories (Pty) Ltd	Amlate 10	Amlodipine Maleate	Tablets	Each tablet contains Amlodipine Maleate equiv. to Amlodipine 10,0 mg	08/7.1/0046	2008/02/20
47	Dr. Reddy's Laboratories (Pty) Ltd	Demax 250	Terbinafine Hydrochloride	Tablets	Each tablet contains Terbinafine Hydrochloride equiv. to Terbinafine 250,0 mg	08/20.2/0047	2008/02/20
48	Dr. Reddy's Laboratories (Pty) Ltd	Finderm 250	Terbinafine Hydrochloride	Tablets	Each tablet contains Terbinafine Hydrochloride equiv. to Terbinafine 250,0 mg	08/20.2/0048	2008/02/20
49	Dr. Reddy's Laboratories (Pty) Ltd	Rezak 20	Fluoxetine Hydrochloride	Capsules	Each capsule contains Fluoxetine Hydrochloride equiv. to Fluoxetine 20,0 mg	08/1.2/0049	2008/02/20
50	Dr. Reddy's Laboratories (Pty) Ltd	Diva 35	Cyproterone Acetate, Ethinylestradiol	Tablets	Each hormonal tablet contains Cyproterone Acetate 2,0 mg, Ethinylestradiol 0,035 mg	08/21.8.2/0050	2008/02/20
51	Dr. Reddy's Laboratories (Pty) Ltd	DRL-Omeprazole 20	Omeprazole	Capsules	Each capsule contains Omeprazole 20,0 mg	08/11.4.3/0051	2008/02/20
52	Dr. Reddy's Laboratories (Pty) Ltd	DRL-Omeprazole 10	Omeprazole	Capsules	Each capsule contains Omeprazole 10,0 mg	08/11.4.3/0052	2008/02/20

53	GlaxoSmithKline S.A. (Pty) Ltd	Cervarix	Combination	Injection	Each 0,5 ml dose contains Human Papillomavirus type 16 L1 protein 20 µg, Human Papillomavirus type 18 L1 protein 20 ng, 3-O-deacyl-4'-monophosphoryl lipid A (MPL) 50mcg, Aluminium Hydroxide (Hydrated) 0,5 mg.	08/30.1/0053	2008/02/20
54	Sandoz (Pty) Ltd	Hexal Paroxetine 20	Paroxetine Hydrochloride	Tablets	Each tablet contains Paroxetine Hydrochloride equiv. to Paroxetine 20,0 mg	08/L2/0054	2008/02/20
55	Sandoz (Pty) Ltd	Bisoprolol Hexal 10	Bisoprolol Fumarate	Tablets	Each film coated tablet contains Bisoprolol Fumarate 10,0 mg	08/5.2/0055	2008/02/20
56	Biogaran SA (Pty) Ltd	Vectoryl 14 mg	Perindopril Terbutyramine	Tablets	Each tablet contains Perindopril Terbutyramine 4,0 mg	08/7.1.3/0056	2008/02/20
57	Biogaran SA (Pty) Ltd	Vectoryl Plus	Perindopril Terbutyramine, Indapamide	Tablets	Each tablet contains Perindopril Terbutyramine 4,0 mg, Indapamide 1,25 mg	08/7.1.3/0057	2008/02/20
58	Hoffmann-La Roche Ltd	Bonviva 150 mg	Ibandronic Acid	Tablets	Each film-coated tablet contains Ibandronate Monosodium Monohydrate equiv. to Ibandronic Acid 150,0mg	08/26/0058	2008/02/20
59	Hoffmann-La Roche Ltd	Bonviva 2,5 mg	Ibandronic Acid	Tablets	Each film-coated tablet contains Ibandronate Monosodium Monohydrate equiv. to Ibandronic Acid 2,5mg	08/26/0059	2008/02/20
60	MSD (Pty) Ltd	Arcoxia 90 mg	Etoricoxib	Tablets	Each tablet contains Etoricoxib 90,0 mg	08/3.1/0060	2008/02/20
61	MSD (Pty) Ltd	Arcoxia 60 mg	Etoricoxib	Tablets	Each tablet contains Etoricoxib 60,0 mg	08/3.1/0061	2008/02/20
62	MSD (Pty) Ltd	Arcoxia 120 mg	Etoricoxib	Tablets	Each tablet contains Etoricoxib 120,0 mg	08/3.1/0062	2008/02/20

63	Aventis Pharma (Pty) Ltd	Pentaxim	Combination	Suspension for Injection	Each 0,5ml contains; Purified diphth. Toxoid ≥ 30 IU, Purified Tetanus Toxoid ≥ 40 IU, Pertusis Toxoid 25 µg, Purified filamentous haemagglutinin 25 µg, Inactivated type 1 poliovirus 40 D Units, Inactivated type 2 poliovirus 8 D units, Inactivated type 3 poliovirus 32 D Units, Haemophilus influenzae type b polysaccharide conjugated to Tetanus toxoid 10 µg	08/30.1/0063	2008/02/20
64	Aventis Pharma (Pty) Ltd	Acti-HIB Multidose	Combination	Powder for Injection	Each 0,5 ml reconstituted vaccine contains; Haemophilus influenzae type b polysaccharide conjugated to tetanus protein 10 µg	08/30.1/0064	2008/02/20
65	Pharma Dynamics (Pty) Ltd	Zartan 12,5 mg	Losartan Potassium	Tablets	Each tablet contains Losartan Potassium equiv. to Losartan 12,5 mg	08/7.1.3/0065	2008/02/20
66	Pharma Dynamics (Pty) Ltd	Zartan 25 mg	Losartan Potassium	Tablets	Each tablet contains Losartan Potassium equiv. to Losartan 25,0 mg	08/7.1.3/0066	2008/02/20
67	Pharma Dynamics (Pty) Ltd	Zartan 50 mg	Losartan Potassium	Tablets	Each tablet contains Losartan Potassium equiv. to Losartan 50,0 mg	08/7.1.3/0067	2008/02/20
68	Sandoz (Pty) Ltd	Claro 35	Cyproterone Acetate, Ethinyl Estradiol	Tablets	Each hormonal tablet contains; Cyproterone Acetate 2,0 mg, Ethinyl Estradiol 0,035 mg; Each non-hormonal tablet contains Sugar	08/21.8.2/0068	2008/02/20
69	Sandoz (Pty) Ltd	Sandoz Mirtazapine 30	Mirtazapine	Tablets	Each film coated tablet contains Mirtazapine 30,0 mg	08/1.2/0069	2008/02/20
70	Sandoz (Pty) Ltd	Sandoz Mirtazapine 15	Mirtazapine	Tablets	Each film coated tablet contains Mirtazapine 15,0 mg	08/1.2/0070	2008/02/20
71	Sandoz (Pty) Ltd	Sandoz Mirtazapine 45	Mirtazapine	Tablets	Each film coated tablet contains Mirtazapine 45,0 mg	08/1.2/0071	2008/02/20

72	Sandoz (Pty) Ltd	Sandoz Amlodipine 5	Amlodipine Maleate	Tablets	Each tablet contains Amlodipine Maleate equiv. to Amlodipine 5,0 mg	08/7.1/0072	2008/02/20
73	Sandoz (Pty) Ltd	Sandoz Amlodipine 10	Amlodipine Maleate	Tablets	Each tablet contains Amlodipine Maleate equiv. to Amlodipine 10,0 mg	08/7.1/0073	2008/02/20
74	Sandoz (Pty) Ltd	Binozyt 500	Azithromycin Monohydrate	Tablets	Each film-coated tablet contains Azithromycin Monohydrate equiv. to Azithromycin 500,0 mg	08/20.1.1/0074	2008/02/20
75	Sandoz (Pty) Ltd	CuroAx 500	Cefuroxime Axetil	Tablets	Each tablet contains Cefuroxime Axetil equiv. to Cefuroxime 500,0 mg	08/20.1.1/0075	2008/02/20
76	Sandoz (Pty) Ltd	CuroAx 250	Cefuroxime Axetil	Tablets	Each tablet contains Cefuroxime Axetil equiv. to Cefuroxime 250,0 mg	08/20.1.1/0076	2008/02/20
77	Sandoz (Pty) Ltd	CuroAx 125	Cefuroxime Axetil	Tablets	Each tablet contains Cefuroxime Axetil equiv. to Cefuroxime 125,0 mg	08/20.1.1/0077	2008/02/20
78	Sandoz (Pty) Ltd	Arthrocox 7,5	Meloxicam	Tablets	Each tablet contains Meloxicam 7,5 mg	08/3.1/0078	2008/02/20
79	Sandoz (Pty) Ltd	Arthrocox 15	Meloxicam	Tablets	Each tablet contains Meloxicam 15,0 mg	08/3.1/0079	2008/02/20
80	Sandoz (Pty) Ltd	Lamepti 125	Lamotrigine	Tablets	Each tablet contains Lamotrigine 25,0 mg	08/2.5/0080	2008/02/20
81	Sandoz (Pty) Ltd	Lamepti 50	Lamotrigine	Tablets	Each tablet contains Lamotrigine 50,0 mg	08/2.5/0081	2008/02/20
82	Sandoz (Pty) Ltd	Lamepti 100	Lamotrigine	Tablets	Each tablet contains Lamotrigine 100,0 mg	08/2.5/0082	2008/02/20
83	Sandoz (Pty) Ltd	Lamepti 200	Lamotrigine	Tablets	Each tablet contains Lamotrigine 200,0 mg	08/2.5/0083	2008/02/20
84	Ranbaxy (SA) (Pty) Ltd S	Serlife 100	Sertraline Hydrochloride	Tablets	Each film coated tablet contains Sertraline Hydrochloride equiv. to Sertraline 100,0 mg	08/1.2/0084	2008/02/20
85	Ranbaxy (SA) (Pty) Ltd	Serlife 50	Sertraline Hydrochloride	Tablets	Each film coated tablet contains Sertraline Hydrochloride equiv. to Sertraline 50,0 mg	08/1.2/0085	2008/02/20

86	Pharma Dynamics (Pty) Ltd	Zartan 100 mg	Losartan Potassium	Tablets	Each tablet contains Losartan Potassium equiv. to Losartan 100,0 mg	08/7.1.3/0086	2008/02/20
87	Ranbaxy (SA) (Pty) Ltd	Klarithran MR 500	Clarithromycin	Tablets	Each modified release tablet contains Clarithromycin 500,0 mg	08/20.1.1/0087	2008/02/20
88	Ranbaxy (SA) (Pty) Ltd	Glimpid 4	Glimepiride	Tablets	Each tablet contains Glimepiride 4,0mg	08/21.2/0088	2008/02/20
89	Ranbaxy (SA) (Pty) Ltd	Glimpid 2	Glimepiride	Tablets	Each tablet contains Glimepiride 2,0mg	08/21.2/0089	2008/02/20
90	Ranbaxy (SA) (Pty) Ltd	Glimpid 1	Glimepiride	Tablets	Each tablet contains Glimepiride 1,0mg	08/21.2/0090	2008/02/20