



# GOVERNMENT GAZETTE

## OF THE

# REPUBLIC OF NAMIBIA

N\$2.00

WINDHOEK - 3 June 2011

No. 4726

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## Government Notice

### MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 71

2011

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

In terms of section 23 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) (hereinafter referred to as “the Act”), I give notice that the medicines set out in the attached schedule have been registration 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 section 35 of the Act;
- (c) the information in the package insert must, on a regular basis, be updated to conform with the package insert approved by the Council;
- (d) the holder of the certificate of registration which is 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 of 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**

Windhoek, 17 May 2011

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S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REG. NO. NAMIBIA	REG. DATE	SCHEM. STATUS
1	Abbott Laboratories SA (Pty) Ltd	Synagis 50	palivizumab	injection	Each 0.5ml vial when reconstituted contains Palivizumab 50,0 mg	11/30.2/0047	4/14/2011	NS2
2	Abbott Laboratories SA (Pty) Ltd	Synagis 100	palivizumab	injection	Each 1ml vial when reconstituted contains Palivizumab 100 mg	11/30.2/0048	4/14/2011	NS2
3	Cipla Medpro (Pty) Ltd	Ciplatec 10	enalapril maleate	tablet	Each tablet contains Enalapril maleate 10,0 mg	11/7.1.3/0049	4/14/2011	NS2
4	Cipla Medpro (Pty) Ltd	Ciplatec 20	enalapril maleate	tablet	Each tablet contains Enalapril maleate 20,0 mg	11/7.1.3/0050	4/14/2011	NS2
5	Cipla Medpro (Pty) Ltd	Uromax	tamsulosin hydrochloride	capsule	Each capsule contains Tamsulosin Hydrochloride 400,0 mg	11/34/0051	4/14/2011	NS2
6	Cipla Life Sciences (Pty) Ltd	Cipla-Cyproterone acetate 100	cyproterone acetate	tablet	Each tablet contains Cyproterone acetate 100,0 mg	11/21.12/0052	4/14/2011	NS2
7	Cipla-Medpro (Pty) Ltd	Beclate Cream	beclomethasone dipropionate	cream	Each 1,0 g cream contains Beclomethasone Dipropionate 0,25 mg	11/13.4.1/0053	4/14/2011	NS2
8	Cipla-Medpro (Pty) Ltd	Danogen 100	danazol	capsule	Each capsule contains Danazol 100,0 mg	11/21.12/0054	4/14/2011	NS2
9	Cipla-Medpro (Pty) Ltd	Foratec HFA	formoterol fumarate	inhaler	Each actuation delivers Formoterol Fumarate 12,0 µg	11/10.2.1/0055	4/14/2011	NS2
10	Cipla-Medpro (Pty) Ltd	Cipla-loratadine	loratadine	tablet	Each tablet contains Loratadine 10 mg	11/5.7.1/0056	4/14/2011	NS2
11	Cipla-Medpro (Pty) Ltd	Clamelle	azithromycin dihydrate	capsule	Each capsule contains Azithromycin dihydrate equivalent to Azithromycin 250,0 mg	11/20.1.1/0057	4/14/2011	NS2
12	Cipla-Medpro (Pty) Ltd	Cipla-Pioglitazone 15	pioglitazone hydrochloride	tablet	Each tablet contains Pioglitazone hydrochloride equivalent to Pioglitazone 15 mg	11/21.2/0058	4/14/2011	NS2
13	Cipla-Medpro (Pty) Ltd	Cipla-Pioglitazone 30	pioglitazone hydrochloride	tablet	Each tablet contains Pioglitazone hydrochloride equivalent to Pioglitazone 30 mg	11/21.2/0059	4/14/2011	NS2
14	Cipla-Medpro (Pty) Ltd	Medazine T	cyclizine hydrochloride	tablet	Each tablet contains Cyclizine hydrochloride 50 mg	11/5.7.2/0060	4/14/2011	NS2
15	Cipla-Medpro (Pty) Ltd	Medazine S	cyclizine hydrochloride	syrup	Each 5 ml syrup contains Cyclizine hydrochloride 12,5 mg	11/5.7.2/0061	4/14/2011	NS2

16	Cipla-Medpro (Pty) Ltd	Medaspor Vaginal Cream	clotrimazole	cream	Each 1 g cream contains Clotrimazole 10 mg	11/20.2.2/0062	4/14/2011	NS2
17	Cipla-Medpro (Pty) Ltd	Pynmed Syrup	codeine phosphate; paracetamol; promethazine hydrochloride	syrup	Each 5 ml syrup contains Codeine phosphate 5 mg, Paracetamol 120 mg and Promethazine hydrochloride 6,5 mg	11/2.8/0063	4/14/2011	NS1
18	Cipla Medpro (Pty) Ltd	Ipvent 40 HFA	ipratropium bromide	inhaler	Each actuation contains Ipratropium bromide 40,0 mg	11/10.2/0064	4/14/2011	NS2
19	F. Hoffmann-La Roche Ltd	Actemra 80	tocilizumab	solution for infusion	Each 4 ml vial contains Tocilizumab 80 mg	11/30.1/0065	4/14/2011	NS2
20	F. Hoffmann-La Roche Ltd	Actemra 200	tocilizumab	solution for infusion	Each 10 ml vial contains Tocilizumab 200 mg	11/30.1/0066	4/14/2011	NS2
21	F. Hoffmann-La Roche Ltd	Actemra 400	tocilizumab	solution for infusion	Each 20 ml vial contains Tocilizumab 400 mg	11/30.1/0067	4/14/2011	NS2
22	GlaxoSmithKline South Africa (Pty) Ltd	Valoid Children's Suppositories	cyclizine hydrochloride	suppository	Each suppository contains Cyclizine hydrochloride 50,0 mg	11/5.7.2/0068	4/14/2011	NS1
23	GlaxoSmithKline South Africa (Pty) Ltd	Valoid Tablets	cyclizine hydrochloride	tablet	Each tablet contains Cyclizine Hydrochloride 50 mg	11/5.7.2/0069	4/14/2011	NS1
24	GlaxoSmithKline South Africa (Pty) Ltd	Valoid Paediatric Syrup	cyclizine hydrochloride	syrup	Each 5 ml syrup contains Cyclizine Hydrochloride 12,5 mg	11/5.7.2/0070	4/14/2011	NS1
25	GlaxoSmithKline South Africa (Pty) Ltd	Valoid AS	cyclizine hydrochloride	suppository	Each suppository contains Cyclizine Hydrochloride 100,0 mg	11/5.7.2/0071	4/14/2011	NS1
26	GlaxoSmithKline South Africa (Pty) Ltd	Niquitin Lozenges 2 mg	nicotine polacrilex	lozenge	Each lozenge contains Nicotine Polacrilex equivalent to Nicotine 2,0 mg	11/34/0072	4/14/2011	NS1
27	GlaxoSmithKline South Africa (Pty) Ltd	Niquitin Lozenges 4 mg	nicotine polacrilex	lozenge	Each lozenge contains Nicotine Polacrilex equivalent to Nicotine 4,0 mg	11/34/0073	4/14/2011	NS1
28	GlaxoSmithKline South Africa (Pty) Ltd	Alli	orlistat	capsule	Each capsule contains Orlistat 60,0 mg	11/11.3/0074	4/14/2011	NS2

29	Pharmaco Distribution (Pty) Ltd	Suplasyn	sodium hyaluronate	injection	Each vial/syringe contains Hyaluronic Acid sodium salt 20 mg	11/3.2/0075	4/14/2011	NS2
30	Nycomed (Pty) Ltd	Daxas	roflumilast	tablet	Each film-coated tablet contains Roflumilast 500 µg	11/10.3/0076	4/14/2011	NS2
31	Nycomed (Pty) Ltd	Topzole 20	pantoprazole sodium sesquihydrate	tablet	Each tablet contains Pantoprazole sodium sesquihydrate equivalent to Pantoprazole 20 mg (sugar-free)	11/11.4.3/0077	4/14/2011	NS2
32	Nycomed (Pty) Ltd	Topzole 40	pantoprazole sodium sesquihydrate	tablet	Ech tablet contains Pantoprazole Sodium Sesquihydrate equiv. to Pantoprazole 40,0 mg	11/11.4.3/0078	4/14/2011	NS2
33	Janssen Pharmaceutica (Pty) Ltd	Invega 3 mg	paliperidone	prolonged-release tablet	Each Prolonged-Release tablet contains Paliperidone 3,0 mg	11/2.6.5/0079	4/14/2011	NS3
34	Janssen Pharmaceutica (Pty) Ltd	Invega 6 mg	paliperidone	prolonged-release tablet	Each Prolonged-Release tablet contains Paliperidone 6,0 mg	11/2.6.5/0080	4/14/2011	NS3
35	Janssen Pharmaceutica (Pty) Ltd	Invega 9 mg	paliperidone	prolonged-release tablet	Each Prolonged-Release tablet contains Paliperidone 9,0 mg	11/2.6.5/0081	4/14/2011	NS3
36	Janssen Pharmaceutica (Pty) Ltd	Sibelium T 5 mg	flunarazine	tablet	Each tablet contains Flunarazine base 5,0 mg	11/5.7.1/0082	4/14/2011	NS2
37	Janssen Pharmaceutica (Pty) Ltd	Risperdal Quicklet 0,5 mg	risperidone	orodispersible tablet	Each orodispersible tablet contains Risperidone 0,5 mg	11/2.6.5/0083	4/14/2011	NS3
38	Janssen Pharmaceutica (Pty) Ltd	Risperdal Quicklet 1,0 mg	risperidone	orodispersible tablet	Each orodispersible tablet contains Risperidone 1,0 mg	11/2.6.5/0084	4/14/2011	NS3
39	Janssen Pharmaceutica (Pty) Ltd	Risperdal Quicklet 2,0 mg	risperidone	orodispersible tablet	Each orodispersible tablet contains Risperidone 2,0 mg	11/2.6.5/0085	4/14/2011	NS3

40	Janssen Pharmaceutica (Pty) Ltd	Risperdal Quicklet 3,0 mg	risperidone	orodispersible tablet	Each orodispersible tablet contains Risperidone 3,0 mg	11/2.6.5/0086	4/14/2011	NS3
41	Specpharm (Pty) Ltd	Macorel 30 SR	nifedipine	tablet	Each Sustained Release tablet contains Nifedipine 30,0 mg	11/7.1/0087	4/14/2011	NS2
42	Specpharm (Pty) Ltd	Macorel 60 SR	nifedipine	tablet	Each Sustained Release tablet contains Nifedipine 60,0 mg	11/7.1/0088	4/14/2011	NS2
43	Specpharm (Pty) Ltd	Spec Nifedipine 30 SR	nifedipine	tablet	Each Sustained Release tablet contains Nifedipine 30,0 mg	11/7.1/0089	4/14/2011	NS2
44	Ranbaxy (S.A.) (Pty) Ltd	Numox 400	moxifloxacin hydrochloride	tablet	Each film-coated tablet contains Moxifloxacin hydrochloride equivalent to Moxifloxacin 400 mg	11/20.1.1/0090	4/14/2011	NS2
45	Sanofi-Aventis South Africa (Pty) Ltd	Apidra	insulin glulisine	injection	Each 1,0 ml solution contains Insulin glulisine equimolar to Insulin 100,0 iu	11/20.1/0091	4/14/2011	NS1
46	Ranbaxy (S.A.) (Pty) Ltd	Diole 80 Co	valsartan; hydrochlorothiazide	tablet	Each film-coated tablet contains Valsartan 80 mg and Hydrochlorothiazide 12.5 mg	11/7.1.3/0092	4/14/2011	NS2
47	Ranbaxy (S.A.) (Pty) Ltd	Diole 160 Co	valsartan; hydrochlorothiazide	tablet	Each film-coated tablet contains Valsartan 160 mg and Hydrochlorothiazide 12.5 mg	11/7.1.3/0093	4/14/2011	NS2
48	Ranbaxy (S.A.) (Pty) Ltd	Diole Plus	valsartan; hydrochlorothiazide	tablet	Each film-coated tablet contains Valsartan 160 mg and Hydrochlorothiazide 25 mg	11/7.1.3/0094	4/14/2011	NS2
49	Ranbaxy (S.A.) (Pty) Ltd	Zirinak 2,5	bisoprolol fumarate; hydrochlorothiazide	tablet	Each tablet contains Bisoprolol fumarate 2.5 mg and Hydrochlorothiazide 6.25 mg	11/7.1/0095	4/14/2011	NS2
50	Ranbaxy (S.A.) (Pty) Ltd	Zirinak 5	bisoprolol fumarate; hydrochlorothiazide	tablet	Each tablet contains Bisoprolol fumarate 5 mg and Hydrochlorothiazide 6.25 mg	11/7.1/0096	4/14/2011	NS2
51	Ranbaxy (S.A.) (Pty) Ltd	Zirinak 10	bisoprolol fumarate; hydrochlorothiazide	tablet	Each tablet contains Bisoprolol fumarate 10 mg and Hydrochlorothiazide 6.25 mg	11/7.1/0097	4/14/2011	NS2

52	Johnson & Johnson (Pty) Ltd	Sinutab Sinus Allergy Congestion and Pain	paracetamol; chlorpheniramine maleate and pseudoephedrine hydrochloride	tablet	Each tablet contains Paracetamol 500,0 mg, Chlorpheniramine maleate 2,0 mg and Pseudoephedrine hydrochloride 30,0 mg	11/5.8/0098	4/14/2011	NS1
53	Pharma Dynamics (Pty) Ltd	Pollentyme ND	desloratadine	tablet	Each tablet contains Desloratadine 5,0 mg	11/5.7.1/0099	4/28/2011	NS2