



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 6 October 2020

No. 7353

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 248

2020

NOTIFICATION OF 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 medicines set out in the Schedule have been registered in terms of that Act, subject to the following conditions:

- (a) the applicant must ensure that the medicine is manufactured and controlled in terms of the existing current good manufacturing practices as determined by the World Health Organisation;
- (b) inspections and investigations may be carried out regularly by inspectors authorised in terms of sections 35 of the Act, to assess compliance with existing current good manufacturing practices;
- (c) the applicant must, subject to the approval of Namibia Medicines Regulatory Council (hereafter referred to as "the Council"), ensure that the information contained in the medicine package insert is regularly updated so as to provide accurate information to the user of the medicine;

- (d) the holder of the certificate of registration in terms of section 19(4) must comply with the provisions of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003);
- (e) the registration of medicine is subject to regular review by the Council regarding its quality, safety and efficacy and the Council may vary the registration of the medicine, as it considers necessary;
- (f) the applicant must validate the first two production batches in terms of the detailed process validation protocol which was submitted at the time of the application for registration and that validation report must be submitted to the Council within 30 days from the date of completion of the validation;
- (g) the Council may review the registration dossier and may determine the intervals when the reviews will take place; and
- (h) the information of the product must comply with regulations 11, 12 and 13 of the Regulations relating to Medicines and Related Substances published under Government Notice No. 178 of 25 July 2008.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 22 September 2020

SCHEDULE

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REGISTRATION NUMBER	REGISTRATION DATE	SCHED. STATUS
1	Soflens (Pty) Ltd	Besivance	Besifloxacin	Ophthalmic suspension (eye drops)	Each ml contains: Besifloxacin (as hydrochloride) 6mg (0,6% m/v)	20/15.1/0062	02.07.2020	NS2
2	Sandoz South Africa (Pty) Ltd	SCAPHO 150mg	Secukinumab	Powder for solution for injection	Each ml contains: Secukinumab 150mg/vail	20/30.1/0063	02.07.2020	NS2
3	Blumed Laboratories Cc	Dektroflam	Dexketoprofen trometamol	Film-coated tablets	Each film-coated tablets contains Dexketoprofen trometamol 36.9mg corresponding to dexketoprofen 25mg.	20/3.1/0064	02.07.2020	NS1 for the 20's pack and NS2 for 50's & 500's
4	Blumed Laboratories Cc	Culaire Forte	Duloxetine hydrochloride	Gastro-resistant capsule	Each hard gastro-resistant capsule contains Duloxetine 30mg	20/1.2/0065	02.07.2020	NS3
5	Roche Products (Pty) Ltd.	ROCALTROL®	Calcitriol	Capsule	Each capsule contains calcitriol 0.25 µg	20/32.2/0066	02.07.2020	NS2
6	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Combiwave SF 50	Salmeterol xinafoate and fluticasone propionate	Inhalation	Each actuation delivers: Salmeterol xinafoate equivalent to 25 µg salmeterol and 50 µg fluticasone propionate.	20/15.2/0067	02.07.2020	NS2
7	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Combiwave SF 125	Salmeterol xinafoate and fluticasone propionate	Inhalation	Each actuation delivers: Salmeterol xinafoate equivalent to 25 µg salmeterol and 125 µg fluticasone propionate.	20/15.2/0068	02.07.2020	NS2

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8	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Combiwave SF 250	Salmeterol xinafoate and fluticasone propionate	Inhalation	Each actuation delivers: Salmeterol xinafoate equivalent to 25 µg salmeterol and 250 µg fluticasone propionate.	20/15.2/0069	02.07.2020	NS2
9	VHB Medi Sciences Limited	Vansafe CP 500	Vancomycin hydrochloride	Powder for solution for infusion	Each vial contains Vancomycin hydrochloride 500mg	20/20.1.1/0070	02.07.2020	NS2
10	Abbvie (Pty) Ltd	Humira 40mg/0.4ml	Adalimumab	Solution for injection	Each 0.4ml contains Adalimumab 40mg	20/30.1/0071	02.07.2020	NS2
11	Forrester Pharma (Pty) Ltd	Alltexx	Cetirizine hydrochloride	Tablet	Each tablet contains Cetirizine hydrochloride 10mg	20/5.7.1/0072	02.07.2020	NS1
12	Umsebe Healthcare	Bacentra Intrathecal 0.05mg/ml	Baclofen	Solution for injection	Each ml contains Baclofen 0.05mg	20/2.11/0073	02.07.2020	NS2
13	Umsebe Healthcare	Bacentra Intrathecal 0.5mg/ml	Baclofen	Solution for injection	Each ml contains Baclofen 0.5mg	20/2.11/0074	02.07.2020	NS2
14	Umsebe Healthcare	Bacentra Intrathecal 2mg/ml	Baclofen	Solution for injection	Each ml contains Baclofen 2mg	20/2.11/0075	02.07.2020	NS2
15	Aurobindo Pharma (Pty) Ltd	Liracem 5mg	Ramipril	Capsule	Each hard gelatin capsule contains Ramipril 5mg.	20/7.1.3/0076	02.07.2020	NS2
16	Aurobindo Pharma (Pty) Ltd	Liracem 10mg	Ramipril	Capsule	Each hard gelatin capsule contains Ramipril 10mg.	20/7.1.3/0077	02.07.2020	NS2
17	Innovata Pharmaceuticals (Pty) Ltd	Avatocin 10	Oxytocin	Liquid injection	Each vial contains Oxytocin 10IU	20/19/0078	02.07.2020	NS2
18	Innovata Pharmaceuticals (Pty) Ltd	Esoprex 20	Esomeprazole	Tablet	Each gastro resistant tablet contains Esomeprazole magnesium equivalent to Esomeprazole 20mg	20/11.4.3/0079	02.07.2020	NS2

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19	Innovata Pharmaceuticals (Pty) Ltd	Esoprex 40	Esomeprazole	Tablet	Each gastro resistant tablet contains Esomeprazole magnesium equivalent to Esomeprazole 40mg	20/11.4.3/0080	02.07.2020	NS2
20	Octapharma AG	Albunorm 20%	Human albumin	Solution for infusion	Each litre of infusion contains Human albumin 200 g	20/30.3/0081	02.07.2020	NS2
21	Erongo Agencies	Medi-Azithromycin 250mg	Azithromycin	Tablet	Each tablet contains Azithromycin 250mg	20/20.1.1/0082	02.07.2020	NS2
22	Erongo Agencies	Medi-Azithromycin 500mg	Azithromycin	Tablet	Each tablet contains Azithromycin 500mg	20/20.1.1/0083	02.07.2020	NS2
23	Mylan Laboratories Limited	Ogivri 150mg/vial	Trastuzumab	Lyophilized Powder for concentrate for solution for intravenous infusion	Each vial contains Trastuzumab 150mg	20/26/0084	02.07.2020	NS2
24	GlaxoSmithKline South Africa (Pty) Ltd	Juluca	Dolutegravir and Rilpivirine	Film-coated tablet	Each film-coated tablet contains 50mg of dolutegravir (as dolutegravir sodium) and 25mg of rilpivirine (as rilpivirine hydrochloride).	20/20.2.8/0085	02.07.2020	NS2
25	Namax Pharmaceutical (Pty) Ltd	Poliomyelitis (Live) Vaccine Type I/Type III (Human Diploid Cell) Oral	Poliomyelitis (Live) Vaccine Type I/Type III (Human Diploid Cell) Oral	Liquid	Each dose (0.1 ml) contains: Virus Polio (Sabin) OPV Sabin bivalent strain Type I and III: NLT 6.21 LgCCID ₅₀ OPV Sabin strain Type I viruses: 6.0 LgCCID ₅₀ OPV Sabin strain Type III viruses, 1b $\geq 10^{5.8}$ CCID ₅₀	20/30.1/0086	02.07.2020	NS1

S/N	APPLICANT	PROPRIETARY NAME	APPROVED NAME OF ACTIVE(S)	DOSAGE FORM	STRENGTH/DOSE UNIT	REGISTRATION NUMBER	REGISTRATION DATE	SCHED. STATUS
26	Mylan Laboratories Limited	Hulio 40mg PFS	Adalimumab	Solution for injection	Each 0.8ml contains Adalimumab 40mg	20/30.1/0087	02.07.2020	NS2
27	Trinity Pharma (Pty) Ltd	Vildusmet 50/850	Vidagliptin and Metformin hydrochloride	Tablet	Each tablet contains Vidagliptin 50mg and Metformin hydrochloride 850mg	20/21.2/0088	02.07.2020	NS2
28	Trinity Pharma (Pty) Ltd	Vildusmet 50/1000	Vidagliptin and Metformin hydrochloride	Tablet	Each tablet contains Vidagliptin 50mg and Metformin hydrochloride 1000mg	20/21.2/0089	02.07.2020	NS2
29	Mylan Laboratories Limited	Casposungin Mylan 50mg	Casposungin	Lyophilised powder for injection	Each vial contains Casposungin 50mg	20/20.2.2/0090	02.07.2020	NS2
30	Mylan Laboratories Limited	Casposungin Mylan 70mg	Casposungin	Lyophilised powder for injection	Each vial contains Casposungin 70mg	20/20.2.2/0091	02.07.2020	NS2
31	Cospharm Investment (Pty) Ltd	Prodart 0.5	Dutasteride	Soft Gelatin capsule	Each soft gelatin capsule contains Dutasteride 0.5mg	20/21.12/0092	02.07.2020	NS2
32	Macleods Pharmaceuticals Ltd.	Dolutegravir 50mg, Lamivudine 300mg and Tenofovir Disoproxil Fumarate 300mg Tablets	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate	Film coated Tablets	Each Film coated tablet contains Dolutegravir 50mg, Lamivudine 300mg and Tenofovir Disoproxil Fumarate 300mg	20/20.2.8/0093	02.07.2020	NS2
33	Laurus Labs Limited	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate 600mg/300mg/300mg tablets	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate	Tablet	Each tablet contains Efavirenz 600mg, Lamivudine 300mg and Tenofovir disoproxil fumarate 300mg	20/20.2.8/0094	02.07.2020	NS2

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34	Laurus Labs Limited	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate 400mg/300mg/300mg tablets	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate	Tablet	Each tablet contains Efavirenz 400mg, Lamivudine 300mg and Tenofovir disoproxil fumarate 300mg	20/20.2.8/0095	02.07.2020	NS2
35	Innovata Pharmaceuticals (Pty) Ltd	Furosem 250mg	Cefuroxime	Film-coated tablets	Each Tablet Contains Cefuroxime 250mg	20/20.1.1/0096	02.07.2020	NS2
36	Innovata Pharmaceuticals (Pty) Ltd	Furosem 500mg	Cefuroxime	Film-coated tablets	Each Tablet Contains Cefuroxime 500mg	20/20.1.1/0097	02.07.2020	NS2
37	Erongo Agencies	Napresmo	Esomeprazole sodium	Powder for solution for injection	Each vial contains Esomeprazole 40mg	20/11.4.3/0098	02.07.2020	NS2
38	Erongo Agencies	Naprocil 250	Fluorouracil injection BP 250mg/5ml	Solution for infusion	Each 5ml contains Fluorouracil 250mg	20/26/0099	02.07.2020	NS2
39	Erongo Agencies	Naprocil 500	Fluorouracil injection BP 500mg/5ml	Solution for infusion	Each 5ml contains Fluorouracil 500mg	20/26/0100	02.07.2020	NS2
40	Bal Pharma Limited	Balfen 400mg	Ibuprofen	Film coated tablets	Each Tablet contains Ibuprofen BP 400mg	20/2.8/0101	02.07.2020	NS1
41	Equity Pharmaceuticals (Pty) Ltd.	Garsun 60mg	Artesunate.	Powder for injection	Each vial or ampoule contains 60mg artesunate.	20/20.2.6/0102	02.07.2020	NS2
42	Cospharm Investment (Pty) Ltd	CP-Azithromycin	Azithromycin	Film coated tablets	Each Film coated tablet contains Azithromycin 500mg	20/20.1.1/0103	02.07.2020	NS2
43	Eurolab (Pty) Ltd	Tronson	Palonosetron hydrochloride	Solution for IV injection	Each Vial Contains 250 µg Palonosetron hydrochloride	20/5.10/0104	02.07.2020	NS2

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44	Ranbaxy Pharmaceuticals (Pty) Ltd	Vonel	Levonorgestrel	Tablet	Each tablet contains 0,75mg Levonorgestrel	20/18.7/0105	02.07.2020	NS1
45	Cipla Quality Chemical Industries Limited	Lumet	Artemether and Lumefantrine	Uncoated tablets	Each uncoated tablet contains artemether 20mg and lumefantrine 120mg	20/20.2.6/0106	02.07.2020	NS2
46	M/s Biological E. Limited	Measles and Rubella Vaccine (Live) (Attenuated, Freeze Dried) with 0.9% w/v Sodium Chloride	Measles and Rubella Vaccine (Live) (Attenuated, Freeze Dried) with 0.9% w/v Sodium Chloride	Vaccine	Each reconstituted dose of 0.5ml (5 dose and 10 dose) contains Measles virus (CAM-70 strain), propagated in chicken embryo fibroblast cells \geq 1000 CCID50 and Rubella virus (Wistar RA27/3 strain) propagated in MRC 5 cells \geq 1000 CCID50.	20/30.1/0107	02.07.2020	NS1
47	Cospharm Investment (Pty) Ltd	Pethidine Injection BP	Pethidine Hydrochloride BP	Sterile Solution for Injection (Ampoule)	Each ml of sterile solutions contains 50mg Pethidine Hydrochloride BP	20/2.10/0108	02.07.2020	NS4
48	Eurolab (Pty) Ltd	Zelbeen 150mg	Capecitabine	Tablet	Each tablet contains Capecitabine 150mg	20/26/0109	02.07.2020	NS2
49	Eurolab (Pty) Ltd	Zelbeen 500mg	Capecitabine	Tablet	Each tablet contains Capecitabine 500mg	20/26/0110	02.07.2020	NS2