



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 3 January 2023

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 1	NOTIFICATION OF REGISTRATION OF CERTAIN MEDICINES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003	2023
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In terms of section 23 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), I give notice of the registration of the medicines whose particulars are set out in the Schedule.

F. N. NAMBAHU
REGISTRAR OF MEDICINES

SCHEDULE

Particulars required under section 23(a)(i) to (v) of the Act					
S/N	Name under which the medicine is registered	Active components of medicine	Name of Applicant	Name of Manufacturer	Registration number allocated to a medicine in terms of section 19(9) of the Act
1	Tafgado	Tenofovir Alafenamide Fumarate	Mylan Laboratories Limited	Mylan Laboratories Limited, Plot No. 11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist - Dhar, Madhya Pradesh, India	22/20.2.8/0046
2	Voriconazole Mylan	Voriconazole	Mylan Laboratories Limited	Mylan Laboratories Limited [HSF], Plot No. 14, SIPCOT II, Krishnagiri Road, Hosur, Tamil Nadu - 635 109, India	22/20.1.7/0047
3	Atorstatin 20	Atorvastatin Calcium USP	Cospharm Investment	Acme Formulation Pvt. Ltd., Ropar Road Nalagarh, Distt. Solan, Himachal Pradesh - 174101, India	22/7.5/0048
4	Lafeks 37.5	Venlafaxine Hydrochloride	Innovata Pharmaceuticals (Pty) Ltd	Alembic Pharmaceuticals Limited, Unit -I And Unit -Ii, Panelav, P.O Tajpura, Taluka- Halol	22/1.2/0049
5	Lafeks 75	Venlafaxine Hydrochloride	Innovata Pharmaceuticals (Pty) Ltd	Alembic Pharmaceuticals Limited, Unit -I And Unit -Ii, Panelav, P.O Tajpura, Taluka- Halol	22/1.2/0050
6	Lafeks 150	Venlafaxine Hydrochloride	Innovata Pharmaceuticals (Pty) Ltd	Alembic Pharmaceuticals Limited, Unit -I And Unit -Ii, Panelav, P.O Tajpura, Taluka- Halol	22/1.2/0051
7	Radd 18 mg	Methylphenidate hydrochloride	Pharma Dynamics (Pty) Ltd	Balkanphanna Dupnitsa A.D., Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria	22/1.2/0052
8	Radd 27 mg	Methylphenidate hydrochloride	Pharma Dynamics (Pty) Ltd	Balkanphanna Dupnitsa A.D., Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria	22/1.2/0053
9	Radd 36 mg	Methylphenidate hydrochloride	Pharma Dynamics (Pty) Ltd	Balkanphanna Dupnitsa A.D., Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria	22/1.2/0054
10	Radd 54 mg	Methylphenidate hydrochloride	Pharma Dynamics (Pty) Ltd	Balkanphanna Dupnitsa A.D., Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria	22/1.2/0055
11	Accord Carboplatin 10 mg/ml Injection	Carboplatin	Accord Healthcare (Pty) Ltd	Intas Pharmaceuticals Ltd., Plot No. 457, 458, Village-Matoda, Bavla Road, Taluka, Sanand, Dist. Ahmedabad-382-210, Gujarat, India	22/26/0056

12	Accord-Gemcitabine 200 mg	Gemcitabine hydrochloride	Accord Healthcare (Pty) Ltd	Intas Pharmaceuticals Ltd., Plot No. 457, 458, Village-Matoda, Bavla Road, Taluka, Sanand, Dist. Ahmedabad-382-210, Gujarat, India	22/26/0057
13	Accord-Gemcitabine 1g	Gemcitabine hydrochloride	Accord Healthcare (Pty) Ltd	Intas Pharmaceuticals Ltd., Plot No. 457, 458, Village-Matoda, Bavla Road, Taluka, Sanand, Dist. Ahmedabad-382-210, Gujarat, India	22/26/0058
14	Betadexamine	Betamethasone Dexchlorpheniramine maleate	Pharmacare Limited	Aspen SA Manufacturing Operations (Pty) Ltd, Robbie de Lange Road, Wilsonia East London, 5201-	22/32.2/0059
15	Varnil 5	Vardenafil Hydrochloride Trihydrate Ph.Eur.	Mylan Laboratories Limited	Mylan Laboratories Limited, Plot No. S16 & S17/A, Survey Nos. 408(P), 410(P), 458(P), SEZ APIIC, Green Industrial Park, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar District – 509301, Telangana State, India	22/7.1.5/0060
16	Varnil 10	Vardenafil Hydrochloride Trihydrate Ph.Eur.	Mylan Laboratories Limited	Mylan Laboratories Limited, Plot No. S16 & S17/A, Survey Nos. 408(P), 410(P), 458(P), SEZ APIIC, Green Industrial Park, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar District – 509301, Telangana State, India	22/7.1.5/0061
17	Varnil 20	Vardenafil Hydrochloride Trihydrate Ph.Eur.	Mylan Laboratories Limited	Mylan Laboratories Limited, Plot No. S16 & S17/A, Survey Nos. 408(P), 410(P), 458(P), SEZ APIIC, Green Industrial Park, Polepally (Village), Jadcherla (Mandal), Mahaboobnagar District – 509301, Telangana State, India	22/7.1.5/0062
18	Depocillin	Procaine benzylpenicillin	Intervet SA (Pty) Ltd	Intervet Productions S.r.l, Via Nettunese Km 20,300 04011 Aprilia (Latina) Italy	V22/17.1.10/1507
19	Cepravin Dry Cow	Cefalonium	Intervet SA (Pty) Ltd	1. TriRx Segre, La Grindoliere, Zone Artisanale Segre, 49500 Segre en Anjou Bleu, France 2. Intervet International GmbH, Feldstrasse 1a, 85716 Unterschleissheim, Germany	V22/16.1/1508
20	Phivax SLE	Attenuated intermediate Infectious Bursal Disease virus, M.B. strain	Phibro Animal Health	Abic Biological Laboratories Ltd, West Industrial Zone, P.O.B 489 Beit-Shemesh 9905503, Israel	V22/24.3/1509
21	Newxxitek HVT + ND	Serotype 3 Marek's disease vector expressing a Newcastle Disease virus Fusion gene	Boehringer Ingelheim Animal Health South Africa (Pty) Ltd	Boehringer Ingelheim Animal Health USA Inc, 1168 Airport Parkway, SW, Gainesville, GA 30501-6816, USA	V22/24.3/1510

As required under section 23(a)(iv) of the Act, the medicines whose particulars are specified in these Schedules are registered subject to the following conditions:

- (a) The manufacture and control of the medicines must be in accordance with the existing Good Manufacturing Practices as required by the World Health Organisation;
- (b) In order to assess compliance with paragraph (a) above, inspections and investigations may be carried out regularly by inspectors authorised in terms of sections 35 of the Act to undertake such inspections and investigations;
- (c) Every manufacturer of a medicine must, with the approval of the Namibia Medicines Regulatory Council, ensure that the information contained in the medicine package insert is regularly updated and varied so as to provide accurate information to the user of the medicine;
- (d) The holder of the certificate of registration which is referred to in section 19(7)(b) of the Act must comply with the provisions of the Act;
- (e) The registration of medicine is subject to regular review regarding its quality, safety and efficacy and the Namibia Medicines Regulatory Council may, if 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 Namibia Medicines Regulatory Council within one month from the date of completion of the validation referred to in paragraph (f); and
- (h) The Namibia Medicines Regulatory Council may review the registration dossier and may determine the intervals when such review will take place.

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 2

2023

NOTIFICATION OF CANCELLATION 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 the registration of the medicines set out in the Schedule is cancelled.

F. NAMBAHU**REGISTRAR OF MEDICINES**

Windhoek, 23 November 2022

SCHEDULE

Particulars required under section 23(b) of the Act			
S/N	Name under which medicine was registered	Name of holder of certificate of registration	Registration number which was allocated to medicine
1	Peploc IV	Pharma Dynamics (Pty) Ltd	12/11.4.3//0141
2	Inderal 10	AstraZeneca Pharmaceuticals (Pty) Ltd	90/5.2/00270
3	Oxis Turbuhaler 9	AstraZeneca Pharmaceuticals (Pty) Ltd	04/10.2.1/1768

4	Panado Children's Tablets Chewable 120mg	Adcock Ingram Limited	90/2.7/00155
5	Panado-Co Tablets	Adcock Ingram Limited	90/2.8/00160
6	Prepidil 0,5 mg gel	Pfizer Laboratories Limited	90/19/001346
7	Dovonex Ointment	Adcock Ingram Limited	04/13.9.1/1566
8	Dovonex Cream	Adcock Ingram Limited	05/13.9.1/0147
9	Celestamine Syrup	MSD (Pty) Ltd	14/13.4.1/0470
10	Celestamine Tablets	MSD (Pty) Ltd	14/13.4.1/0474
11	Janumet 50/500 mg	MSD (Pty) Ltd	10/21.2/0292
12	Axim E-Z-Gas	Axim Pharmaceuticals (Pty) Ltd	05/11.4.1/0422
13	Axim Polibar Rapid	Axim Pharmaceuticals (Pty) Ltd	05/28/0385
14	Axim Polibar Plus	Axim Pharmaceuticals (Pty) Ltd	05/28/0386
15	Jopamiron 200 10 ml	Axim Pharmaceuticals (Pty) Ltd	90/28/001370
16	Jopamiron 300 10 ml	Axim Pharmaceuticals (Pty) Ltd	90/28/001371
17	Jopamiron 300 20 ml	Axim Pharmaceuticals (Pty) Ltd	90/28/001372
18	Jopamiron 370 20 ml	Axim Pharmaceuticals (Pty) Ltd	90/28/001375
19	Theoplus 200 mg	Takeda (Pty) Ltd	90/10.2/00520
20	Theoplus 300 mg	Takeda (Pty) Ltd	90/10.2/00521
21	Climara 100	Bayer (Pty) Ltd	04/21.8.1/1013
22	Climara 50	Bayer (Pty) Ltd	04/21.8.1/1012
23	Climara 75	Bayer (Pty) Ltd	04/21.8.1/1014
24	AdalatXL 20	Bayer (Pty) Ltd	10/7.1/0222
25	AdalatXL 60	Bayer (Pty) Ltd	04/7.1/0354
26	Spiriva Respimat	Ingelheim Pharmaceuticals (Pty) Ltd	10/10.2.1/0488
27	Sotahexal 80 mg Tablets	Sandoz SA (Pty) Ltd	04/5.211355
28	Sotahexal 160 mg Tablets	Sandoz SA (Pty) Ltd	04/5.2/1356
29	Hycamtin IV	Sandoz SA (Pty) Ltd	14/26/0029
30	Atorvastatin Winthrop 20 mg	Sanofi-Aventis South Africa (Pty) Ltd	13/7.5/0264
31	Flagyl 500 mg Suppositories	Sanofi-Aventis South Africa (Pty) Ltd	90/20.2/00309
32	Zyrtec Tablets 10 mg	GlaxoSmithKline South Africa (Pty) Ltd	04/5.7.1/0823
33	Lescol XL	Novartis South Africa (Pty) Ltd	04/7.5/0561
34	Prohexal 40T Dispers. Tablets	Sandoz SA (Pty) Ltd	04/1.2/1351
35	Sandoz Pravastatin 40	Sandoz SA (Pty) Ltd	14/7.5/0046
36	Sandoz Pravastatin 20	Sandoz SA (Pty) Ltd	14/7.5/0047
37	Sandoz Pravastatin 10	Sandoz SA (Pty) Ltd	14/7.5/0048
38	Quinazide 10/12.5 Tablet	Sandoz SA (Pty) Ltd	13/7.1.3/0137
39	Quinazide 20/12.5 Tablet	Sandoz SA (Pty) Ltd	13/7.1.3/0138
40	Hexal-Allopurinol 300	Sandoz SA (Pty) Ltd	08/3.3/0010
41	Hexai-Allopurinol 300	Sandoz SA (Pty) Ltd	06/3.3/0128
42	Zaprine 25	Sandoz SA (Pty) Ltd	14/26/0006
43	Clatax 0,5 g	Sandoz SA (Pty) Ltd	12/20.1.1/0193
44	Clatax 1,0 g	Sandoz SA (Pty) Ltd	12/20.1.1/0194
45	Sandoz-Diclofenac Sodium 50	Sandoz SA (Pty) Ltd	90/3.1/001468
46	Hx-Doxorubicin 10mg/5ml	Sandoz SA (Pty) Ltd	06/26/0167
47	Fluvoxamine Hexal 50	Sandoz SA (Pty) Ltd	14/1.2/0051
48	Fluvoxamine-Hexal 100	Sandoz SA (Pty) Ltd	12/1.2/0132
49	Andaran 300mg	Sandoz SA (Pty) Ltd	16/7.1.3/0067
50	Andaran 150mg	Sandoz SA (Pty) Ltd	16/7.1.3/0066

51	Andaran HCT 150/12.5	Sandoz SA (Pty) Ltd	16/7.1.3/0062
52	Andaran HCT 300/12.5	Sandoz SA (Pty) Ltd	16/7.1.3/0063
53	Andaran HCT 300/25	Sandoz SA (Pty) Ltd	16/7.1.3/0064
54	Andaran 75mg	Sandoz SA (Pty) Ltd	16/7.1.3/0065
55	Omiloc 40 IVI	Sandoz SA (Pty) Ltd	10/11.4.3/0074
56	Sandoz Tamsulosin 0.4	Sandoz SA (Pty) Ltd	14/34/0072
57	Sandoz- Zopiclone 3.75	Sandoz SA (Pty) Ltd	14/2.2/0007
