



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 13 October 2021

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Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 221 2021

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 of the cancellation of registration of the medicines whose particulars are specified in the Schedule.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 29 September 2021

SCHEDULE

Particulars required under section 23(b) of the Act			
S/N	Name under which that medicine was registered	Name of the holder of the certificate of registration issued in respect of that medicine	Registration number which was allocated to that medicine in terms of section 19(9)
1	Jurnista 8mg	Janssen Pharmaceutica (Pty) Ltd	12/2.9/0159
2	Jurnista 16mg	Janssen Pharmaceutica (Pty) Ltd	12/2.9/0160
3	Forane	Abbvie (Pty) Ltd	90/2.1/0060
4	Sinemet 25/250 compressed tablets	MSD (Pty) Ltd	13/5.4.1/0006
5	Ciavor 20	El Lilly (SA) (Pty) Limited	15/7.1.5/0173
6	Cymgen 30	El Lilly (SA) (Pty) Limited	16/1.2/0201
7	Cymgen 60	El Lilly (SA) (Pty) Limited	16/1.2/0202
8	Agrippal	Kahma Biotech (Pty) Ltd	04/30.1/1423
9	Fortzaar Tablets	MSD (Pty) Ltd	04/7.1.3/1447
10	Zinacef 1,5g Injection	GlaxoSmithKline South Africa (Pty) Ltd	90/20.1.1/00595
11	Zinacef 250mg Injection	GlaxoSmithKline South Africa (Pty) Ltd	90/20.1.1/00596
12	Zinacef 750mg Injection	GlaxoSmithKline South Africa (Pty) Ltd	90/20.1.1/00597
13	Bactroban Topical	GlaxoSmithKline South Africa (Pty) Ltd	90/20.1.6/001584
14	Zyrtec Oral Drops 10mg/ml	GlaxoSmithKline South Africa (Pty) Ltd	04/5.7.1/0822
15	Flixotide 125 CFC Free Inhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0856
16	Lamictin P 100 Tablets	GlaxoSmithKline South Africa (Pty) Ltd	04/2.5/0864
17	Lamictin 50mg Tablets	GlaxoSmithKline South Africa (Pty) Ltd	04/2.5/0867
18	Flixotide 500 Accuhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0874
19	Flixotide 100 Accuhaler	GlaxoSmithKline South Africa (Pty) Ltd	04/21.5.1/0876
20	Aropax 20mg Tablets	GlaxoSmithKline South Africa (Pty) Ltd	04/1.2/0895
21	Bactroban Cream	GlaxoSmithKline South Africa (Pty) Ltd	04/20.1.6/0896
22	Naramig Tablets	GlaxoSmithKline South Africa (Pty) Ltd	04/7.3/0903
23	Zelitrex 500	GlaxoSmithKline South Africa (Pty) Ltd	04/20.2.8/0914
24	Zantac Effervescent 300mg	GlaxoSmithKline South Africa (Pty) Ltd	04/11.4.3/0923
25	Zyban Tablets	GlaxoSmithKline South Africa (Pty) Ltd	04/34/0945
26	Keppra 250mg	GlaxoSmithKline South Africa (Pty) Ltd	04/2.5/1712
27	Malanil Paediatric	GlaxoSmithKline South Africa (Pty) Ltd	10/20.2.6/0335
28	Malanil	GlaxoSmithKline South Africa (Pty) Ltd	05/20.2.6/0237
29	Wellbutrin SR	GlaxoSmithKline South Africa (Pty) Ltd	05/34/0508
30	Bovi- Shield FP4+L5	Zoetis SA (Pty) Ltd	V09/24.4/205

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 222

2021

**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 of the registration of the medicines whose particulars are specified in the Schedule.

J. GAESEB
REGISTRAR OF MEDICINES

Windhoek, 29 September 2021

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	Besivance	Besifloxacin	Soflens (Pty) Ltd	Bausch & Lomb Incorporated, USA	20/15.1/0062
2	Scapho 150mg	Secukinumab	Sandoz South Africa (Pty) Ltd	Novartis Pharma Stein AG, Switzerland	20/30.1/0063
3	Dektoflam	Dexketoprofen trometamol	Bluemed Laboratories Cc	Lesvi Laboratories, S.L., Spain.	20/3.1/0064
4	Culaire Forte	Duloxetine hydrochloride	Bluemed Laboratories Cc	Lesvi Laboratories, S.L., Spain.	20/1.2/0065
5	Rocaltrol®	Calcitriol	Roche Products (Pty) Ltd.	Catalent Germany Eberbach GmbH, Germany	20/32.2/0066
6	Combiwave SF 50	Salmeterol xinafoate and fluticasone propionate	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Ltd, India	20/15.2/0067
7	Combiwave SF 125	Salmeterol xinafoate and fluticasone propionate	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Ltd, India	20/15.2/0068
8	Combiwave SF 250	Salmeterol xinafoate and fluticasone propionate	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Ltd, India	20/15.2/0069
9	Vansafe CP 500	Vancomycin hydrochloride	VHB Medi Sciences Limited	VHB Medi Sciences Limited, India	20/20.1.1/0070
10	Humira 40mg/0.4ml	Adalimumab	Abbvie (Pty) Ltd	1. Vetter Pharma-Fertigung GmbH & Co. KG, Germany 2. Abbvie Biotechnology Ltd., USA 3. Vetter Pharma-Fertigung GmbH & Co. KG, Germany	20/30.1/0071
11	Alletexx	Cetirizine hydrochloride	Forrester Pharma (Pty) Ltd	Square Pharmaceutical Ltd, India	20/5.7.1/0072
12	Bacentra Intrathecal 0.05mg/ml	Baclofen	Umsebe Healthcare	Sintetica S.A., Switzerland	20/2.11/0073
13	Bacentra Intrathecal 0.5mg/ml	Baclofen	Umsebe Healthcare	Sintetica S.A., Switzerland	20/2.11/0074
14	Bacentra Intrathecal 2mg/ml	Baclofen	Umsebe Healthcare	Sintetica S.A., Switzerland	20/2.11/0075
15	Liracen 5mg	Ramipril	Aurobindo Pharma (Pty) Ltd	Aurobindo Pharma Limited, Unit III, India	20/7.1.3/0076
16	Liracen 10mg	Ramipril	Aurobindo Pharma (Pty) Ltd	Aurobindo Pharma Limited, Unit III, India	20/7.1.3/0077
17	Avatocin 10	Oxytocin	Innovata Pharmaceuticals (Pty) Ltd	Steril-Gene Life Sciences (Pty) Ltd, India	20/19/0078
18	Esoprex 20	Esomeprazole	Innovata Pharmaceuticals (Pty) Ltd	Jubilant Generics Limited, India	20/11.4.3/0079
19	Esoprex 40	Esomeprazole	Innovata Pharmaceuticals (Pty) Ltd	Jubilant Generics Limited, India	20/11.4.3/0080

20	Albumorm 20%	Human albumin	Octapharma AG	Octapharma Produktionsgesellschaft Deutschland GmbH, Germany	20/30.3/0081
21	Medi-Azithromycin 250mg	Azithromycin	Erongo Agencies	Jubilant Life Sciences Limited, India	20/20.1.1/0082
22	Medi-Azithromycin 500mg	Azithromycin	Erongo Agencies	Jubilant Life Sciences Limited, India	20/20.1.1/0083
23	Ogivri 150mg/vial	Trastuzumab	Mylan Laboratories Limited	Biocon Limited, India	20/26/0084
24	Juluca	Dolutegravir and Rilpivirine	GlaxoSmithKline South Africa (Pty) Ltd	Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations), United Kingdom	20/20.2.8/0085
25	Poliomyelitis (Live) Vaccine Type I/Type III (Human Diploid Cell) Oral	Poliomyelitis (Live) Vaccine Type I/Type III (Human Diploid Cell) Oral	Namax Pharmaceutical (Pty) Ltd	Beijing Institute of Biological Products Co., Ltd, India	20/30.1/0086
26	Hulio 40mg PFS	Adalimumab	Mylan Laboratories Limited	Terumo Yamaguchi D&D Corporation, Japan	20/30.1/0087
27	Vildusmet 50/850	Vidagliptin and Metformin hydrochloride	Trinity Pharma (Pty) Ltd	Oman Pharmaceuticals Products Co. LLC, Sultanate of Oman	20/21.2/0088
28	Vildusmet 50/1000	Vidagliptin and Metformin hydrochloride	Trinity Pharma (Pty) Ltd	Oman Pharmaceuticals Products Co. LLC, Sultanate of Oman	20/21.2/0089
29	Caspofungin Mylan 50mg	Caspofungin	Mylan Laboratories Limited	Mylan Laboratories Limited, India	20/20.2.2/0090
30	Caspofungin Mylan 70mg	Caspofungin	Mylan Laboratories Limited	Mylan Laboratories Limited, India	20/20.2.2/0091
31	Prodart 0.5	Dutasteride	Cospharm Investment (Pty) Ltd	Olive Healthcare – Unit III, India	20/21.12/0092
32	Dolutegravir 50mg, Lamivudine 300mg and Tenofovir Disoproxil Fumarate 300mg Tablets	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate	Macleods Pharmaceuticals Ltd.	Macleods Pharmaceuticals Limited Block No. 2, India	20/20.2.8/0093
33	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate 600mg/300mg/300mg tablets	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate	Laurus Labs Limited	Laurus Labs Limited, (Unit-2), India	20/20.2.8/0094
34	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate 400mg/300mg/300mg tablets	Efavirenz, Lamivudine and Tenofovir disoproxil fumarate	Laurus Labs Limited	Laurus Labs Limited, (Unit-2), India	20/20.2.8/0095
35	Furosem 250mg	Cefuroxime	Innovata Pharmaceuticals (Pty) Ltd	Nectar Lifesciences Limited Unit VI, India	20/20.1.1/0096
36	Furosem 500mg	Cefuroxime	Innovata Pharmaceuticals (Pty) Ltd	Nectar Lifesciences Limited Unit VI, India	20/20.1.1/0097
37	Napresmo	Esomeprazole sodium	Erongo Agencies	Naprod Life Sciences Pvt Ltd, India	20/11.4.3/0098
38	Naprocil 250mg	Fluorouracil injection BP 250mg/5ml	Erongo Agencies	Naprod Life Sciences Pvt Ltd, India	20/26/0099

39	Naprocil 500mg	Fluorouracil injection BP 500mg/5ml	Erongo Agencies	Naprod Life Sciences Pvt Ltd, India	20/26/0100
40	Balfen 400mg	Ibuprofen	Bal Pharma Limited	Bal Pharma Limited, India	20/2.8/0101
41	Garsun 60mg	Artesunate.	Equity Pharmaceuticals (Pty) Ltd.	Guilin Pharmaceutical Co. Ltd, China	20/20.2.6/0102
42	CP-Azithromycin	Azithromycin	Cospharm Investment (Pty) Ltd	Acme Formulation Pvt. Ltd, India	20/20.1.1/0103
43	Tronson	Palonosetron hydrochloride	Eurolab (Pty) Ltd	Gland Pharma Limited, India	20/5.10/0104
44	Vonel	Levonorgestrel	Ranbaxy Pharmaceuticals (Pty) Ltd	Sun Pharmaceutical Industries Ltd, India	20/18.7/0105
45	Lumet	Artemether and Lumefantrine	Cipla Quality Chemical Industries Limited	Cipla Quality Chemical Industries Limited, Uganda	20/20.2.6/0106
46	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	M/s Biological E. Limited	M/s. Biological E. Limited, India	20/30.1/0107
47	Pethidine Injection BP	Pethidine Hydrochloride BP	Cospharm Investment (Pty) Ltd	M/s Verve Human Care Laboratories, India	20/2.10/0108
48	Zelbeen 150mg	Capecitabine	Eurolab (Pty) Ltd	Remedica Ltd, Cyprus	20/26/0109
49	Zelbeen 500mg	Capecitabine	Eurolab (Pty) Ltd	Remedica Ltd, Cyprus	20/26/0110
50	Simpatrica 5mg	Sarolaner	Zoetis SA (Pty) Ltd	1. Hovione FarmaCiencia SA, USA. 2. Zoetis Inc, USA.	V20/18.3/1453
51	Simpatrica 10mg	Sarolaner	Zoetis SA (Pty) Ltd	1. Hovione FarmaCiencia SA, USA. 2. Zoetis Inc, USA.	V20/18.3/1454
52	Simpatrica 20mg	Sarolaner	Zoetis SA (Pty) Ltd	1. Hovione FarmaCiencia SA, USA. 2. Zoetis Inc, USA.	V20/18.3/1455
53	Simpatrica 40mg	Sarolaner	Zoetis SA (Pty) Ltd	1. Hovione FarmaCiencia SA, USA. 2. Zoetis Inc, USA.	V20/18.3/1456
54	Simpatrica 80mg	Sarolaner	Zoetis SA (Pty) Ltd	1. Hovione FarmaCiencia SA, USA. 2. Zoetis Inc, USA.	V20/18.3/1457
55	Simpatrica 120mg	Sarolaner	Zoetis SA (Pty) Ltd	1. Hovione FarmaCiencia SA, USA. 2. Zoetis Inc, USA.	V20/18.3/1458

As required under section 23(a)(iv) of the Act, the medicines whose particulars are specified in this Schedule 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 Organization;
 - (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(4) 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 determine the intervals when such review will take place.
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