



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 12 April 2023

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CONTENTS

Page

GOVERNMENT NOTICES

No. 87	Notification of cancellation of registration of certain medicines: Medicines and Related Substances Control Act, 2003	1
No. 88	Notification of registration of certain medicines: Medicines and Related Substances Control Act, 2003	3

Government Notices

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 87

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

F. NAMBAHU
REGISTRAR OF MEDICINES

Windhoek, 21 February 2023

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.	Vibrocil-S Nasal Gel	GlaxoSmithKline Consumer Healthcare South Africa (Pty) Ltd	90/16.1/00681
2.	Paroven Capsules 250	GlaxoSmithKline Consumer Healthcare South Africa (Pty) Ltd	14/7/0087
3.	Intelence 25mg Tablets	Janssen-Cilag International NV	15/20.2.8/0128
4.	Nerisone Cream	Adcock Ingram Limited	90/13.4.1/014
5.	Nerisone Ointment	Adcock Ingram Limited	90/13.4.1/015
6.	Nerisone Fatty Ointment	Adcock Ingram Limited	90/13.4.1/016
7.	Nerisone Forte Ointment	Adcock Ingram Limited	90/13.4.1/017
8.	Nerisone Forte Fatty Ointment	Adcock Ingram Limited	90/13.4.1/018
9.	Prefrin Liquifilm Sterile Eye Drops	Abbvie (Pty) Ltd	90/15.4/00264
10.	Kaletra Solution	AbbVie (Pty) Ltd	04/20.2.8/0229
11.	Lyrinel 5 mg	Janssen Pharmaceutica (Pty) Ltd	09/5.4/0002
12.	Lyrinel 10 mg	Janssen Pharmaceutica (Pty) Ltd	09/5.4/0003
13.	Adco-Betamethasone Cream	Adcock Ingram Limited	04/13.4.1/1557
14.	Winlomyon Suspension	Adcock Ingram Limited	04/20.2.5/1601
15.	Fenwal Blood pack unit	Adcock Ingram Critical Care (Pty) Ltd	90/8.2/00186
16.	Fenwal Plasmapheresis Blood-Pack Unit with 4% Sodium Citrate Dihydrate Anticoagulant Solution	Adcock Ingram Critical Care (Pty) Ltd	90/8.2/00187
17.	Fenwal Primary Container with Citrate Phosphate Glucose Adenine Anticoagulant	Adcock Ingram Critical Care (Pty) Ltd	90/8.2/00188
18.	Fenwal Primary Container with Citrate Phosphate Glucose Anticoagulant	Adcock Ingram Critical Care (Pty) Ltd	90/8.2/00189
19.	Fenwal Secondary Container with Saline Adenine Glucose Mannitol (SAG-M)	Adcock Ingram Critical Care (Pty) Ltd	04/8.2/1709
20.	Adco Cefuroxime 1,5 g (50 ml)	Adcock Ingram Critical Care (Pty) Ltd	04/20.1.1/1963
21.	Adco Cefuroxime 250 mg	Adcock Ingram Critical Care (Pty) Ltd	05/20.1.1/0228
22.	Adco Cefuroxime 750 mg	Adcock Ingram Critical Care (Pty) Ltd	05/20.1.1/0229
23.	Fenwal Secondary Container with Adsol Red Cell Preservation Solution	Adcock Ingram Critical Care (Pty) Ltd	90/8.2/00190
24.	Sabax Cefuroxime 1,5 g (20 ml)	Adcock Ingram Critical Care (Pty) Ltd	04/20.1.1/1962
25.	Sabax Glucose 50%	Adcock Ingram Critical Care (Pty) Ltd	90/25/00214

26.	Sabax Morphine Sulphate 10mg	Adcock Ingram Critical Care (Pty) Ltd	14/2.9/0667
27.	Lopresor 100 mg film coated tablets	Novartis South Africa (Pty) Ltd	90/5.2/00704
28.	Emadine Eye Drops	Novartis South Africa (Pty) Ltd	06/15.4/0179
29.	Sabax Propofol 1% (20 ml)	Adcock Ingram Critical Care (Pty) Ltd	05/2.1/0454
30.	Sabax Propofol 1% (50 ml)	Adcock Ingram Critical Care (Pty) Ltd	05/2.1/0455
31.	Sabax Propofol 1% (100 ml)	Adcock Ingram Critical Care (Pty) Ltd	05/2.1/0456
32.	Sabax Propofol 2% (20 ml)	Adcock Ingram Critical Care (Pty) Ltd	05/2.1/0457
33.	Sabax Propofol 2% (50 ml)	Adcock Ingram Critical Care (Pty) Ltd	05/2.1/0458
34.	Sabax Propofol 2% (100 ml)	Adcock Ingram Critical Care (Pty) Ltd	05/2.1/0459
35.	Tramahexal 50 mg	Sandoz SA (Pty) Ltd	04/2.9/1357
36.	Scourmune-C	Intervet South Africa (Pty) Ltd	V07/24.5/748

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 88

2023

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 of the registration of the medicines of which the particulars are specified in the Schedule.

F. NAMBAHU
REGISTRAR OF MEDICINES

Windhoek, 21 February 2023

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.	Paracetamol Biotech IV	Paracetamol	Biotech Laboratories (Pty) Ltd	Unique Pharmaceutical Laboratories (A division of J.B. Chemicals and Pharmaceuticals Ltd.) Plot no. 4, Phase-IV, GIDC Industrial area, Panoli – 394 116, Dist: Bharuch Gujarat, India	23/2.7/0001
2.	Glenex 5	Desloratadine	Glenmark Pharmaceuticals South Africa (Pty) Ltd	Glenmark Pharmaceuticals Limited, Plot No. S-7, Colvale Industrial Estate, Colvale, Baredéz – Goa, 403513	23/5.7.1/0002
3.	Zenziket 1mg/ml	Ketamine hydrochloride equivalent to Ketamine base	Umsebe Healthcare	Sintetica-Bioren S.A. 4B, Rue des Iles CH-2108 Couvet Switzerland	23/2.1/0003
4.	Zenziket 10mg/ml	Ketamine hydrochloride equivalent to Ketamine base	Umsebe Healthcare	Sintetica S.A. Via Penate 5 CH-6850 Mendrisio, Switzerland	23/2.1/0004
5.	Zenziket 50mg/ml	Ketamine hydrochloride equivalent to Ketamine base	Umsebe Healthcare	Sintetica S.A. Via Penate 5 CH-6850 Mendrisio, Switzerland	23/2.1/0005
6.	Roz	Ethinylestradiol, Drospirenone	Innovata Pharmaceuticals (Pty) Ltd	Oman Pharmaceutical Products Co. L.L.C. Plot No. 101, Raysut Industrial Estate	23/18.8/0007
7.	Roslyn	Ethinylestradiol, Drospirenone	Innovata Pharmaceuticals (Pty) Ltd	Oman Pharmaceutical Products Co. L.L.C. Plot No. 101, Raysut Industrial Estate	23/18.8/0008
8.	Cynex 500mg Injection	Tranexamic Acid	Ranbaxy Pharmaceuticals (Pty) Ltd	Sun Pharmaceutical Medicare Limited (SPML), Survey No. 22 and 24, Village: Ujeti, Post: Baska, Halol 389 350, District Panchmahal, Gujarat, India	23/8.1/0009

9.	Inbec	Abacavir, Dolutegravir, Lamivudine	Emcure Pharmaceuticals Ltd	Emcure Pharmaceuticals Limited., Plot No. P-1, P-2, I.T.B.T. Park Phase-II, MIDC, Hiniwadi, Pune, Maharashtra, 411057, INDIA	23/20.2.8/0010
10.	Olegra 50mg	Dolutegravir Sodium	Aurobindo Pharma Limited	M/s Aurobindo Pharma Limited, Unit –VII, SEZ, TSIC, Plot No. SI, Survey No. 411/P, 425/P, 434/P, 435/P and 458/P, Green Industrial Park, Polepally Village, Jedcherla Mandal, Mahaboob Nagar District, Telangana State, INDIA, Zip Code – 509 302	23/20.2.8/0011
11.	Kyleena®	Levonorgestrel	Bayer (Pty) Ltd	Bayer Oy Pansiontie 47 FIN-20210 TURKU, Finland	23/32.9/0012
12.	Phesgo FDC 600/600	Pertuzumab, Trastuzumab	Roche Products (Pty) Ltd	F. Hoffmann-La Roche Ltd Wurmisweg, 4303 Kaiseraugst Switzerland	23/26/0013
13.	Phesgo FDC 1 200/600	Pertuzumab, Trastuzumab	Roche Products (Pty) Ltd	F. Hoffmann-La Roche Ltd Wurmisweg, 4303 Kaiseraugst Switzerland	23/26/0014
14.	Zee Suspension	Azithromycin Dihydrate	Innovata Pharmaceuticals Ltd	World Medicine İlaç San. ve Tic. A.Ş. Evren Mah. Camiyolu Cad. No:50 K:3 34212 Güneşli – Bağcılar, İstanbul, Turkey	23/20.1.1/0015
15.	Postpil	Levonorgestrel	Cospharm Investments Cc	Naaril Pharma Private Limited, Plot No 14-16 and 55-57 Sector-5, IIE, Pantnagar, Rudrapur-263153, Dist. Udham Singh Nagar, Uttarakhand, India	23/18.8/0016
16.	Triclofem 150mg/ml	Medroxyprogesterone Acetate	Ascendis Pharma (Pty) Ltd	PT Tunggal Idaman Abdi Hormonal Plant 2 Jl. Jend. Ahmad Yani No. 7, Jakarta Timur 13230 Indonesia	23/21.8.2/0019
17.	Lampremine	Clofazimine	Fortunda Int'l Mfg Limited	Dong-A ST Co., Ltd. Cheonan Plant Address : 200-23, Baekseokgongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Korea (2F Section B, 3F, 4F Section B)	23/20.2.3/0020
18.	Closerin	Cycloserine	Fortunda Int'l Mfg Limited	Dong-A ST Co., Ltd., 200-23, Baekseokgongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea (2/F Section B, 3/F, 4/F Section B)	23/20.2.3/0021

19.	Sumabid 100 IV	Sugammadex	Ranbaxy Pharmaceuticals (Pty) Ltd	Wasserburger Arzneimittelwerk GmbH, Herderstrasse 2, Burgerfeld, 83512 Wasserburg a. Inn, Bavaria, Germany	23/32.2/0022
20.	Abacavir Sulfate/ Lamivudine Dispersible Tablets 120mg /60mg	Abacavir Sulfate, Lamivudine	Mylan Laboratories Limited	Mylan Laboratories Limited, F-4 and F-12, Malegaon MIDC, Sinnar, Nashik -422113, Maharashtra, India	23/20.2.8/0023
21.	Abacavir Sulfate/ Lamivudine Dispersible Tablets 60mg /30mg	Abacavir Sulfate, Lamivudine	Mylan Laboratories Limited	Mylan Laboratories Limited, F-4 and F-12, Malegaon MIDC, Sinnar, Nashik -422113, Maharashtra, India	23/20.2.8/0024
22.	Zarzio 30 MU	Filgrastim	Sandoz Pharmaceuticals D.	Sandoz GmbH, Biochemiestrasse 10, A-6336 Langkampfen, Austria	23/32.2/0025
23.	Zarzio 48 MU	Filgrastim	Sandoz Pharmaceuticals D.	Sandoz GmbH, Biochemiestrasse 10, A-6336 Langkampfen, Austria	23/32.2/0026
24.	Tafnext-EM	Emtricitabine, Tenofovir Alafenamide	Hetero Labs Limited	Annora Pharma Private Limited Sy.No. 261, Annaram Village, Gummadidala Mandal, Sangareddy District-502313, Telangana, India	23/20.2.8/0027
25.	Rozlytrek® 200mg	Entrectinib	Roche Products (Pty) Ltd	Mayne Pharma Inc 1240 Sugg Parkway, Greenville NC 27834, USA	23/26/0028
26.	Rozlytrek® 100mg	Entrectinib	Roche Products (Pty) Ltd	Mayne Pharma Inc 1240 Sugg Parkway, Greenville NC 27834, USA	23/26/0029
27.	Dolutegravir Tablets 50mg	Dolutegravir	Shanghai Desano Bio-Pharmaceutical Co. Ltd	Shanghai Desano Bio-Pharmaceutical Co., Ltd. Block No.: 2 1479 Zhangheng Road, China (Shanghai) PilotFree Trade Zone Shanghai 201203, P.R.China	23/20.2.8/0031
28.	Clofazimine Tablets 50mg	Clofazimine	Macleods Pharmaceuticals Limited	Macleods Pharmaceuticals Limited, At, Oxalis Labs, Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101, India	23/20.2.3/0032
29.	Clofazimine Tablets 100mg	Clofazimine	Macleods Pharmaceuticals Limited	Macleods Pharmaceuticals Limited, At, Oxalis Labs, Village Theda, P.O Lodhimajra, Baddi, Distt. Solan, Himachal Pradesh, 174101, India	23/20.2.3/0033

30.	Smectago®	Diosmectite	Acino Pharma (Pty) Ltd	Beaufour Ipsen Industrie, Rue Ethé Virton, 28100 Dreux, France	23/8.7/0034
31.	Smecta® Strawberry	Diosmectite	Acino Pharma (Pty) Ltd	Beaufour Ipsen Industrie, Rue Ethé Virton, 28100 Dreux, France	23/8.7/0035
32.	Smecta® Orange/Vanilla	Diosmectite	Acino Pharma (Pty) Ltd	Beaufour Ipsen Industrie, Rue Ethé Virton, 28100 Dreux, France	23/8.7/0036
33.	Bovi-Shield Gold FP 5	Bovine Rhinotracheitis Virus, Bovine Virus Diarrhoea Type 1, Bovine Virus Diarrhoea Type 2, Parainfluenza 3 Virus, Bovine Respiratory Syncytial Virus	Zoetis S.A (Pty) Ltd	Zoetis Inc. 601 West Cornhusker Highway, Lincoln, Nebraska 698521, USA	V22/24.4/1511
34.	Cytopoint 10mg	Lokivetmab	Zoetis S.A (Pty) Ltd	Zoetis Belgium SA Rue Laid Burniat 1, Louvain-la-Neuve, 1348, Belgium	V22/24.9/1512
35.	Cytopoint 20mg	Lokivetmab	Zoetis S.A (Pty) Ltd	Zoetis Belgium SA Rue Laid Burniat 1, Louvain-la-Neuve, 1348, Belgium	V22/24.9/1513
36.	Cytopoint 30mg	Lokivetmab	Zoetis S.A (Pty) Ltd	Zoetis Belgium SA Rue Laid Burniat 1, Louvain-la-Neuve, 1348, Belgium	V22/24.9/1514
37.	Cytopoint 40mg	Lokivetmab	Zoetis S.A (Pty) Ltd	Zoetis Belgium SA Rue Laid Burniat 1, Louvain-la-Neuve, 1348, Belgium	V22/24.9/1515
38.	Inforce 3	Bovine Rhinotracheitis Virus, Bovine Parainfluenza 3 Virus, Bovine Respiratory Syncytial Virus	Zoetis S.A (Pty) Ltd	Zoetis Inc. 601 West Cornhusker Highway, Lincoln, Nebraska 698521, USA	V22/24.4/1516
39.	Rimifen 100	Carprofen	Intervet S.A	Chanelle Pharmaceuticals Manufacturing Ltd, Dublin Road, Loughrea, Co. Galway, Ireland	V22/3.1.2.3/1517
40.	Rimifen 20	Carprofen	Intervet S.A	Chanelle Pharmaceuticals Manufacturing Ltd, Dublin Road, Loughrea, Co. Galway, Ireland	V23/3.1.2.3/1518

As required under section 23(a)(iv) of the Act, the medicines of which the 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 Organization;
 - (b) In order to assess compliance with paragraph (a) above, inspections and investigations may be carried out regularly by inspectors authorized 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 verified 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 may determine the intervals when such review will take place.
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