



# GOVERNMENT GAZETTE

## OF THE

# REPUBLIC OF NAMIBIA

---

N\$6.00

WINDHOEK - 18 July 2019

No. 6956

---

### CONTENTS

*Page*

#### GOVERNMENT NOTICES

No. 200	Notification of cancellation of registration of certain medicines: Medicines and Related Substances Control Act, 2003 .....	1
No. 201	Notification of registration of certain medicines: Medicines and Related Substances Control Act, 2003	3

---

## Government Notices

---

### MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 200

2019

#### 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.

**J. GAESEB**  
**REGISTRAR OF MEDICINES**

Windhoek, 4 July 2019

## SCHEDULE

S/N	Applicant	Registered Name	Approved name of active(s)	Registration Number
1	MSD (Pty) Ltd	Intron A (HAS-Free) Redipen 3 million I.U.	Interferon Alfa-2b	05/34/0108
2	MSD (Pty) Ltd	Intron A (HAS-Free) Redipen 5 million I.U.	Interferon Alfa-2b	05/34/0109
3	Roche Products (Pty) Ltd	Pegasy 135mcg	peginterferon alfa-2a	10/26/0613
4	Ranbaxy (SA) (Pty) Ltd	Diolo 80	Valsartan	10/7.1.3/0640
5	Ranbaxy (SA) (Pty) Ltd	Diolo 160	Valsartan	10/7.1.3/0641
6	Ranbaxy (SA) (Pty) Ltd	Diolo Co 80	Valsartan, Hydrochlorothiazide	11/7.1.3/0092
7	Ranbaxy (SA) (Pty) Ltd	Diolo Co 160	Valsartan, Hydrochlorothiazide	11/7.1.3/0093
8	Ranbaxy (SA) (Pty) Ltd	Candagen 8	Candesartan	10/7.1.3/0458
9	Ranbaxy (SA) (Pty) Ltd	Candagen 16	Candesartan	10/7.1.3/0459
10	Ranbaxy (SA) (Pty) Ltd	Lohype 25	Losartan	10/7.1.3/0135
11	Ranbaxy (SA) (Pty) Ltd	Lohype 50	Losartan	10/7.1.3/0136
12	Ranbaxy (SA) (Pty) Ltd	Lohype 100	Losartan	10/7.1.3/0137
13	Ranbaxy (SA) (Pty) Ltd	Lohype Plus	Losartan, Hydrochlorothiazide	10/7.1.3/0138
14	Ranbaxy (SA) (Pty) Ltd	Lohype Forte Plus	Losartan, Hydrochlorothiazide	10/7.1.3/0139
15	Pharma Dynamics (Pty) Ltd	Dynafloc 250	Ciprofloxacin	04/20.1.1/1653
16	Pharma Dynamics (Pty) Ltd	Dynafloc 750	Ciprofloxacin	04/20.1.1/1655
17	Novartis South Africa (Pty) Ltd	Afinitor 2.5 mg tablet	Everolimus	14/26/0653
18	Novartis South Africa (Pty) Ltd	Trileptal Oral Suspension 60mg/ml	Oxcarbazepine	07/2.5/0014
19	Novartis South Africa (Pty) Ltd	Lamisil 125 mg	Terbinafine Hydrochloride	04/20.2.2/0565
20	Novartis South Africa (Pty) Ltd	Lamisil 250 mg	Terbinafine Hydrochloride	04/20.2.2/0566
21	Abbvie (Pty) Ltd	Ethrane	Enflurane	90/2.1/0058
22	Ingelheim Pharmaceuticals (Pty) Ltd	Jentadueto 2,5/500mg tablets	Linagliptin, Metformin Hydrochloride	12/21.2/0269
23	Ingelheim Pharmaceuticals (Pty) Ltd	Jentadueto 2,5/850mg tablets	Linagliptin, Metformin Hydrochloride	12/21.2/0270
24	Ingelheim Pharmaceuticals (Pty) Ltd	Jentadueto 2,5/1000mg tablets	Linagliptin, Metformin Hydrochloride	12/21.2/0271

**MINISTRY OF HEALTH AND SOCIAL SERVICES**

No. 201

2019

**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 the 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 Namibia Medicines Regulatory Council (hereafter referred to as “the Council”);
- (b) inspections and investigations may be carried out regularly by inspectors authorised in terms of sections 35 of the Act, in order to assess compliance with existing good manufacturing practices;
- (c) the applicant must 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 applicant 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; and
- (g) the Council may review the registration dossier and may determine the intervals when the reviews will take place.

**J. GAESEB**  
**REGISTRAR OF MEDICINES**

Windhoek, 4 July 2019

## SCHEDULE

S/N	Applicant	Proprietary Name	Approved Name Of Active(S)	Dosage Form	Strength/Dose Unit	Registration Number	Registration Date	Sched. Status
1	Trinity Pharma SA (Pty) Ltd	Clamentrin 5ml Powder for Oral Suspension	Amoxicillin + Clavulanic acid	Powder for Oral Suspension	Each 5ml suspension contains amoxicillin trihydrate equivalent to 600 mg amoxicillin and potassium clavulanate equivalent to 42.9 mg clavulanic acid	19/20.1.1/0045	09.05.2019	NS2
2	Unosource Pharma Ltd	Tradmin	Tramadol Hydrochloride	Solution for Injection or Infusion	Each ml contains Tramadol hydrochloride 50mg	19/2.9/0046	09.05.2019	NS3
3	Merck (Pty) Ltd	Euthyrox 75mcg	Levothyroxine sodium	Tablet	Each tablet contains Levothyroxine sodium 75 mcg	19/21.3/0047	09.05.2019	NS2
4	Key Oncologies SA (Pty) Ltd	Dacin 100	Dacarbazine	Powder for injection	Each vial contains Dacarbazine 100mg	19/26/0048	09.05.2019	NS2
5	Key Oncologies SA (Pty) Ltd	Dacin 200	Dacarbazine	Powder for injection	Each vial contains Dacarbazine 200mg	19/26/0049	09.05.2019	NS2
6	Svizera Europe BV	Rifampicin 150mg/ Isoniazid 75mg Tablets	Rifampicin, Isoniazid	Film-coated tablets	Each film-coated tablet contains Rifampicin 150mg and Isoniazid 75mg	19/20.2.3/0050	09.05.2019	NS2
7	Svizera Europe BV	Ethambutol hydrochloride 275mg/ Isoniazid 75mg/ Rifampicin 150mg	Ethambutol hydrochloride, Isoniazid, Rifampicin	Film-coated tablets	Each film-coated tablet contains Rifampicin 150mg, Ethambutol 275mg and Isoniazid 75mg	19/20.2.3/0051	09.05.2019	NS2
8	Bliss GVS	Anomex	Hydrocortisone acetate, lidocaine, zinc oxide, allantoin	Suppositories	Each suppository contains; Hydrocortisone Acetate BP 0.25%; Lidocaine USP 3,0%; Zinc Oxide USP 5%; Allantoin BP 0.5%	19/13.4.1/0052	09.05.2019	NS1
9	Ingelheim Pharmaceuticals (Pty) Ltd	Praxbind	Idarucizumab	Solution for infusion	One vial of 50 mL contains Idarucizumab 2,5 g	19/30.1/0053	09.05.2019	NS2

10	Cipla Medpro SA (Pty) Ltd	Purgolene	Macrogol (PEG) 3350, Sodium bicarbonate, Sodium chloride, Potassium chloride	Powder for oral solution	Each 13.8 g sachet contains Macrogol (PEG) 3350 13.125 g, Sodium bicarbonate 178.5 mg, Sodium chloride 350.7 mg, Potassium chloride 46.6 mg	19/11.5/0054	09.05.2019	NS0
11	Trinity Pharma SA (Pty) Ltd	Aciclovir Trinity Topical Cream	Aciclovir	Cream	Each gram of topical cream contains aciclovir 50 mg	19/20.2.8/0055	09.05.2019	NS2
12	Rusan Pharma Ltd	Rusamin 500	Metformin hydrochloride	Tablet	Each tablet contains Metformin 500mg	19/21.2/0056	09.05.2019	NS2
13	Rusan Pharma Ltd	Rusamin 850	Metformin hydrochloride	Tablet	Each tablet contains Metformin 850mg	19/21.2/0057	09.05.2019	NS2
14	Varichem Pharmaceuticals (PVT) Ltd	Corilief Tablets	Paracetamol, Diphenhydramine HCl, Pseudoephedrine HCl	Tablet	Each tablet contains Paracetamol 500mg, Diphenhydramine HCl 12.5 mg and Pseudoephedrine HCl 22.5 mg	19/5.8/0058	09.05.2019	NS1
15	Novartis SA (Pty) Ltd	Cosentyx 150 mg/ml Solution for Injection	Secukinumab	Pre-filled syringe+Autoinjector (pen)	Each ml contains Secukinumab 150 mg	19/30.1/0059	09.05.2019	NS2
16	Roche Products (Pty) Ltd	Tarceva 100 mg FCT	Erlotinib	Tablet	Each tablet contains Erlotinib 100mg	19/26/0060	09.05.2019	NS2
17	Roche Products (Pty) Ltd	Tarceva 150 mg FCT	Erlotinib	Tablet	Each tablet contains Erlotinib 150mg	19/26/0061	09.05.2019	NS2
18	Astellas Pharma (Pty) Ltd	Betmiga 25 mg prolonged release tablets	Mirabegron	Prolonged release tablets	Each prolonged release tablets contains Mirabegron 25 mg	19/32.2/0062	09.05.2019	NS2
19	Astellas Pharma (Pty) Ltd	Betmiga 50 mg prolonged release tablets	Mirabegron	Prolonged release tablets	Each prolonged release tablets contains Mirabegron 50 mg	19/32.2/0063	09.05.2019	NS2
20	Cipla Medpro (Pty) Ltd	Imavec 400	Imatinib mesylate	Capsule	Each capsule contains Imatinib mesylate equivalent to imatinib 400 mg	19/26/0064	09.05.2019	NS2
21	FDC Limited	Iobrim Eye Drops	Brimonidine Tartrate	Eye Drops	Brimonidine Tartrate 0.2% w/w	19/15.4/0065	09.05.2019	NS2
22	Varichem Pharmaceuticals (PVT) Ltd	Cipyne	Paracetamol, Ibuprofen, Codeine Sulphate	Capsules	Each Capsule contains Paracetamol 250mg, Ibuprofen 200mg and Codeine Sulphate 10mg	19/2.9/0066	09.05.2019	NS2

23	Varichem Pharmaceuticals (PVT) Ltd	Neutragerl	Dried Aluminium Hydroxide/ Magnesium Hydroxide/ Simethicone	Suspension	Each 10ml contains Dried Aluminium Hydroxide 400mg, Magnesium Hydroxide 318.4mg and Simethicone 50mg	19/11.4.1/0067	09.05.2019	NS0
24	Cospharm Investment CC	Refpain Plain	Aceclofenac	Film Coated Tablets	Each Film Coated Tablet Contains Aceclofenac 100mg	19/2.8/0068	09.05.2019	NS2
25	Galentic Pharma Pvt Ltd	Metacaine 2% Jelly (lignocaine Hydrochloride Jelly USP)	Lignocaine Hydrochloride Jelly	Jelly	Each 1g Contains Lignocaine Hydrochloride Jelly USP 20mg	19/13.3/0069	09.05.2019	NS1
26	Galentic Pharma (India) Pvt Ltd	Sofudac Cream	Fusidic Acid Cream BP 2%	Cream	Each 1g Contains Fusidic Acid BP 20mg	19/20.1.6/0070	09.05.2019	NS2
27	Trinity Pharma (Pty) Ltd	Zita Suspension	Azithromycin Dihydrate	Powder for oral suspension	Each 5ml contains Azithromycin Anhydrous 200mg	19/20.1.1/0071	09.05.2019	NS2
28	AstraZeneca Pharmaceuticals (Pty) Limited	Faslodex	Fulvestrant	Injection	Each pre-filled syringe contains 250 mg/5 ml	19/21.12/0072	09.05.2019	NS2
29	Blue Med Laboratories	Tramavescent	Tramadol Hydrochloride, Paracetamol	Effervescent Tablets	Each tablet Contains Tramadol 37.5mg, Paracetamol 325mg	19/2.9/0073	09.05.2019	NS3
30	Pharma Dynamics (Pty) Ltd.	TAMOLTRA	Tramadol hydrochloride, Paracetamol	Tablets	Each tablet contains tramadol hydrochlorid 37,5 mg and paracetamol 325 mg	19/2.9/0074	09.05.2019	NS3
31	Varichem Pharmaceuticals	Amlovar 5mg	Amlodipine Besylate	Tablets	Each tablets contains Amlodipine Besylate 5mg	19/7.1/0075	09.05.2019	NS2
32	Varichem Pharmaceuticals	Amlovar 10mg	Amlodipine Besylate	Tablets	Each tablets contains Amlodipine Besylate 10mg	19/7.1/0076	09.05.2019	NS2
33	Mylan Laboratories Limited	ALLTERA 50	Lopinavir, Ritonavir	Oral Granules	Each sachet contains Lopinavir 40 mg and Ritonavir 10 mg	19/20.2.8/0077	09.05.2019	NS2
34	GlaxoSmithKline South Africa (Pty) Limited	Tivicay 10mg	Dolutegravir sodium	Film-coated tablets	Each film-coated tablet contains Dolutegravir 10mg	19/20.2.8/0078	09.05.2019	NS2
35	GlaxoSmithKline South Africa (Pty) Limited	Tivicay 25mg	Dolutegravir sodium	Film-coated tablets	Each film-coated tablet contains Dolutegravir 25mg	19/20.2.8/0079	09.05.2019	NS2

36	MSN Laboratories Private Limited	Cosamide 50mg	Lacosamide	Film-coated tablets	Each film-coated tablet contains Lacosamide 50mg	19/2.6/0080	09.05.2019	NS2
37	MSN Laboratories Private Limited	Cosamide 100mg	Lacosamide	Film-coated tablets	Each film-coated tablet contains Lacosamide 100mg	19/2.6/0081	09.05.2019	NS2
38	N2SA Limited	Amlodipine (as Besylate) Tablet USP 10mg	Amlodipine Besylate	Uncoated Tablet	Each uncoated tablet contains Amlodipine Besylate 10mg	19/7.1/0082	09.05.2019	NS2
39	Ranbaxy (SA) (Pty) Ltd	Atolip Cryst 10	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 10mg	19/7.5/0083	09.05.2019	NS2
40	Ranbaxy (SA) (Pty) Ltd	Atolip Cryst 20	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 20mg	19/7.5/0084	09.05.2019	NS2
41	Ranbaxy (SA) (Pty) Ltd	Atolip Cryst 40	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 40mg	19/7.5/0085	09.05.2019	NS2
42	Ranbaxy (SA) (Pty) Ltd	Atolip Cryst 80	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 80mg	19/7.5/0086	09.05.2019	NS2
43	Ranbaxy (SA) (Pty) Ltd	Lipogen cryst 10	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 10mg	19/7.5/0087	09.05.2019	NS2
44	Ranbaxy (SA) (Pty) Ltd	Lipogen cryst 20	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 20mg	19/7.5/0088	09.05.2019	NS2
45	Ranbaxy (SA) (Pty) Ltd	Lipogen cryst 40	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 40mg	19/7.5/0089	09.05.2019	NS2
46	Ranbaxy (SA) (Pty) Ltd	Lipogen cryst 80	Atorvastatin calcium trihydrate	Film-coated tablets	Each film coated tablet contains Atorvastatin calcium trihydrate equivalent to Atorvastatin 80mg	19/7.5/0090	09.05.2019	NS2