

## DEPARTMENT OF HEALTH

NO. R. 1739

11 February 2022

**NOTIFICATION OF REGISTRATION OF MEDICINES IN TERMS OF SECTION 17 OF THE MEDICINES  
AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965) AS AMENDED**

Registration number	Date issued	Product name	Dosage form	Applicant	API	Conditions of Registration
54/11.4.3/0021	2021/10/05	LOKIT OTC	CAPSULE	TEVA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS OMEPRAZOLE 20,0 mg	Annexure A
54/20.1.7/0024	2021/10/05	MYCANDIN 50	INFUSION	TEVA PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS MICAFUNGIN SODIUM 50,0 mg	Annexure A
54/20.1.7/0025	2021/10/05	MYCANDIN 100	INFUSION	TEVA PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS MICAFUNGIN SODIUM 100,0 mg	Annexure A
11/1.4.3/06	2021/10/05	ANTIPAM	INJECTION	CIPLA MEDPRO (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS ATIPAMEZOLE HYDROCHLORIDE 5,0 mg	Annexure A
19/1.2/21	2021/10/05	ALFAXAN MULTIDOSE 10 mg/ml	INJECTION	AFRIVET BUSINESS MANAGEMENT (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS ALFAXALONE 10,0 mg	Annexure A
55/26/0423	2021/10/12	TANICEP 150	TABLET	HETERO DRUGS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS CAPECITABINE 150,0 mg	Annexure A
55/26/0424.423	2021/10/12	BINECAP 150	TABLET	HETERO DRUGS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS CAPECITABINE 150,0 mg	Annexure A
55/26/0425.423	2021/10/12	CAPTERO	TABLET	HETERO DRUGS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS CAPECITABINE 150,0 mg	Annexure A
54/11.4.3/0022	2021/10/12	LOKIT DR 20	CAPSULE	TEVA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS OMEPRAZOLE 20,0 mg	Annexure A
54/11.4.3/0023	2021/10/12	LOKIT DR 40	CAPSULE	TEVA PHARMACEUTICALS (PTY) LTD	EACH CAPSULE CONTAINS OMEPRAZOLE 40,0 mg	Annexure A
54/10.2.1/0867	2021/10/12	ATECTURA BREEZHALER 150/80	POWDER FOR INHALATION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 80,0 ug	Annexure A
54/10.2.1/0868	2021/10/12	ATECTURA BREEZHALER 150/160	POWDER FOR INHALATION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 160,0 ug	Annexure A
54/10.2.1/0869	2021/10/12	ATECTURA BREEZHALER 150/320	POWDER FOR INHALATION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 320,0 ug	Annexure A



54/10.2.1/0870.867	2021/10/12	BEMRIST BREEZHALER 150/80	POWDER FOR INHALATION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 80,0 ug	Annexure A
54/10.2.1/0871.868	2021/10/12	BEMRIST BREEZHALER 150/160	POWDER FOR INHALATION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 160,0 ug	Annexure A
54/10.2.1/0872.869	2021/10/12	BEMRIST BREEZHALER 150/320	POWDER FOR INHALATION	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS INDACATEROL ACETATE EQUIVALENT TO INDACATEROL 150,0 ug MOMETASONE FUROATE 320,0 ug	Annexure A
12/17.1.1.2/08	2021/10/12	CEVAXEL RTU	INJECTION	CEVA ANIMAL HEALTH (PTY) LTD	EACH 1,0 ml SUSPENSION CONTAINS CETIOFUR HYDROCHLORIDE 50,0 mg	Annexure A
19/26//25	2021/10/12	FORCYL16 % SOLUTION FOR INJECTION	INJECTION	AFRIVET BUSINESS MANAGEMENT (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS MARBOFLOXACIN 160,0 mg	Annexure A
19/17.1.4/20	2021/10/19	TULLISIN 100	INJECTION	VIRBAC RSA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS TULATHROMYCIN 100,0 mg	Annexure A
53/26/0564	2021/10/19	ALILOMA 100	INFUSION	KAHMA BIOTECH (PTY) LTD	EACH VIAL CONTAINS PEMTREXED SODIUM EQUIVALENT TO PEMTREXED 100,0 mg	Annexure A
53/26/0565	2021/10/19	ALILOMA 500	INFUSION	KAHMA BIOTECH (PTY) LTD	EACH VIAL CONTAINS PEMTREXED SODIUM EQUIVALENT TO PEMTREXED 500,0 mg	Annexure A
55/26/0115	2021/10/26	GEFIRIX	TABLET	EUROLAB (PTY) LTD	EACH TABLET CONTAINS GEFITINIB 250,0 mg	Annexure A
16/1.3.1/11	2021/10/26	TORBUGESIC 1 %	INJECTION	ZOETIS SOUTH AFRICA (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS BUTORPHANOL TARTRATE EQUIVALENT TO BUTORPHANOL 10,0 mg	Annexure A
17/11.4/07	2021/11/02	SYNCRAPART PMSG 6 000 IU	INJECTION	CEVA ANIMAL HEALTH (PTY) LTD	EACH VIAL CONTAINS GONADOTROPHIN (PREGNANT MARE SERUM) 6 000,0 IU	Annexure A
54/30.1/0711	2021/11/02	AUOVY	INJECTION	TEVA PHARMACEUTICALS (PTY) LTD	EACH SYRINGE OR PEN CONTAINS FREMANEZUMAB 225,0 mg	Annexure A
54/30.1/0712.711	2021/11/02	FREMANEZUMAB TEVA	INJECTION	TEVA PHARMACEUTICALS (PTY) LTD	EACH SYRINGE OR PEN CONTAINS FREMANEZUMAB 225,0 mg	Annexure A
54/2.9/0839	2021/11/09	METHADONE ADCO 10 mg	SOLUTION	ADCOCK INGRAM CRITICAL CARE (PTY) LTD	EACH 1,0 ml SOLUTION CONTAINS METHADONE HYDROCHLORIDE 10,0 mg	Annexure A
55/2.9.0741	2021/11/09	MISYO 10 mg/ml	SOLUTION	UMSEBE HEALTHCARE	EACH 1,0 ml SOLUTION CONTAINS METHADONE HYDROCHLORIDE 10,0 mg	Annexure A



55/20.2.8/0301	2021/11/09	DALIDUO	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg RILPIVIRINE HYDROCHLORIDE 25,0 mg	Annexure A
55/20.2.8/0302.301	2021/11/09	DALIVINE	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DOLUTEGRAVIR SODIUM 50,0 mg RILPIVIRINE HYDROCHLORIDE 25,0 mg	Annexure A
55/6.1/0352	2021/11/09	HYPOPRESS 0,1 mg/ml	INJECTION	UMSEBE HEALTHCARE	EACH 1,0 ml SOLUTION CONTAINS PHENYLEPHRINE HYDROCHLORIDE 0,1 mg	Annexure A
55/6.1/0353	2021/11/09	HYPOPRESS 10 mg/ml	INJECTION	UMSEBE HEALTHCARE	EACH 1,0 ml SOLUTION CONTAINS PHENYLEPHRINE HYDROCHLORIDE 10,0 mg	Annexure A
55/26/0174	2021/11/16	DIZALET	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ENZALUTAMIDE 40,0 mg	Annexure A
55/26/0175.174	2021/11/16	DIZALUM	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ENZALUTAMIDE 40,0 mg	Annexure A
55/26/0176.174	2021/11/16	ZILADE	CAPSULES	AUROGEN SOUTH AFRICA (PTY) LTD	EACH CAPSULE CONTAINS ENZALUTAMIDE 40,0 mg	Annexure A
19/3.2.2/22	2021/11/30	GALLIPRANT 20 mg	TABLET	ELI LILLY (SA) (PTY) LTD	EACH TABLET CONTAINS GRAPIPRANT 20,0 mg	Annexure A
19/3.2.2/23	2021/11/30	GALLIPRANT 60 mg	TABLET	ELI LILLY (SA) (PTY) LTD	EACH TABLET CONTAINS GRAPIPRANT 60,0 mg	Annexure A
19/3.2.2/24	2021/11/30	GALLIPRANT 100 mg	TABLET	ELI LILLY (SA) (PTY) LTD	EACH TABLET CONTAINS GRAPIPRANT 20,0 mg	Annexure A
55/20.1.1/0075	2021/11/30	CLARICULE	INJECTION	RUBY PHARMACEUTICALS (PTY) LTD	EACH VIAL CONTAINS CLARITHROMYCIN 500,0 mg	Annexure A
55/20.2.8/0079	2021/11/30	PRIPREMA	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS EMTRICITABINE 200,0 mg TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
55/20.2.8/0080.079	2021/11/30	TAFBIN	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS EMTRICITABINE 200,0 mg TENOFOVIR ALAFENAMIDE 25,0 mg	Annexure A
55/26/0290	2021/11/30	PIVIKTO 50 mg	TABLET	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS ALPESIB 50,0 mg	Annexure A
55/26/0291	2021/11/30	PIVIKTO 150 mg	TABLET	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS ALPESIB 150,0 mg	Annexure A
55/26/0292	2021/11/30	PIVIKTO 200 mg	TABLET	NOVARTIS SOUTH AFRICA (PTY) LTD	EACH TABLET CONTAINS ALPESIB 200,0 mg	Annexure A
54/26/0736	2021/11/30	BLINCYTO	INFUSION	AMGEN SOUTH AFRICA (PTY) LTD	EACH VIAL CONTAINS BLINATUMOMAB 38,5 ug	Annexure A
53/27/0576	2021/12/07	NUJADE 90 mg	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DEFERASIROX 90,0 mg	Annexure A
53/27/0577	2021/12/07	NUJADE 180 mg	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DEFERASIROX 180,0 mg	Annexure A
53/27/0578	2021/12/07	NUJADE 360 mg	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DEFERASIROX 360,0 mg	Annexure A



53/27/0579.576	2021/12/07	DEFERASIROX 90 mg CIPLA	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DEFERASIROX 90,0 mg	Annexure A
53/27/0580.577	2021/12/07	DEFERASIROX 180 mg CIPLA	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DEFERASIROX 180,0 mg	Annexure A
53/27/0581.578	2021/12/07	DEFERASIROX 360 mg CIPLA	TABLET	CIPLA MEDPRO (PTY) LTD	EACH TABLET CONTAINS DEFERASIROX 360,0 mg	Annexure A
54/20.2.2/0748	2021/12/07	FLUCYTOSINE MYLAN 250 mg	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS FLUCYTOSINE 250,0 mg	Annexure A
54/20.2.2/0749	2021/12/07	FLUCYTOSINE MYLAN 500 mg	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS FLUCYTOSINE 500,0 mg	Annexure A
54/20.2.2/0750.748	2021/12/07	CANDOBON 250 mg	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS FLUCYTOSINE 250,0 mg	Annexure A
54/20.2.2/0751.749	2021/12/07	CANDOBON 500 mg	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS FLUCYTOSINE 500,0 mg	Annexure A
54/20.2.2/0752.748	2021/12/07	ANCOMYL 250 mg	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS FLUCYTOSINE 250,0 mg	Annexure A
54/20.2.2/0753.749	2021/12/07	ANCOMYL 500 mg	TABLET	MYLAN (PTY) LTD	EACH TABLET CONTAINS FLUCYTOSINE 500,0 mg	Annexure A
55/20.2.8/0350	2021/12/07	PREPETAM	TABLET	AUSTELL PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS EMTRICITABINE 200,0 mg TENOFOVIR DISOPROXIL FUMARATE 300,0 mg	Annexure A
55/5.7.1/0293	2021/12/07	RAZTROL	TABLET	RANBAXY PHARMACEUTICALS (PTY) LTD	EACH TABLET CONTAINS RUPATADINE 10,0 mg	Annexure A
54/20.2.3/0648	2021/12/14	AKURIT KID 75/50 ODT	TABLET	PHARMA DYNAMICS (PTY) LTD	EACH TABLET CONTAINS ISONIAZID 50,0 mg RIFAMPICIN 75,0 mg	Annexure A

## ANNEXURE A

### CONDITIONS OF REGISTRATIONS

1. The applicant shall ensure that the medicine is manufactured and controlled in terms of current Good Manufacturing Practices as determined by SAHPRA.
2. The manufacture of this medicine is subject to regular investigation and inspections by the inspectors appointed in terms of Section 26 of the Act, to assess compliance with current Good Manufacturing Practices.
3. The information in the professional information shall be updated on a regular basis to conform to the professional information recently approved by SAHPRA.
4. The applicant must comply with all the legal requirements of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended.
5. The registration of this medicine shall be subject to review at intervals as determined by SAHPRA regarding its quality, safety and efficacy, and the registration of this medicine may be varied subject to issues SAHPRA may deem fit.
6. The first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration, and the validation report must be submitted within a month after completion of the validation.
7. The product may be advertised to the professions only.