

# MEDICINES CONTROL COUNCIL



## NOTIFICATION OF REGISTRATION OF MEDICINES BY THE REGISTRAR IN TERMS OF SECTION 17 OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT 101 OF 1965

Application Number	Holder of registration of Certificate	Proprietary Name	Active Compound
00/21.1/7	NORBROOK LABORATORIES S.A. (PTY) LTD	NOROCLAV INJECTION	EACH 1,0 ml SUSPENSION CONTAINS AMOXYCILLIN TRIHYDRATE, EQUIVALENT TO AMOXYCILLIN 140,0 mg POTASSIUM CLAVULANATE, EQUIVALENT TO CLAVULANIC ACID 35,0 mg
00/21.9/5	PFIZER LABORATORIES (PTY) LTD	ADVOCIN 180	EACH 1,0 ml SOLUTION CONTAINS DANOFLOXACIN, 180,0 mg
34/1.2/0129	RANBAXY (SA) (PTY) LTD	RANFLOCS 20 CAPSULES	EACH CAPSULE CONTAINS FLUOXETINE HYDROCHLORIDE, EQUIVALENT TO FLUOXETINE 20,0 mg
34/20.1.1/0348	RANBAXY (SA) (PTY) LTD	CEROXIM 125 TABLETS	EACH TABLET CONTAINS CEFUROXIME AXETIL, EQUIVALENT TO CEFUROXIME 125,0 mg
34/20.1.1/0349	RANBAXY (SA) (PTY) LTD	CEROXIM 250 TABLETS	EACH TABLET CONTAINS CEFUROXIME AXETIL, EQUIVALENT TO CEFUROXIME 250,0 mg
34/20.1.1/0350	RANBAXY (SA) (PTY) LTD	CEROXIM 500 TABLETS	EACH TABLET CONTAINS CEFUROXIME AXETIL, EQUIVALENT TO CEFUROXIME 500,0 mg
34/20.1.1/0351	RANBAXY (SA) (PTY) LTD	MAGNASPOR 125 TABLETS	EACH TABLET CONTAINS CEFUROXIME AXETIL, EQUIVALENT TO CEFUROXIME 125,0 mg
34/20.1.1/0352	RANBAXY (SA) (PTY) LTD	MAGNASPOR 250 TABLETS	EACH TABLET CONTAINS CEFUROXIME AXETIL, EQUIVALENT TO CEFUROXIME 250,0 mg
34/20.1.1/0353	RANBAXY (SA) (PTY) LTD	MAGNASPOR 500 TABLETS	EACH TABLET CONTAINS CEFUROXIME AXETIL, EQUIVALENT TO CEFUROXIME 500,0 mg
34/34/0482	ADCOCK INGRAM LTD (CRITICAL)	PLATELET ADDITIVE SOLUTION (T-SOL)	EACH 500,0 ml SOLUTION CONTAINS SODIUM ACETATE,

## Administration

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	CARE)		4,080 g SODIUM CHLORIDE, 6,750 g SODIUM CITRATE, 2,940 g
34/7.1.3/0433	CIPLA-MEDPRO (PTY) LTD	CARLOC 12,5	EACH TABLET CONTAINS CARVEDILOL, 12,5 mg
35/1.2/0145	ADCOCK INGRAM LTD	ADCO- MOCLOBEMIDE 150 MG	EACH TABLET CONTAINS MOCLOBEMIDE, 150,0 mg
35/1.2/0146	ADCOCK INGRAM LTD	ADCO- MOCLOBEMIDE 300 MG	EACH TABLET CONTAINS MOCLOBEMIDE, 300,0 mg
35/10.2.2/0397	MSD (PTY) LTD	SINGULAIR 4 MG	EACH TABLET CONTAINS MONTELUKAST SODIUM, EQUIVALENT TO MONTELUKAST 4,0 mg
35/13.4.2/0375	PHARMAPLAN (PTY) LTD	ORATANE 10 MG	EACH CAPSULE CONTAINS ISOTRETINOIN, 10,0 mg
35/13.4.2/0376	PHARMAPLAN (PTY) LTD	ORATANE 20 MG	EACH CAPSULE CONTAINS ISOTRETINOIN, 20,0 mg
35/15.4/0088	SMITH & NEPHEW PHARMACEUTICALS (PTY) LTD	MINIMS PROXYMETACAINE HCL 0,5 %	EACH 0,5 ml SOLUTION CONTAINS PROXYMETACAINE HYDROCHLORIDE, 0,0025 g
35/15.4/0089	SMITH & NEPHEW PHARMACEUTICALS (PTY) LTD	MINIMS PROXYMETACAINE & FLUORESCEIN	EACH 0,5 ml SOLUTION CONTAINS FLUORESCEIN SODIUM, 0,00125 g PROXYMETACAINE HYDROCHLORIDE, 0,0025 g
35/15.4/0090	SMITH & NEPHEW PHARMACEUTICALS (PTY) LTD	MINIMS DEXAMETHASONE SODIUM PHOSPHATE 0, 1 %	EACH 0,5 ml SOLUTION CONTAINS DEXAMETHASONE SODIUM PHOSPHATE, 0,0005 g
35/16/0015	BOOTS HEALTHCARE (SOUTH AFRICA) (PTY) LTD	STREFEN	EACH LOZENGE CONTAINS FLURBIPROFEN, 8,75 mg
35/2.5/0099	WARNER-LAMBERT SA (PTY) LTD	NEURONTIN 600	EACH TABLET CONTAINS GABAPENTIN, 600,0 mg
35/2.5/0100	WARNER-LAMBERT SA (PTY) LTD	NEURONTIN 800	EACH TABLET CONTAINS GABAPENTIN, 800,0 mg
35/2.8/0167	GROUP LABORATORIES SA (PTY) LTD	GRAND-PA EFFERVESCENT HEADACHE POWDERS	EACH SACHET CONTAINS ASPIRIN, 453,60 mg CAFFEINE, 64,80 mg PARACETAMOL, 324,0 mg
35/21.10/0135	DONMED PHARMACEUTICALS (PTY) LTD	PUREGON 50 IU/0,5 ml	EACH 0,5 ml SOLUTION CONTAINS FOLLITROPIN BETA, 50,0 iu,
35/21.10/0136	DONMED PHARMACEUTICALS (PTY) LTD	PUREGON 100 IU/0,5 ML	EACH 0,5 ml SOLUTION CONTAINS FOLLITROPIN BETA, 100,0 iu
35/21.10/0137	DONMED PHARMACEUTICALS (PTY) LTD	PUREGON 150 IU/0,5 ML	EACH 0,5 ml SOLUTION CONTAINS FOLLITROPIN BETA, 150,0 iu
35/21.10/0138	DONMED PHARMACEUTICALS (PTY) LTD	PUREGON 200 IU/0,5 ml	EACH 0,5 ml SOLUTION CONTAINS FOLLITROPIN BETA, 200,0 iu
35/21.5.1/0404	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	SYMBICORD TURBUHALER 80:4,5 ug/DOSE	EACH DELIVERED DOSE CONTAINS BUDESONIDE, 160,0 ug FORMOTEROL FUMARATE, DIHYDRATE 4,5 ug
35/21.5.1/405	ASTRAZENECA PHARMACEUTICALS (PTY) LTD	SYMBICORD 5 ug/DOSE TURBUHALER 160:4	EACH DELIVERED DOSE CONTAINS BUDESONIDE, 160,0 ug FORMOTEROL FUMARATE, DIHYDRATE 4,5 ug

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35/30.1/0030	RHONE-POULENC RORER SA (PTY) LTD	FLUZONE-PASTEUR	EACH 0,5 ml SOLUTION CONTAINS INFLUENZA VIRUS A/BEIJING/535/95 (H1N1), 15,0 ug INFLUENZA VIRUS A/SYDNEY/5/97-LIKE (H3N2), 15,0 ug
35/30.1/0401	AVENTIS PHARMA (PTY) LTD	AVAXIM 80	EACH 0,5 ml SUSPENSION CONTAINS HEPATITIS A VIRUS, 80,0 antigen units
35/7.1.3/0209	RANBAXY (SA) (PTY) LTD	SINOPREN 5 TABLETS	EACH TABLET CONTAINS LISINOPRIL, 5,0 mg
35/7.1.3/0210	RANBAXY (SA) (PTY) LTD	SINOPREN 10 TABLETS	EACH TABLET CONTAINS LISINOPRIL, 10,0 mg
35/7.1.3/0211	RANBAXY (SA) (PTY) LTD	SINOPREN 20 TABLETS	EACH TABLET CONTAINS LISINOPRIL, 20 mg
36/1.2/0048	HEXAL PHARMA (SA) (PTY) LTD	MOCLOBEMIDE-HEXAL 150 mg	EACH TABLET CONTAINS MOCLOBEMIDE, 150,0 mg
36/1.2/0049	HEXAL PHARMA (SA) (PTY) LTD	MOCLOBEMIDE-HEXAL 300 mg	EACH TABLET CONTAINS MOCLOBEMIDE, 300,0 mg
36/1.2/0096	ADCOCK INGRAM LTD	ADCO-PAROXETINE 20 MG	EACH TABLET CONTAINS PAROXETINE, 20,0 mg
36/10.2.2/0287	ADCOCK INGRAM LTD	ADCO-SALBUTAMOL CLICKHALER	EACH INHALED DOSE CONTAINS SALBUTAMOL SULPHATE, EQUIVALENT TO SALBUTAMOL 90,0 ug
36/11.5/0104	GROUP LABORATORIES SA (PTY) LTD	BROOKLAX BISACODYL LAXATIVE PILLS	EACH TABLET CONTAINS BISACODYL, 5,0 mg
36/11.5/0239	MEDPRO PHARMACEUTICA (PTY) LTD	LAXETTE DRY - LEMON	EACH SACHET CONTAINS LACTULOSE, 10,0 g
36/11.5/0240	MEDPRO PHARMACEUTICA (PTY) LTD	LAXETTE DRY	EACH SACHET CONTAINS LACTULOSE, 10,0 g
36/2.5/0409	NOVARTIS SOUTH AFRICA (PTY) LTD	TRILEPTAL ORAL SUSPENSION	EACH 5,0 ml SOLUTION CONTAINS OXCARBAZEPINE, 300,0 mg
36/2.9/0119	PHARMACIA SOUTH AFRICA (PTY) LTD	RAYZON 20 MG IV/IM	EACH 1,0 ml SOLUTION CONTAINS PARECOXIB SODIUM, EQUIVALENT TO PARECOXIB 20,0 mg
36/2.9/0120	PHARMACIA SOUTH AFRICA (PTY) LTD	RAYZON 40 MG IV/IM	EACH 5,0 ml VIAL CONTAINS PARECOXIB SODIUM, EQUIVALENT TO PARECOXIB 40,0 mg
36/2.9/0199	ADCOCK INGRAM LTD	NOCTAGESIC TABLETS	EACH TABLET CONTAINS DIPHENHYDRAMINE HYDROCHLORIDE, 25,0 mg PARACETAMOL, 500,0 mg
36/20.1.1/0036	ELI LILLY (SA) (PTY) LTD	LILLY-CYCLOSERINE	EACH CAPSULE CONTAINS CYCLOSERINE, 250,0 mg
36/20.1.1/0170	HEXAL PHARMA (SA) (PTY) LTD	CIPRO-HEXAL 250	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE, EQUIVALENT TO CIPROFLOXACIN 250,0 mg,
36/20.1.1/0171	HEXAL PHARMA (SA) (PTY) LTD	CIPRO-HEXAL 500	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE, EQUIVALENT TO CIPROFLOXACIN 500,0 mg
36/20.1.1/0172	HEXAL PHARMA (SA) (PTY) LTD	CIPRO-HEXAL 750	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE, EQUIVALENT TO CIPROFLOXACIN 750,0 mg
36/20.1.1/0190	PFIZER LABORATORIES (PTY) LTD	ZITHROMAX IV	EACH TABLET CONTAINS CIPROFLOXACIN HYDROCHLORIDE, EQUIVALENT TO CIPROFLOXACIN 750,0 mg
36/20.2.2/0453	KEY ONCOLOGICS (PTY) LTD	AMBISOME	EACH VIAL CONTAINS AZITHROMYCIN DIHYDRATE, EQUIVALENT TO AZITHROMYCIN 500,0 mg
36/21.1/0074	AVENTIS PHARMA (PTY) LTD	INSUMAN RAPID (300 IU/3 ML)	EACH VIAL CONTAINS AMPHOTERICIN B, 50,0 mg

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36/21.1/0075	AVENTIS PHARMA (PTY) LTD	INSUMAN RAPID (500 IU/5 ML)	EACH 3,0 ml SOLUTION CONTAINS INSULIN HUMAN, 300,0 iu,
36/21.1/0077	AVENTIS PHARMA (PTY) LTD	INSUMAN BASAL (300 IU/3 ML)	EACH 5,0 ml SOLUTION CONTAINS INSULIN HUMAN, 500,0 iu
36/21.1/0078	AVENTIS PHARMA (PTY) LTD	INSUMAN BASAL (500 IU/5 ML)	EACH 3,0 ml SOLUTION CONTAINS INSULIN HUMAN, 300,0 iu
36/21.1/0079	AVENTIS PHARMA (PTY) LTD	INSUMAN BASAL (1000 IU/10 ML)	EACH 10,0 ml SOLUTION CONTAINS INSULIN HUMAN, 1000,0 iu
36/21.1/0080	AVENTIS PHARMA (PTY) LTD	INSUMAN COMB 30/70 (300 IU/3 ML)	EACH 3,0 ml SOLUTION CONTAINS INSULIN HUMAN, 300,0 iu
36/21.1/0081	AVENTIS PHARMA (PTY) LTD	INSUMAN COMB 30/70 (500 IU/5 ML)	EACH 5,0 ml SOLUTION CONTAINS INSULIN HUMAN, 500,0 iu
36/21.1/0082	AVENTIS PHARMA (PTY) LTD	INSUMAN COMB 30/70 (1000 IU/10 ML)	EACH 10,0 ml SOLUTION CONTAINS INSULIN HUMAN, 1000,0 iu
36/21.5.1/0191	CIPLA LIFE SCIENCES (PTY) LTD	PREFLAM	EACH 5,0 ml SYRUP CONTAINS PREDNISOLONE, 15,0 mg
36/21.8.2/0169	MEDI-CHALLENGE (PTY) LTD	LEVONOR	EACH TABLET CONTAINS LEVONORGESTREL, 0,75 mg
36/26/0012	TEMA MEDICAL (PTY) LTD	NAVELBINE ORAL 20 MG	EACH CAPSULE CONTAINS VINOURELBINE TARTRATE, EQUIVALENT TO VINOURELBINE 20,0 mg
36/26/0013	TEMA MEDICAL (PTY) LTD	NAVELBINE ORAL 30 MG	EACH CAPSULE CONTAINS VINOURELBINE TARTRATE, EQUIVALENT TO VINOURELBINE 30,0 mg
36/26/0014	TEMA MEDICAL (PTY) LTD	NAVELBINE ORAL 40 MG	EACH CAPSULE CONTAINS VINOURELBINE TARTRATE, EQUIVALENT TO VINOURELBINE 40,0 mg
36/26/0015	TEMA MEDICAL (PTY) LTD	NAVELBINE ORAL 80 MG	EACH CAPSULE CONTAINS VINOURELBINE TARTRATE, EQUIVALENT TO VINOURELBINE 80,0 mg
36/30.1/0358	BIOVAC SA (PTY) LTD	HEBERBIOVAC HB 10 UG/0	EACH 0,5 ml SUSPENSION CONTAINS HEPATITIS B ANTIGEN, DNA RECOMBINANT VACCINE 10,0 ug
36/30.1/0359	BIOVAC SA (PTY) LTD	HEBERBIOVAC HB 20 UG/1	EACH 1,0 ml SUSPENSION CONTAINS HEPATITIS B ANTIGEN, DNA RECOMBINANT VACCINE 20,0 ug
36/30.1/0360	BIOVAC SA (PTY) LTD	HEBERBIOVAC HB 100 UG/5	EACH 5,0 ml SUSPENSION CONTAINS HEPATITIS B ANTIGEN, DNA-RECOMBINANT VACCINE 100,0 ug
36/34/0121	PHARMACIA SOUTH AFRICA (PTY) LTD	RAYZON 1 ML SOLVENT	EACH AMPOULE CONTAINS SODIUM CHLORIDE, 9,0 mg
36/34/0122	PHARMACIA SOUTH AFRICA (PTY) LTD	RAYZON 2 ML SOLVENT	EACH AMPOULE CONTAINS SODIUM CHLORIDE, 18,0 mg
36/34/0484	B BRAUN MEDICAL (PTY) LTD	COMBIBIC SH-EL 00	EACH 1000,0 ml SOLUTION CONTAINS CALCIUM CHLORIDE, 1,98 g GLUCOSE, 9,0 g MAGNESIUM CHLORIDE, HEXAHYDRATE 0,91 g SODIUM CHLORIDE, 4,21 g
36/5.1/0449	PHARMACIA SOUTH AFRICA (PTY) LTD	DETRUSITOL SR 4 MG	EACH CAPSULE CONTAINS TOLTERODINE L-TARTRATE, 4,0 mg
36/5.4/0448	PHARMACIA SOUTH AFRICA (PTY) LTD	DETRUSITOL SR 2 MG	EACH CAPSULE CONTAINS TOLTERODINE L-TARTRATE, 2,0 mg
36/5.7.1/0005	ROLAB (PTY) LTD	ROLOR	EACH TABLET CONTAINS LORATADINE, 10,0 mg
36/7.1.3/0067	NOVARTIS SOUTH AFRICA (PTY) LTD	TAREG 80 TABLET	EACH TABLET CONTAINS VALSARTAN, 80,0 mg
36/7.1.3/0068	NOVARTIS SOUTH	TAREG 160 TABLET	EACH TABLET CONTAINS

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	AFRICA (PTY) LTD		VALSARTAN, 160,0 mg
36/7.1.3/0112	RANBAXY (SA) (PTY) LTD	RENOTENS 5 TABLETS	EACH TABLET CONTAINS LISINOPRIL, 5,0 mg
36/7.1.3/0113	RANBAXY (SA) (PTY) LTD	RENOTENS 10 TABLETS	EACH TABLET CONTAINS LISINOPRIL, 10,0 mg
36/7.1.3/0114	RANBAXY (SA) (PTY) LTD	RENOTENS 20 TABLETS	EACH TABLET CONTAINS LISINOPRIL, 20,0 mg
36/7.1.5/0384	ELI LILLY (SA) (PTY) LTD	CIALIS	EACH TABLET CONTAINS TADALAFIL, 20,0 mg
37/2.7/0104	EDUAN STOLTZ	DAS-FENTANYL 0	EACH 2,0 ml SOLUTION CONTAINS FENTANYL CITRATE, EQUIVALENT TO FENTANYL 0,1 mg
37/2.7/0105	EDUAN STOLTZ	DAS-FENTANYL 0	EACH 10,0 ml SOLUTION CONTAINS FENTANYL CITRATE, EQUIVALENT TO FENTANYL 0,5 mg
37/20.2.8/0110	PHARMACARE LIMITED	AP STAVUDINE 15 MG	EACH CAPSULE CONTAINS STAVUDINE, 15,0 mg
37/20.2.8/0111	PHARMACARE LIMITED	AP STAVUDINE 20 MG	EACH CAPSULE CONTAINS STAVUDINE, 20,0 mg
37/20.2.8/0112	PHARMACARE LIMITED	AP STAVUDINE 30 MG	EACH CAPSULE CONTAINS STAVUDINE, 30,0 mg
37/20.2.8/0113	PHARMACARE LIMITED	AP STAVUDINE 40 MG	EACH CAPSULE CONTAINS STAVUDINE, 40,0 mg
37/21.5.1/0022	CIPLA-MEDPRO (PTY) LTD	CIPLA-PREDNISOLONE 15 MG/5 ML	EACH 5,0 ml SYRUP CONTAINS PREDNISOLONE, 15,0 mg
37/7.1.3/0020	EGIS PHARMACEUTICALS SOUTH AFRICA (PTY) LTD	EGIS PERINDOPRIL 4 MG	EACH TABLET CONTAINS PERINDOPRIL, 4,0 mg
37/7.1.3/0021	BIOGARAN SOUTH AFRICA (PTY) LTD	BIOGARAN PERINDOPRIL 4 MG	EACH TABLET CONTAINS PERINDOPRIL, 4,0 mg

**REGISTRAR OF MEDICINES  
MS M.P. MATSOSO**