

MEDICINES CONTROL COUNCIL



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

Application Number	Holder of registration of Certificate	Proprietary Name	Active Compound
32/30.1/0044	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	INFANRIX	EACH 0,5 ml SUSPENSION CONTAINS EIPHTHERIA TOXOID 30,0 iu PERTUSSIS TOXOID 25,0 ug PROTEINS 8,0 ug TETANUS TOXOID 40,0 iu FILAMENTOUS HAEMAGGLUTININ 25,0 ug
32/2.6.5/0326	HEXAL PHARMA (S.A)(PTY) LTD	BUSPIRONE-HEXAL	EACH TABLET CONTAINS BUSPIRONE HYDROCHLORIDE 10,0 mg
33/20.1.1/0050	PHARMCARE LIMITED	COMPU-CEPHRADINE 1000	EACH VIAL CONTAINS CEPHRADINE 1000,0 mg
34/1.2/0266	GLAXOSMITHKLINE	WELLBURTIN SR	EACH TABLET CONTAINS BUPROPION HYDROCHLORIDE 150,0 mg
34/18.1/0372	LEBASI PHARMACEUTICALS CC	EUROMED MANNITOL 20% INTRAVENOUS INJECTION	EACH 100,0 ml SOLUTION CONTAINS MANNITOL 20,0 g
34/34/0459	SCHERING-PLOUGH (PTY) LTD	PEG-INTRON 50 MICROGRAMS	EACH VIAL CONTAINS: PEGINTEREFERON ALFA-2b 50,0ug
34/34/0460	SCHERING-PLOUGH (PTY) LTD	PEG-INTRON 100 MICROGRAMS	EACH VIAL CONTAINS: PEGINTEREFERON ALFA-2b 100,0ug
34/34/0461	SCHERING-PLOUGH (PTY) LTD	PEG-INTRON 150 MICROGRAMS	EACH VIAL CONTAINS: PEGINTEREFERON ALFA-2b 150,0ug
34/34/0462	SCHERING-PLOUGH (PTY) LTD	DILUENT FOR PEG-INTRON	EACH AMPOULE CONTAINS: WATER FOR INJECTION 0,7ml
35/20.1.1/0058	PHARMACARE LIMITED	FACTIVE 320 MG	EACH TABLET CONTAINS GEMIFLOXACIN MESYLATE EQUIVALENT TO GEMIFLOXACIN 320,0 mg
35/5.8/0153	PHARMACARE LIMITED	HISTACON EFFERVESCENT	EACH TABLET CONTAINS PARACETAMOL 500,0 mg CHLORPHENIRAMINE MALEATE 4,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE

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			50,0 mg VITAMIN C 330,0 mg
35/5.8/0154	PHARMACARE LIMITED	FLUDACTIL EFFERVESCENT	EACH TABLET CONTAINS PARACETAMOL 500,0 mg CHLORPHENIRAMINE MALEATE 4,0 mg PSEUDOEPHEDRINE HYDROCHLORIDE 50,0 mg VITAMIN C 330,0 mg
36/21.8.2/0168	MEDI-CHALLENGE (PTY) LTD	MEDILEVO	EACH TABLET CONTAINS LEVONORGESTREL 0,75 mg
36/2.2/0328	PHARMACARE LIMITED	ZOLNOXS 10 MG TABLETS	EACH TABLET CONTAINS ZOLPIDEM TARTRATE 10,0 mg
36/2.9/0337	MC PHARMA (PTY) LTD	DOLOTRAM 50	EACH 1,0 ml SOLUTION CONTAINS TRAMADOL HYDROCHLORIDE 50,0 mg
36/2.9/0338	MC PHARMA (PTY) LTD	DOLOTRAM 100	EACH 2,0 ml SOLUTION CONTAINS TRAMADOL HYDROCHLORIDE 100,0 mg
36/2.9/0397	HEXAL PHARMA (S.A) (PTY) LTD	TRAMAHEXAL 100 MG/ 2ML	EACH 2,0 ml AMPOULE CONTAINS TRAMADOL HYDROCHLORIDE 100,0 mg
36/2.8/0406	AUSTELL LABORATORIES (PTY) LTD	AUSTELL- PARACETAMOL	EACH TABLET CONTAINS PARACETAMOL 500,0 mg
36/20.1.1/0482	ALLIANCE PHARMA (PTY) LTD	ORITAXIM 500	EACH VIAL CONTAINS CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 500,0 mg
36/20.1.1/0483	ALLIANCE PHARMA (PTY) LTD	ORITAXIM 1000	EACH VIAL CONTAINS CEFOTAXIME SODIUM EQUIVALENT TO CEFOTAXIME 1000,0 mg
36/24/0487	FRESENIUS KABI	GLYCOPHOS	EACH 1,0ml SOLUTION CONTAINS: SODIUM GLYCEROPHOSPHATE PENTAHYDRATE EQUIVALENT TO SODIUM GLYCEROPHOSPHATE 216,0mg
36/18.7/0491	JANSSEN PHARMACEUTICA (PTY) LTD	EVRA	EACH PATCH CONTAINS: NORELGESTROMIN 6,0mg ETHINYLESTRADIOL 750,0ug
37/20.1.1/0012	CIPLA LIFE SCIENCES (PTY) LTD	DUOLIN RESPULES	EACH 2,5ml SOLUTION CONTAINS: IPRATROPIUM BROMIDE 0,5mg SALBUTAMOL SULPHATE EQUIVALENT TO SALBUTAMOL 2,5mg
37/10.2.1/0084	CIPLA LIFE SCIENCES (PTY) LTD	FORATEC DP-CAPS	EACH CAPSULE CONTAINS: FORMOTEROL FUMARATE 12,0ug
37/20.1.2/0085	SANDOZ (PTY) LTD	AMOCLAN BID	EACH 5,0 ml SUSPENSION CONTAINS AMOXYCILLIN ITRIHYDRATE EQUIVALENT TO AMOXYCILLIN 400,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 57,0 mg
37/15.4/0092	ALLERGAN PHARMACEUTICALS (PTY) LTD	REFRESH TEARS	EACH 1,0 ml SOLUTION CONTAINS CARBOXYMETHYLCCELLULOSE SODIUM 5,0 mg
37/11.4.3/0326	CPLA-MEDPRO (PTY) LTD	ULTAK-75	EACH TABLET CONTAINS: RANITIDINE HYDROCHLORIDE EQUIVALENT TO RANITIDINE 75,0mg
37/14.1/0333	SMITH & NEPHEW PHARMACEUTICALS (PTY)	IODOSORB OINTMENT	EACH 1,0 g OINTMENT CONTAINS CADEXOMER IODINE EQUIVALENT TO

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	LTD		CADEXOMER 0,491 g and IODINE 0,009 g
37/5.8/0406	WYETH S.A. (PTY) LTD	DIMETAPP PEADIATRIC ELIXIR	EACH 5,0ml LIQUID CONTAINS: BROMPHENIRAMINE MALEATE 1,0mg PSEUDOEPHEDRINE HYDROCHLORIDE 15,0mg
37/14.1/0427	SMITH & NEPHEW PHARMACEUTICALS (PTY) LTD	IODOSORB PASTE	EACH 1,0 g PASTE CONTAINS CADEXOMER IODINE EQUIVALENT TO CADEXOMER 0,591 g and IODINE 0,009 g
37/20.2.2/0544	MSD (PTY) LTD	CANCIDAS 50 MG INJECTION	EACH VIAL CONTAINS CASPOFUNGIN ACETATE EQUIVALENT TO CASPOFUNGIN 50,0 mg
37/20.2.2/0545	MSD (PTY) LTD	CANCIDAS 70 MG INJECTION	EACH VIAL CONTAINS CASPOFUNGIN ACETATE EQUIVALENT TO CASPOFUNGIN 70,0 mg
37/21.8.2/0458	NOVARTIS SOUTH AFRICA (PTY) LTD	ESTALIS SEQUI 50/140 (PHASE I AND II)	EACH PHASE 1 PATCH CONTAINS OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 4,33 mg EACH PHASE II PATCH CONTAINS OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 0,62 mg NORETHISTERONE ACETATE 2,70 mg
37/21.8.2/0459	NOVARTIS SOUTH AFRICA (PTY) LTD	ESTALIS SEQUI 50/250(PHASE I AND II)	EACH PHASE I PATCH CONTAINS OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 0,433 mg EACH PHASE II PATCH CONTAINS OESTRADIOL HEMIHYDRATE EQUIVALENT TO OESTRADIOL 0,512 mg NORETHISTERONE ACETATE 4,80 mg
375.7.1/0490	PHARMACARE LIMITED	ASPEN CETIRIZINE 10 MG	EACH TABLET CONTAINS CETIRIZINE HYDROCHLORIDE 10,0 MG
37/20.1.2/0619	GENERIX INTERNATIONAL (S.A) (PTY) LTD	AMPIJECT 0,5 G INJECTION	EACH VIALCONTAINS AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 500,0 mg
37/20.1.2/0620	GENERIX INTERNATIONAL (S.A) (PTY) LTD	AMPIJECT 1,0 G INJECTION	EACH VIAL CONTAINS AMPICILLIN SODIUM EQUIVALENT TO AMPICILLIN 1,0 g
38/20.2.2/0013	AUSTELL LABORATORIES (PTY) LTD	AUSTELL-FLUCONAZOLE 50 MG CAPSULE	EACH CAPSULE CONTAINS FLUCONAZOLE 50,0 mg
38/20.2.2/0014	AUSTELL LABORATORIES (PTY) LTD	AUSTELL-FLUCONAZOLE 200 MG CAPSULE	EACH CAPSULE CONTAINS FLUCONAZOLE 200,0 mg
38/20.1.2/0320	SANDOZ (PTY) LTD	CURAM 1,2 G 20 ML	EACH 20,0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 1000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 200,0 mg
38/20.1.2/0321	SANDOZ (PTY) LTD	CURAM 1,2 G 50 ML	EACH 50,0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO

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			AMOXYCILLIN 1000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 200,0 mg
38/20.1.2/0322	SANDOZ (PTY) LTD	CURAM 0,6 G 10 ML	EACH 10,0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 100,0 mg
38/20.1.2/0323	SANDOZ (PTY) LTD	CURAM 0,6 G 20 ML	EACH 20,0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 100,0 mg
38/20.1.2/0324	SANDOZ (PTY) LTD	SANDOZ-AMOCCLAV 1,2G 20 ML	EACH 20,0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 1000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 200,0 mg
38/20.1.2/0325	SANDOZ (PTY) LTD	SANDOZ-AMOCCLAV 1,2 G 50 ML	EACH 50,0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 1000,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 200,0 mg
38/20.1.2/26	SANDOZ (PTY) LTD	SANDOZ-AMOCCLAV 0,6 G 10ML	EACH 10, 0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 100,0 mg
38/20.1.2/0327	SANDOZ (PTY) LTD	SANDOZ-AMOCCLAV 0,6 G 20ML	EACH 20, 0 ml VIAL CONTAINS AMOXYCILLIN SODIUM EQUIVALENT TO AMOXYCILLIN 500,0 mg POTASSIUM CLAVULANATE EQUIVALENT TO CLAVULANIC ACID 100,0 mg
A38/21.5.1/344	ADCOCK INGRAM LIMITED	ASMABEC 50 CLICKHALER	EACH METERED ACTUATION CONTAINS BECLOMETHASONE DIPROPIONATE 50,0 mg
A38/21.5.1/345	ADCOCK INGRAM LIMITED	ASMABEC 100 CLICKHALER	EACH METERED ACTUATION CONTAINS BECLOMETHASONE DIPROPIONATE 100,0 mg
A38/21.5.1/0346	ADCOCK INGRAM LIMITED	ASMABEC 250 CLICKHALER	EACH METERED ACTUATION CONTAINS BECLOMETHASONE DIPROPIONATE 250,0 mg
A38/20.2.8/0357	PHARMACARE LIMITED	ASPEN LAMIVUDINE SYRUP	EACH 1, 0 ml SOLUTION CONTAINS LAMIVUDINE 10,0 mg
A38/20.2.2/0451	CAMOX PHARMACEUTICALS (PTY) LTD	APEX-FLUCONAZOLE 50 MG CAPSULES	EACH CAPSULE CONTAINS FLUCONAZOLE 50,0 mg
A38/20.2.2/0452	CAMOX PHARMACEUTICALS (PTY) LTD	APEX-FLUCONAZOLE 150 MG CAPSULES	EACH CAPSULE CONTAINS FLUCONAZOLE 150,0 mg
A38/20.2.2/0453	CAMOX PHARMACEUTICALS (PTY) LTD	APEX-FLUCONAZOLE 200 MG CAPSULES	EACH CAPSULE CONTAINS FLUCONAZOLE 200,0 mg
A38/7.1/0652	BE-TABS PHARMACEUTICALS (PTY) LTD	AMDEPIN 5	EACH TABLET CONTAINS AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 5,0 mg
A38/7.1/0653	BE-TABS PHARMACEUTICALS (PTY) LTD	AMDEPIN 10	EACH TABLET CONTAINS AMLODIPINE BESILATE EQUIVALENT TO AMLODIPINE 10,0 mg
A38/20.2.8/0614	GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD	COMBID TABLETS	EACH TABLET CONTAINS ZIDOVUDINE 300,0 mg LAMIVUDINE 150,0 mg

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A39/7.1/0119	CIPLA-LIFE SCIENCES (PTY) LTD	CIPLA-AMLODIPINE 10	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 10,0mg
A39/7.1/0121	CIPLA-LIFE SCIENCES (PTY) LTD	CIPLA-AMLODIPINE 5	EACH TABLET CONTAINS: AMLODIPINE BESYLATE EQUIVALENT TO AMLODIPINE 5,0mg
34/3.3/0177	HEXAL PHARMA S.A. (PTY) LTD	HEXAL-ALLOPURINOL 100	EACH TABLET CONTAINS ALLOPURINOL 100,0 mg
34/3.3/0178	HEXAL PHARMA S.A. (PTY) LTD	HEXAL-ALLUPURINOL 300	EACH TABLET CONTAINS ALLOPURINOL 300,0 mg
97/3.1/11	MERIAL S.A. (PTY) LTD	KETOFEN 1% INJECTION	EACH 1,0ml SOLUTION CONTAINS: KETOPROFEN 10,0mg

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