

LIST OF APPROVED DRUG FROM 01.01.2009 TO 31.12.2009

S. NO.	DRUG NAME	INDICATION	APPROVAL DATE
1.	Zoledronic Acid Injection 5mg/100ml (Addl. Indication)	For the treatment of osteoporosis in post-menopausal women and in men who are at increased risk of fracture, including those with a recent low-trauma hip fracture.	07.01.09
2.	Misoprostol Tablet 600mcg	Addl. Strength	09.01.09
3.	Acebrophylline Syrup 10mg/ ml	For the treatment of adult patients with chronic obstructive pulmonary disease (COPD) and bronchial asthma.	09.01.09
4.	Selamectin Tropical solution (for veterinary use.) 60mg/120mg per ml	(I) For the treatment and lasting prevention of flea infestations, treatment and control of flea allergy dermatitis, prevention of heartworm disease, treatment and prevention of ear mites in dogs and cats; (II) For the treatment and prevention of sarcoptic mange, roundworms and for control of tick infestations in dogs.	09.01.09
5.	Methylcobalamin 1500mcg + Calcium 200mg + Calcitriol 0.25mcg + Folic Acid 1.5mg + Pyridoxine 3mg Capsules	For the treatment of vitamin deficiency states in adults	14.01.09
6.	Metoprolol tartrate tablets 50 mg (Addl. Indication)	Adjunct to the treatment of Hyperthyroidism	14.01.09

7.	Cinacalcet (as HCl) Tablet 30/60/90mg	For the treatment of secondary hyperparathyroidism in patients with chronic kidney diseases (CKD) on dialysis and for hypercalcemia in patients with parathyroid carcinoma	14.01.09
8.	Mycophenolate mofetil Capsules 250mg, Tablets 500mg, Oral suspension 200mg/ml (addl. Indication)	For the prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplantation.	23.01.09
9.	Liquid Paraffin 1.25ml + Milk of Magnesia 3.75ml + Sodium Picosulphate 3.33mg per 5ml	For symptomatic treatment of constipation in adults	29.01.09
10.	Ranolazine 1000mg ER Tabs (Additional Strength)	Same as approved	31.01.09
11.	Hyaluronic acid (cross linked) Pre-filled syringe 18mg/0.6ml and 24mg/0.8ml	For intradermal implantation and facial soft tissue augmentation	31.01.09
12.	Caspofungin acetate Injection (Addl. Indication)	For use in following: (I) Empirical therapy for presumed fungal infections in febrile neutropenic patients. (II) Treatment of Candidemia and the following Candida infections: Intra-abdominal abscesses, Peritonitis and Pleural space infections. (III) Treatment of Esophageal Candidiasis. (IV) Treatment of invasive Aspergillosis in patients who are refractory to or intolerant of other therapies (i.e, amphotericin B, lipid formulations of amphotericin B, and/or itraconazole)	31.01.09

13.	Micafungin (as sodium) Powder for solution for infusion 50mg / vial	For the treatment of patients with candidemia, acute disseminated candidiasis, candida peritonitis, abscess and esophageal candidiasis. For the prophylaxis of Candida infection in patients undergoing hematopoietic stem cell transplantation (HSCT)	31.01.09
14.	Loteprednol Etabonate Nasal spray 0.1% w/v	For prophylaxis and treatment of the nasal symptoms of seasonal allergic rhinitis.	31.01.09
15.	Rasagiline (as mesylate) Tablet 0.5mg/1mg	For the treatment of signs and symptoms of idiopathic Parkinson's disease as initial monotherapy and as an addition to levodopa.	31.01.09
16.	Nicotine Polacrilex Gum 2mg & 4mg (Addl. Indication)	To reduce the withdrawal symptoms, including nicotine craving, associated with quitting the smoking and quitting chewed tobacco and guthka containing tobacco.	03.02.09
17.	Closantel Injection 100mg/ ml (for veterinary use.)	For the infestation of trematodes, nematodes, cestodes and arthropods of domestic animals, including milch and other food producing animals.	05.02.09
18.	Lornoxicam 4mg + Paracetamol 500mg film coated tablets	For the short term use in acute painful & inflammatory conditions in adults	05.02.09
19.	Cetrimide 15% w/v + Chlorhexidine Gluconate 7.5% v/v + Isopropyl Alcohol 7.5% v/v Concentrate Solution	For cleansing of physically contaminated wounds and for pre-operative disinfection	09.02.09
20.	Ketoconazole 2% w/v + Prepared Coal Tar 2% w/v (I.P. 1966) Solution	For the treatment of dandruff	09.02.09
21.	Doripenem (as monohydrate) Injection 250mg/500mg	For the treatment of nosocomial pneumonia in adults.	16.02.09

22.	Halobetasol Scalp Approved 0.05% w/v	For the relief of inflammatory and puritic manifestation of corticosteroid responsive dermatosis	18.02.09
23.	Nicotine (as Polacrilex) Lozenges 2mg & 4mg	To reduce the withdrawal symptoms, including nicotine craving, associated with quitting the smoking and quitting chewed tobacco and gutka containing tobacco.	18.02.09
24.	Tranexamic Acid Tab SR 750mg	For the treatment of menorrhagia	20.02.09
25.	Betahistine Mesilate Tablet 6mg/12mg	For the treatment of dizziness and feeling of dizziness resulting from Meniere's disease, Meniere's syndrome and vertigo.	20.02.09
26.	Abatacept Injection 250mg/vial (Addl. Indication)	In moderately to severely active rheumatoid arthritis in adults and may be used as monotherapy or concomitantly with DMARD's other than TNF antagonists	20.02.09
27.	Anidulafungin Injection (Lyophilized powder) 50mg/100mg per vial	For the treatment of invasive candidiasis including candidemia and esophageal candidiasis in adult patients.	23.02.09
28.	Hydroquinone 2% + Tretinoin 0.05% + Hydrocortisone 1% Cream	For the treatment of patients with skin hyperpigmentation	23.02.09
29.	Doxyphylline 400 mg + Terbutaline 5mg tablets	For the treatment of asthma and chronic obstructive pulmonary disease in adult patients only	23.02.09
30.	Hydroquinone 20mg + Tretinoin 0.25mg + Fluocinolone Acetonide 0.1mg per gm Cream	For the treatment of melasma of face in adults	23.02.09
31.	Ketoconazole 2% + Zinc Pyrithone 1% Lotion	For the treatment of pityriasis and dandruff of the scalp	23.02.09

32.	Lamivudine 30mg + Zidovudine 60mg +Nevirapine 50mg Oral Suspension (Tablets for oral Suspension)	For the treatment of HIV patients	23.02.09
33.	Glibenclamide 5mg + Pioglitazone 15mg + Metformin500mg film coated tablets	As 3rd line treatment of type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glyceic control	23.02.09
34.	Aceclofenac 100mg + Tizanidine 2mg film coated tablets	For the treatment of acute low back pain in adult patients only	23.02.09
35.	Octinoxate 7.5% + Avobenzone 3% + Oxybenzone 3% + Titanium dioxide 2% lotion	As sunscreen lotion for prevention of sunburn skin	23.02.09
36.	Cetirizine 5/10mg + Ambroxol 30mg per 5ml syrup	For the symptomatic relief of productive cough associated with allergic rhinitis, when both anti- histamine and mucolytic agents are desired	23.02.09
37.	Lidocaine Lozenges 200/300mg	For single agent anesthesia in upper gastro intestinal endoscopy.	26.02.09
38.	Calamine 8% + Liquid Paraffin10% lotion	As antipruritic and soothing agent	26.02.09
39.	Nifedipine 0.3% + Lidocaine1.5% cream	For the treatment of anal fissures	26.02.09
40.	Quinapril 20mg + HCTZ 25mg film coated tablet	For the treatment of mild to moderate hypertension in adult patients (in whom combination therapy is appropriate) who have been stabilized on the individual components given in the same proportion	26.02.09

41.	Levodopa 100/100/250 + Carbidopa 10/25/25mg mouth dissolving tablet	For the symptomatic symptoms of idiopathic Parkinson's Disease	04.03.09
42.	Paliperidone ER Tablets 1.5mg	Addl. Strength	04.03.09
43.	Losartan 100mg+ HCTZ 25 mg tablet	Additional higher strength	16.03.09
44.	Darunavir(as ethanolate) Tablet 300mg	For the treatment of human immunodeficiency virus (HIV) infection in antiretroviral treatment experienced adult patients, such as those patients with HIV-1 strains resistant to more than one protease inhibitor when co-administered with 100mg ritonavir, and with other antiretroviral agents.	19.03.09
45.	Ropivacaine HCl Inj.2/5/7.5/10 mg	For the production of local or regional anesthesia for surgery and for acute pain management.	19.03.09
46.	Butaphosphan 100g + Methyl Hydroxybenzoate 1gm + Cyanocobalamin 50 gm Oral powder (Veterinary Drug)	As vitamin and phosphorous supplement for livestock, shirmp and fish.	19.03.09
47.	Fluticasone furoate Nasal spray 27.5mcg per spray	For the treatment of symptoms of allergic rhinitis.	19.03.09
48.	Octinoxate 7.5% + Avobenzene 2% + Oxybenzone 3% + Octocrylene 3%+ Zinc Oxide 2% lotion	A sunscreen lotion for prevention of sunburn skin	19.03.09
49.	Omeprazole 20/40mg + Sodium Bicarbonate 600mg+ Magnesium Hydroxide 700mg sachet	Additional Strength	19.03.09

50.	Ambroxol 30mg + Levo salbutamol 1mg+ Guiphenesin 50mg /5ml syrup	For the symptomatic relief of bronchospasm in bronchial asthma & chronic bronchitis	19.03.09
51.	Montelukast 4 mg+ Levocetizine 2.5 mg tablet	Additional lower paediatric dose	19.03.09
52.	Surgical Sealant	To be indicated for use in sealing suture lines along arterial and venous reconstructions.	26.03.09
53.	Lidocaine Patch 700mg in aqueous base. (50 mg per gram adhesive)	For the relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.	26.03.09
54.	Bimatoprost Ophthalmic solution 0.03%	For the treatment of hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness.	30.03.09
55.	Trabectedin powder for concentrate for solution for infusion 1 mg/ vial	For the treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents.	30.03.09
56.	Acebrophylline Syrup 10mg/ml (Additional Indication)	For the treatment of children (age 6to 12years) with chronic obstructive pulmonary disease(COPD) and bronchial asthma.	30.03.09
57.	Mesalamine PR Tablets 1.2gm	For the induction of remission in patients with active, mild to moderate ulcerative colitis.	30.03.09
58.	Mycophenolate Mofetil Tablets 750mg Additional Strength	Same as approved	31.03.09
59.	Ketorolac Tromethamine Gel 2% w/w	For the treatment of muscle, joint and post-traumatic stress.	31.03.09

60.	Theophylline 400mg SR + Montelukast 10mg Tablet	For the treatment of patients with bronchial asthma	31.03.09
61.	Hyaluronic Acid Sodium Salt 0.2 gm + Silver Sulfadiazine 1.0 gm/25 gm tube Hyaluronic Acid Sodium Salt 50 mg + Silver Sulfadiazine 1.0 gm/ 100 gm gauze pads impregnated with cream.	For the treatment of wound of different etiology	31.03.09
62.	Telmisartan 80mg + Amlodipine 5mg tablet	Additional higher strength	31.03.09
63.	Hyaluronic Acid Sodium Salt (i) Each 15gm tube contains: Hyaluronic Acid Sodium Salt 0.2gm/100gm (ii) Sterile Gauze Pads impregnated with cream: Each gauze pad contains Hyaluronic Acid Sodium Salt 50/100mg	For the treatment of wound of different etiology	31.03.09
64.	Abatacept Injection 250mg/vial (additional indication)	For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis/juvenile rheumatoid arthritis in pediatric patients 6 years of age and older who have had an inadequate response to one or more DMARD's such as MTX	10.04.09
65.	Cetirizine 10 mg + Ambroxol 75 mg SR Tablet	For symptomatic relief of productive cough associated with allergic rhinitis, when both anti-histamine and mucolytic agents are desired	13.04.2009
66.	Ciclesonide 200mcg + Formoterol 6mcg + Tiotropium 9mcg MDI	Indicated as third line treatment of severe cases of COPD, when monotherapy and second line therapy with two drugs do not respond adequately.	13.04.2009

67.	Each film coated bilayered tablet contains: Metoprolol 25mg/50mg + Chlorthalidone 12.5mg	For the treatment of patients with mild to moderate essential hypertension	13.04.2009
68.	Milnacipran 25/50mg Caps (Addl. Indication)	For the management of fibromyalgia.	15.04.2009
69.	Lornoxicam SR 16mg Tabs	For the symptomatic treatment of pain and inflammation in patients of osteoarthritis & rheumatoid arthritis	25.04.2009
70.	Palonosetron Hcl 0.075mg IV Inj (Addl. Strength)	Same as approved	25.04.2009
71.	Each film coated bilayered tablet contains: Metoprolol 25mg/50mg + Chlorthalidone 6.25 mg /12.5mg	Additional strength	25.04.2009
72.	Albendazole 400 mg + Ivermectin 6 mg tablet	For the treatment of intestinal helminths and suppression of microfilaraemia especially with bancrofti infections	25.04.2009
73.	Decitabine Lyophilized powder for injection 50mg/20ml vial	For treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk international Prognostic Scoring System groups.	25.04.2009

74.	Retapamulin Ointment 1%	For the topical treatment of bacterial skin and skin structure infections:-Primary impetigo, secondarily infected traumatic lesions, secondarily infected dermatoses.	25.04.2009
75.	Each ml contains Calamine 15% w/v + Zinc oxide 5% w/v + Bentonite 3% w/v+Glycerin 5%w/v + Sodium citrate 0.05 % w/v lotion	For the treatment of pruritis and prickly heat	08.05.2009
76.	Each 1000 ml of emulsion contains: Medium chain triglycerides 100 gm + Soya oil 80 gm + Omega-3 acidtriglycerides 20 gm + egg lecithin 12 gm + Glycerl 25 gm + Sodium oleate 0.30 gm + Alpha -tocopherol 0.20 gm +Ascorbypalmitate 0.30 gm + Sodium hydroxide max. 0.06 gm + water for injection 784 gm emulsion for infusion	For the supply of fats, including essential omega-6 fatty acids and omega-3 fatty acids, as part of a parenteral nutrition regimen in adults if oral or enteral nutrition is impossible, inadequate or contraindicated.	14.05.2009
77.	Sertaconazole Nitrate Powder 2% w/w & Lotion 2% w/v	For the topical treatment of the superficial fungal infections of the skin.	02.05.2009
78.	Amlodipine Tablets 5mg/10mg (additional indication)	1. To reduce of fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke. 2. To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery disease.	02.05.2009
79.	Clindamycin Phosphate Inj. 150mg/ml & Clindamycin HCl Capsules 150mg/300mg (additional indication)	Prophylaxis of infection in neck and head surgery	02.05.2009

80.	Each 15 gm sachet contains: Lactulose 10 gm + Ispaghula husk 3.50 gm granules	For the treatment of chronic idiopathic constipation in adult patients only	16.05.2009
81.	Sucralose	for use as sweetner in drug formulations	09.05.2009
82.	Carvedilol Tablets 3.125/6.25/12.5/25mg (additional indication)	To reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of $\leq 40\%$ (with or without symptomatic heart failure)	09.05.2009
83.	Dexketoprofen 12.5 mg/25 mg + Paracetamol 500 mg film coated tablets	For the treatment of Acute musculoskeletal pain	18.05.2009
84.	Pregabalin SR Tablet 150/300mg	For the treatment of peripheral neuropathic pain in adults	16.05.2009
85.	Guaiphenesin ER Tablet 1200mg	For the treatment of productive cough accompanied by Phlegm	16.05.2009
86.	Everolimus 5/10mg Tablets (Addl. Indication)	Treatment of advance renal cell carcinoma	16.05.2009
87.	Nimesulide ER 200mg (Additional Indication)	Acute pain in Orthopaedic, ENT, Dental and Post Operative condition	16.05.2009
88.	Palonosetron Injection 0.25mg/5ml (Additional Indication)	For treatment of Post Operative Nausea & vomiting	16.05.2009
89.	Bendamustine Hydrochloride Lyophilized powder Injection 100mg/ vial	For the treatment of patients with chronic lymphocytic leukemia.	16.05.09

90.	Caffeine(as Citrate) 10mg / ml Injection	For the short term treatment of apnoea of prematurity of infants between 28 and < 33 weeks gestational age.	16.05.09
91.	Perindopril arginine 2.5mg/5mg/10mg film coated tablet	For the treatment of arterial hypertension, congestive heart failure and coronary artery disease.	16.05.09
92.	Each gm contains: Halobetasol 0.05% w/w + Mupirocin 2.0 % w/w gel	For the topical treatment of inflammatory dermatitis withsecondary bacterial infection	16.05.09
93.	Mometasone 0.1 % + Fusidic acid 2% cream/ointment	For the treatment of dermatoses where secondary bacterial and/orcandidial infection is present	25.04.09
94.	Thiocolchicoside 8 mg + Etoricoxib 60 mg tablets	Additional strength	25.04.09
95.	Methadone Hydrochloride 5mg/10mg per ml syrup; 5mg/ 10mg/ 20mg / 40mg tablet	For the treatment of opioddependence and in maintainencetreatment for opiod dependence.	28.05.09
96.	Trospium Chloride film coated tablet 20mg	For the treatment of overactive bladder with the symptoms of urge urinary incontinence, urgency, and urinary frequency.	28.05.09
97.	Arformoterol (as Tartrate) 15mcg / 2ml Inhalation Solution	For the long term, twice daily (morning and evening) maintainencetreatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.	29.05.09
98.	Zolmitriptan...5.0% w/v Benzalkonium Chloride NF ... 0.01% w/v Nasal spray	For the acute treatment of migraine with or without aura in adults.	29.05.09

99.	Dexmedetomidine (as HCl) 100mcg /ml Injection	For sedation of initially and mechanically ventilated patients during treatment in an intensive care setting.	29.05.09
100.	Levetiracetam SR Tablet 500/750/1000mg	same as approved	2.05.2009
101.	Glatiramer Acetate Injection (20mg/ ml) & Pre-filled syringe (20mg/ml)	For the reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis.	3.06.2009
102.	Yttrium-90 Microspheres Injection (Yttrium-90...3GBq (at the time of calibration) per vial)	For the treatment of unresectable metastatic liver tumors from primary colorectal cancer with intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine)	3.06.2009
103.	Luliconazole Cream 1%	For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis, Tinea cruris.	3.06.2009
104.	Magnesium Valporate Prolonged release tablet 600mg	1) For the treatment of generalized or partial seizures as monotherapy or adjunctive therapy. 2) For prophylaxis of migraine headache in adults. 3) For the treatment of manic episodes associated with bipolar disorders	4.06.2009
105.	Tenofovir Disoproxil Fumerate 300mg	For the treatment of chronic Hepatitis B in adults	19.6.2009
106.	Bosentan (as monohydrate) Tablets 62.5/125mg	For the treatment of pulmonary arterial hypertension (WHO Group I) in patients with WHO Class III or IV symptoms, to improve exerciseability and decrease the rate of clinical worsening.	23.6.2009

107.	Lornoxicam 12 mg SR (additional strength)	same as approved	26.6.2009
108.	Azithromycin SR Granules for oral suspension 2000mg	for the treatment for mild to moderate susceptible infection including RTI, uncomplicated skin/ skin structure, non gonococcal urethritis, cervicitis	26.6.2009
109.	Metoprolol 50/50/25 mg + Atorvastatin20/10/10 mg + Ramipril 10/5/2.5 mg capsules	As 2nd line treatment of patients with both essential hypertension and hypercholesterolemia who are not adequately controlled by combination of an anti-hypertensive with lipid lowering agent.	1.07.2009
110.	Methyl Phenidate ER Tablet 10/20/30mg	For the treatment of Attention Deficit Hyperactivity Disorder (ADHD)	10.07.2009
111.	Dasatinib Tablets 100mg (addl. Strength)	same as approved	10.07.2009
112.	Voglibose 0.2 mg + Metformin 500mg Tablets	As 2nd line treatment of type II Diabetes mellitus when diet, exercise and the single agent do not result in adequate glycemc control.	13.7.2009

113.	<p>Combipack of artesunate tablet and FDC Tablet of sulphadoxine + pyrimethamine Composition: A. combipack of 1 strip of 3 tablets of artesunate 25 mg and 1 strip of 1 tablet of sulphadoxine 125mg+ pyrimethamine 6.25 mg B. combipack of 1 strip of 3 tablets of artesunate 50 mg and 1 strip of 1 tablet of sulphadoxine 500mg+ pyrimethamine 25 mg C. combipack of 1 strip of 3 tablets of artesunate 100 mg and 1 strip of 2 tablet of sulphadoxine 500mg+ pyrimethamine 25 mg D. combipack of 1 strip of 3 tablets of artesunate 200 mg and 1 strip of 3 tablet of sulphadoxine 500mg+ pyrimethamine 25 mg.</p>	For the treatment of P. falciparum resistant malaria patients	15.7.2009
114.	Milnacipran 100mg (additional Strength)	same as approved	16.7.2009
115.	Rifaximin 400mg (additional Indication)	For the treatment of hepatic encephalopathy	18.7.2009
116.	Nevirapine tablet 50 mg for oral suspension mg	For the treatment of HIV infection in combination with other anti retro viral agents	18.7.2009
117.	Desvenlafaxine (as Succinate) ER Tablets 50mg/100mg	For the treatment of major depressive disorder (MDD)	18.7.2009

118.	Posaconazole Oral Suspension 40mg/ml	For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole. For prophylaxis of invasive Aspergillus and Candida infections in patients, 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.	18.7.2009
119.	Caffeine Citrate 20mg / ml (equivalent to 10mg of Caffeine base) Oral Solution (Addl. Dosage form)	same as approved	18.7.2009
120.	Amphotericin B Emulsion 5mg/ml (Addl. Indication)	Febrile Neutropenia in cancer patients	18.7.2009
121.	Hydroxy ethyl starch 10% Solution for infusion	For the treatment of imminent or manifest hypovolemia and shock.	18.7.2009
122.	Naratriptan (as HCl) Tablets 1/2.5mg	For the acute treatment of migraine with or without aura in adults.	18.7.2009
123.	Colistimethate Sodium powder for solution for injection/infusion 500000IU and 2000000IU (additional Strength)	same as approved	20.7.2009
124.	Simvastatin 20 mg + Ramipril 5mg + Atenolol 50 mg + HCTZ 12.5 mg + Aspirin 100 mg (EC Pellets) Capsules	For secondary prevention of coronary heart disease/stroke in patients where use of such combination is appropriate	21.7.2009

125.	Colistimethate Sodium powder for solution for inhalation 500000IU/1000000IU/2000000IU	Treatment by inhalation of Pseudomonas aeruginosa lung infection in patients with cystic fibrosis	28.7.2009
126.	Ramipril MR capsule 10mg	For the treatment of hypertension/ cardiac failure and myocardial infarction	30.7.2009
127.	Abacavir Sulfate Tablet 60mg	For the treatment of HIV-1 infection in combination with other antiretroviral agents	1.08.2009
128.	Zoledronic Acid Solution for Infusion Addl. Indication	Prevention of clinical fractures after hip fracture in men and women	1.08.2009
129.	Sumatriptan 85 mg + Naproxen 500 mg Tablets	Additional Strength for the treatment of migraine	3.08.2009
130.	Aceclofenac(100mg) + Thiocolchicoside (8 mg) tablets	For the treatment of acute inflammation conditions associated with spasm in adults only	3.08.2009
131.	Aceclofenac(100mg) + Thiocolchicoside (4 mg) tablets (Additional strength)	For the treatment of acute inflammation conditions associated with spasm in adults only	11.08.2009
132.	Oxcarbazepine 150/300/600mg Tablet (Addl. Indication)	Treatment of generalized tonic-clonic seizures in adults and children	13.08.2009
133.	Ofloxacin 2mg + Ornidazole 5 mg per ml Infusion	for the treatment of diarrhoea of mixed infection in adult patients	17.08.2009
134.	Clozapine Tablet200mg (Addl. Strength)	Indicated in the management of Schizophrenic patients	19.08.2009
135.	Oxymetazoline Hydrochloride Nasal Spray50mcg/0.05% w/w	Is indicated for the relief of stuffy,running nose associated with colds and influenza, also post nasal drip, sinusitis.	19.08.2009
136.	Enoxaparin Sodium Injection (Addl.Indication)	Treatment of acute ST-segment elevation myocardial infarction including patients to be managed medically or with subsequent percuaneous coronary intervention (PCI)	19.08.2009
137.	Fluvoxamine Maleate100/150mg ER Tablets	For the treatment of obsessive compulsive disorder (OCD)and depression	19.08.2009

138.	Lidocaine Lozenges 200/300mg (Addl. Indication)	For single agent anesthesia in procedure involving the introduction of instrument & tubes into respiratory tract.	19.08.2009
139.	Risperidone long acting injection (Addl. Indication)	Indicated as monotherapy or as adjunctive therapy in lithium or valproate for the maintenance treatment of Bipolar-1 disorder.	29.08.2009
140	Exemestane 25mg Tablet (Addl. Indication)	Indicated for adjuvant treatment of Post Menopausal Women with estrogen receptor positive early breast cancer who have received two-three year of tamoxifen and are switched to exemestane for completion of total of five years of adjuvant hormonal therapy.	29.08.2009
141	Artesunate (25/50/100mg) + Amodiaquine (67.5 mg/135/270mg) bilayerd Tablets	For the treatment of uncomplicated malaria due to plasmodium falciparum strain in various age groups	01.09.2009
142	Ezetimibe 10 mg + Fenofibrate 145 mg Film coated tablets	For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function	01.09.2009
143	Buprenorphine Transdermal Patch Each Transdermal Patch having an area of 6.25cm ² , 12.5cm ² , and 25cm ² contains: Buprenorphine...5mg/10mg/20 mg having release rate of 5mcg, 10mcg, 20mcg Buprenorphine per hour respectively(over a period of 7 days).	For the treatment of severe opioid responsive painconditions which are not adequately responding to non-opioid analgesics.For Hospital supply only.	03.09.09
144	Trospium Chloride ER Capsules 60 mg	For the treatment of overactive bladder with the symptoms of urge urinary incontinence, urgency and urinary frequency.	04.09.2009
145	Metoclopramide (as HCl) 200mg / 400mg per ml Intranasal Solution	For the treatment of nausea and vomiting.	09.09.09

146	Isosorbide 20 mg + Hydralazine 37.5 mg tablets	For the treatment of heart failure as an adjunct to standard therapy in patients to improve survival, to prolong time to hospitalization for heart failure and to improve patients reported functional status.	18.09.2009
147	Cefixime 200 mg + Dicloxacillin ER 500 mg Tablets	For the treatment of adult patients with Upper and Lower respiratory tract infections, skin and soft tissue infections	22.09.2009
148	Chlorthalidone Tablet 6.25mg	For the treatment of mild to moderate hypertension.	03.10.09
149	Cefovecin(as sodium) 80mg/ml Lyophilised powder for injection (Veterinary)	For the treatment of skin bacterial infections in dogs and cats.	03.10.09
150	Imidacloprid 10% + Moxidectin 1.0% & 2.5% Topical solution (Veterinary) Each pipette contains: (a) 0.4ml, 1.0ml, 2.5ml, 4ml of 10% Imidacloprid and 1.0% moxidectin (b) 0.4ml, 0.8ml of 10% Imidacloprid and 2.5% moxidectin	For the treatment and prevention of flea infestations, prevention of heartworm disease and treatment of infections with gastrointestinal nematodes in dogs and cats.	03.10.09
151	Isoflupredone Acetate Suspension for Injection (2mg per ml) (For Veterinary)	For the glucocorticoid, anti-inflammatory or supportive therapy to cattle suffering from conditions such as: (1) Overwhelming infections with severe toxicity. (2) Bovine ketosis. (3) Musculoskeletal conditions. (4) Shock. (5) Parturient paresis (supportive stress therapy for milk fever).	03.10.09

152	Saxagliptin (as HCl) 2.5mg/ 5mg Tablets	As an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus. (It should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, as it would not be effective in these settings.	24.10.09
153	Calcipotriol Gel 0.005% (additional dosage form)	For the treatment of moderate plaque psoriasis in adults	3.10.2009
154	Lamotrigine MR Tablets 150mg (Addl. Strength)	same as approved	3.10.2009
155	Metoprolol Tartrate ER Tablet 75mg (additional strength)	same as approved	3.10.2009
156	Valganciclovir Powder for Oral Solution 50mg/ml	For the treatment of cytomegalovirus (CMV) retinitis in AIDS patients and for prevention of CMV disease in solid organ transplant patients at high risk	9.10.2009
157	Dexketoprofen Trometamol Gel 12.5mg/gm	For the painful and inflammatory conditions associated with joints, tendons, ligaments and muscle	13.10.2009
158	Donepezil Hydrochloride Orodispersible Tablet 5mg/10mg	For the treatment of mild to moderate severe Alzheimer's Dementia	15.10.2009
159	Dexketoprofen Trometamol Injection 50mg/2ml	Symptomatic treatment of acute pain of moderate to severe intensity, when oral administration is not appropriate such as post-operative pain, renal colic and low back pain.	22.10.2009
160	Bromocriptine Mesylate Tablet IP 0.8mg, (additional Indication)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	22.10.2009
161	Levosulpride ER Tablet 100/150/200mg	For the treatment of depression and schizophrenia in adults	27.10.2009

162	Ambroxol 30 mg+ Terbutaline 2.5 mg + Guaiphenesin 100mg + Menthol 2.5 mg per 5 ml syrup	Additional strength	27.10.2009
163	Propofol 10 mg+ Lignocaine 2.5 mg per ml injection	Additional strength	27.10.2009
164	Mecobalamin 750 mg + Pyridoxine Hydrochloride 1.5 mg + Nicotinamide 45 mg tablets	For the treatment of diabetic neuropathy	27.10.2009
165	Olmesartan (20/40mg)+ Atorvastatin 5/10/20mg film coated tablets	For the treatment of co-existing essential hypertension and hyperlipidemia in adult patients	27.10.2009
166	Deltamethrin (0.50% m/v) and Piperonyl Butoxide (2.0% m/v) per ml Pour-On Solution	Ready to use pour-on for cattle, sheep and goats. 1. For use in Cattle to control ticks, stable flies, horn flies, cattle louse flies and nuisance flies e.g. house flies, to kill lice and protection against blackflies. 2. For use in sheep and goats for controlling Karoo paralysis, bont-legged and red-legged ticks	29.10.2009
167	Glucosamine sulphate potassium chloride 500 mg + Ibuprofen IP 200mg film coated Tablets	For the treatment of adult patients with osteoarthritis of knee and/or hip joints	03.11.2009
168	Methylcobalamin 1500 mcg + Gabapentin SR 600 mg film coated tablets	Additional strength	4.11.2009
169	Propofol 1% for injection (Additional Indication)	1. For conscious sedation for surgical and diagnostic procedures 2. for sedation of patients receiving intensive care	5.11.2009
170	Rupatadine 10 mg + Montelukast 10 mg Tablets (SAR)	For the management of seasonal allergic rhinitis	10.11.2009
171	Eperisone 50 mg + Paracetamol 500 mg Tablets	For improvement of mytonic conditions caused by neck shoulder arm syndrome , scapulhumeral periarthritis and low back pain in adult patients only	10.11.2009
172	Lafutidine Tablets5mg/10mg.	For the treatment of: • gastric ulcers, duodenal ulcers and stromal ulcers • gastric mucosal lesions (erosion, hemorrhage, redness or edema)	11.11.2009

		associated with acute gastritis and acute exacerbation of chronic gastritis.	
173	Ramosetron Hydrochloride Tablets 2.5mcg, 5mcg, 0.1mg & Injecton 0.3mg /2ml	1. Tablets 0.1mg & Injection 0.3-- for the prevention and treatment of gastrointestinal symptoms (nausea and vomiting) associated with emetogenic cancer chemotherapy. 2. Tablets 2.5mcg & 5mcg--- for the treatment of diarrhoea predominant irritable bowel syndrome.	11.11.2009
174	Tadalafil tablet 20 mg (Additional Indication)	For the treatment of pulmonary arterial hypertension	14.11.2009
175	Flurbiprofen Sodium 0.03% Ophthalmic solution USP	for the reduction of post-operative inflammatory condition	14.11.2009
176	Dexmedetomidine HCl Injection (Additional Indication)	Sedation of non-intubated patients prior to and/or during surgical and other procedure	14.11.2009
177	Paliperidone ER tablet 12 mg (Additional Strength)	Same as approved	14.11.2009
178	1) Triticum Vulgare Topical Cream Each 100gm of cream contains: Aqueous extract of Triticum Vulgare (dry residue 200mg / 100ml) 15gm 2-phenoxyethanol Eur. Ph.....1gm 2) Triticum Vulgare Vaginal Pessary Each 3.5gm of vaginal pessary contains: Aqueous extract of Triticum Vulgare (dry residue 200mg/ 100ml)0.60gm 2-phenoxyethanol Eur. Ph.....0.04gm	1) Triticum Vulgare Cream is indicated for the treatment of ulcers and bed sores. 2) Triticum Vulgare Vaginal Pessary is indicated for the treatment of phlogistic and dystrophic disorders of the female genital tract.	14.11.2009
179	Febuxostat Tablets 80mg / 120mg	For treatment of chronic hyperuricemia in conditions where urate depression has already occurred (including a history, or presence of tophus and /or gouty arthritis).	14.11.2009

180	Euphorbia Prostrata Dry Extract :100mg tablet (addl. Indication)	For the treatment of 3° and 4° haemorrhoids (Addl. Indication).	14.11.2009
181	Euphorbia Prostrata dry extract ethanolic 80% v/v[(35-70):1] cream 1% w/w	For the treatment of 1° and 2° internal haemorrhoids.	14.11.2009
182	Lactobacillus Rhammnosus 1 billion cells + Saccharomyces Boulardi 125 mg + Zinc Enriched yeast 20 mg sachets & capsules	For the treatment of acute diarrhoea in children	4.11.2009
183	Nimesulide 1.0% w/w + Ethanol 31% w/w topical solution	For the local application in relieving pain in acute low backache, tendonitis, tenosinovitis and sprains	17.11.2009
184	Diacerein Modified Release Capsule 100mg	Symptomatic treatment of osteoarthritis of knee & hip	20.11.2009
185	Amlodipine 5mg/10mg/5mg/10mg/10mg + Valsartan 160mg/160mg/160mg/160mg/320mg + Hydrochlorothizide 12.5mg/12.5mg/25mg/25mg/25mg Tablets	For the treatment of essential hypertension	24.11.2009
186	Maraviroc Tablets 150mg/300mg.	For the treatment of patients infected with CCR5- trophic HIV-1.	25.11.2009
187	S (+) Etodolac 150/200/300mg + Paracetamol 500/500/500mg Tablets	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis	25.11.2009
188	Tacrolimus Granules for oral suspension 0.2/1 mg per sachet	Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient	26.11.2009
189	Rifaximin Dispersible Tablet 200mg	For infections diarrhoea in adults	26.11.2009
190	Prednisolone Sodium Phosphate Orally Disintegrating Tablet 10/15/30mg	Indicating for condition required Glucocorticoids activity including collagen disease, allergic disease and hypersensitive reaction	26.11.2009
191	Cinitapride Hydrogen Tartrate ER Tablet 3mg	For the treatment of gastroesophageal reflux disease (GERD) and functional inconveniences of the	26.11.2009

		gastrointestinal motility	
192	Sevelamer Carbonate (Additional Indication)	for control of serum phosphorus in patients with chronic kidney disease on haemodialysis or peritoneal dialysis and patients with CKD not on dialysis with serum phosphate > 5.5 mg/dl	26.11.2009
193	Oxcarbazepine Tablets (Additional Indication)150/300/600 mg	Monotherapy in the treatment of partial seizures in children ages 4-16	26.11.2009
194	Ketoprofen plaster 30 mg (7cm X 10 cm)	for the relief of musculoskeletal pain & inflammation	11.12.2009
195	Acipimox Capsules 250mg.	As adjunctive therapy to diet and weight loss in the treatment of type IIa, IIb and IV lipid disorders.	26.11.2009
196	Amisulpiride SR Tablet 100 mg	Same as approved	27.11.2009
197	Mycophenolate Sodium Enteric coated tablet 540 mg (Additional Strength)	Same as approved	29.10.2009
198	Loteprednol etabonate 0.5% w/v + Moxifloxacin 0.5% w/v ophthalmic Suspension	For the treatment of post operative steroid responsive inflammatory ocular infections or risk of bacterial ocular infections exists	1.12.2009
199	Ropinirole ER tablet 2/4/8mg	for the treatment of signs & symptoms of idiopathic Parkinson's disease	3.12.2009
200	Diclofenac Diethyl amine transdermal patch 100 mg/37.5 sq cm (Additional Strength)	same as approved	4.12.2009
201	Lornoxicam ER Tablet 8 mg (Additional Strength)	same as approved	11.12.2009
202	Flurbiprofen plaster 20 mg (7cm X 10cm)	for the relief of pain & inflammation due to rheumatoid arthritis , osteoarthritis and allied disorder	11.12.2009
203	Carvedilol Phosphate ER tablet 10/20/40/80mg	1. Mild to severe chronic heart failure. 2. Left ventricular dysfunction following myocardial infarction in clinically stable patients 3. hypertension	11.12.2009

204	Halometasone monohydrate 0.05% w/w + Fusidic acid 2.00% w/w cream	For the treatment of acute and chronic infected eczematous dermatitis	15.12.2009
205	Glimepiride 1/2 mg + Metformin 500 mg + Atorvastatin 10 mg tablets	For the treatment of type II diabetes mellitus associated with dyslipidemia	17.12.2009
206	Betahistine Di hydrochloride CR capsule 24/32/48mg	indicated in the treatment of Menier's syndrome, characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss	17.12.2009
207	Gefitinib tab 250mg (Additional Indication)	Indicated for the first line treatment of patients with locally advanced or metastatic non small cell lung cancer (NSLC) who have activating mutationof the EGFR TK".	18.12.2009
208	Midazolam Hcl Syrup 2mg/ml	For selection,anxiolysis and amnesia prior to diagnostic, therapeutic or endoscopic procedure or before induction of anesthesia.	18.12.2009
209	Guaiphenasin Syrup 133mg/5ml	For the treatment of productive cough accompanied by phlegm	18.12.2009
210	Balofloxacin Tablet 100mg	for the treatment of uncomplicated urinary tract infectins (such as cystitis and urethritis)	22.12.2009
211	Xylometazoline 0.5 mg + Ipratropium 0.6 mg Nasal spray	For symptomatic treatment of nasal congestion with running nose (rhinorrhea)	23.12.2009
212	Doxofylline 400 mg + Ambroxol 30 mg Tablets	For the treatment of patients with bronchial asthma and COPD, when use of both the drug is appropriate	23.12.2009
213	Ribavirin Capsules 200mg (Addl. Strength)	Indicated in combination with peg interferon alpha-2b for the treatment of naïve adult patients with chronic hepatitis C with clinically stable HIV co-infection.	24.12.2009
214	Formoterol 6 mcg + Mometasone furoate 100/200/400mcg Metered dose Inhaler & Dry Powder Inhalation	For the treatment of patients with bronchial asthma and COPD, where the use of combination is found appropriate	30.12.2009
215	Chlorohexidine Gluconate Gel 0.2%	For the prevention of Plaque and treatment of gengivitis.	30.12.2009
216	Chlorohexidine Gluconate Mouth wash 0.1%	For the prevention of Plaque and treatment of gengivitis.	30.12.2009

217	Levodropizine Eur. Ph. 30mg + Chlorpheniramine maleate IP 2mg per 5 ml Syrup	For the treatment of non-productive cough	06.07.09
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