

LIST OF APPROVED DRUG FROM 01.01.2010 TO 31.12.2010

S.NO	PRODUCT NAME	INDICATION	DATE OF APPROVAL
1	Ferrous ascorbate 100mg + Folic acid 1.1 mg tablet and Omega-3-fatty acid 200mg capsules combikit	For iron, folic acid & omega-3-fatty acid deficiency	08/01/2010
2	Sphaeranthus Indicus Extract Tablets 700mg	For the management of psoriasis.	08/01/2010
3	Febuxostat 40mg Additional Strength	Same As approved	16/01/2010
4	Dexamethasone Intravitreal Implant 0.7mg (in solid polymer drug delivery system)	For the treatment of macular edema following branch retinal vein occlusion (CRVO)	16/01/2010
5	Buclizine Hcl 25mg Tablet (Additional Indication)	For the Symptomatic treatment of various allergic conditions (rhinitis, conjunctivitis and urticaria) and for prevention and treatment of motion sickness	16/01/2010
6	Pemetrexed Disodium 500mg/100mg Powder for Injection (additional indication)	Indicated as a monotherapy for the maintenance treatment of locally advanced or metastatic Non Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel.	16/01/2010
7	Levobetaxolol HCl Ophthalmic Suspension 0.5%	For lowering of intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension.	16/01/2010
8	Sarpogrelate Hydrochloride film coated Tablets 100mg	For the improvement of ischemic symptoms including ulcer, associated with chronic arterial occlusion.	16/01/2010
9	Propanol 1-ol 18gm + Ethanol 100% 45gm/100ml solution	For hygenic and surgical hand disinfection	18/01/2010
10	Aliskiren 150/160mg + Valsartan 300/320mg tablets	For the treatment of hypertension	19/01/2010

11	Piroxicam 20mg tab& Paracetamol 500mg tab combikit	For treatment of fever and pain associated with acute upper respiratory tract inflammation, acute musculoskeletal disorders, pain after operative intervention and following trauma, chronic condition like rheumatoid arthritis, osteoarthritis etc for short term management of acute painful episodes.	19/01/2010
12	Soybean oil 60gm + Triglycerides (medium chain) 50gm + olive oil purified fish oil 30gm + dl-alpha-tocopherol 163-225mg + glycerol (anhydrous) 25gm + Egg lecithin 12gm + sodium hydroxide (to approx pH 8) + sodium phosphate 0.3mg emulsion for infusion in 100ml.	Total parenteral nutrition following major abdominal, major thoracic or major urological surgery	19/01/2010
13	Raltegravir (as Potassium) film coated Tablets 400mg	In combination with other anti retroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in treatment experienced patients with evidence of HIV-1 replication despite ongoing retroviral therapy.	27/01/2010
14	Deflazacort Tablet 18mg (Additional Strength)	Same as approved	30/01/2010
15	Pregabalin SR Tablet 75mg (Additional Strength)	Same as approved	30/01/2010
16	Rivaroxaban film coated Tablets 10mg	For the prevention of venous thromboembolism in patients (VTE) in adult patients undergoing hip or knee replacement surgery.	30/01/2010
17	Cinnarizine 20mg + Dimenhydrinate 40mg tablets	For the treatment of vertigo	03/02/2010
18	Lipid Based Amphotericin-B Gel 0.1%	Indicated in the treatment of cutaneous and mucocutaneous mycotic infections caused by candida (Monilia) species.	05/02/2010
19	Sodium Hyaluronate Injectable Gel 14mg/ml, 18mg/ml, 25.5mg/ml (Additional Strength)	Same as approved	06/02/2010
20	Milnacipran Hcl 12.5mg (Addl. Strength)	Same as approved	06/02/2010
21	Ropinirole 6mg ER Tablets (Addl. Strength)	Same as approved	06/02/2010

22	Coseal Surgical Sealent 2/4/8ml (Addl. Indication)	<p>(1) Enforcement of suture and staple lines in lung resection procedures.</p> <p>(2)Patients undergoing cardiac surgery to prevent or reduce the incidence, severity and extend of post surgical adhesion formation.</p> <p>(3)Patients undergoing laparotomy or laproscopic abdomino-pelvic surgery as an adjunct to good surgical technique intended to reduce the incidence, severity and extent of post surgical adhesion formation.</p>	06/02/2010
23	Pregabalin SR 75/150/300mg + Methylcobalamin 1500mcg tablets	For the treatment of adult patients with peripheral neuropathy	09/02/2010
24	Ivabradine Hcl Tablets 5/7.5mg (Additional Indication)	For Symptomatic Treatment of chronic stable angina pectoris in coronary artery disease patients with normal sinus rhythm, indicated in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is >60bpm.	10/02/2010
25	Paracetamol Solution for Infusion (10mg/ml) in 50ml (Additional Packsize)	Same as approved	10/02/2010
26	Ketorolac Tromethamine Ophthalmic Solution 0.45%	Indicated for the treatment of pain and inflammation following cataract surgery.	10/02/2010
27	Cytarabine Injection 100mg Additional Packsize (20ml)	In combination with other approved anticancer drugs is indicated for remission induction in acute non-lymphocytic leukemia of adults and children. It has also been found useful in the treatment of acute lymphocytic leukemia and the blast phase of chronic myelocytic leukemia. Intrathecal administration of cytarabine is indicated in the prophylaxis and treatment of meningeal leukemia.	10/02/2010
28	Olopatadine Hcl Nasal Spray 0.6% w/w (Additional Indication)	For the relief of the symptoms of seasonal allergic rhinitis in patients 6 years of age and older.	10/02/2010

29	Sodium chloride 6.80gm + Potassium chloride 0.30 gm + Calcium chloride dihydrate 0.37gm + Magnesium chloride hexahydrate 0.20gm + Sodium acetate trihydrate 3.27gm + L-malic acid 0.67gm in 1000ml solution for infusion	Replacement of extracellular fluid losses in case of isotonic dehydration, especially if acidosis is being imminent or present	11/02/2010
30	Chemically Modified Sodium Hyaluronate and Caboxymethylcellulose Absorbable Adhesion Barrier.	As an adjunct in abdominal or pelvic surgery for reducing the incidence, extent and severity of postoperative adhesions at the site of placement.	11/02/2010
31	Lornoxicam 4mg/4mg + Thiocolchicoside 4mg/8mg tablets	For the treatment of patients with acute painful musculoskeletal conditions	12/02/2010
32	Cefixime 100mg/200mg + Cloxacillin 500mg/500mg tablets	For the treatment of adult patients with upper & lower respiratory tract infections, skin and soft tissue infections	12/02/2010
33	Celecoxib Mouth Dissolving Tablet 50/100/200 mg	For the Treatment of Osteoarthritis and Rheumatoid Arthritis	25/02/2010
34	Propofol 2% w/v Injection (additionalStrength)	Same as Approved	27/02/2010
35	Spironolactone 25mg + Furosemide 20mg tablets	For treatment of resistant oedema associated with secondary hyperaldosteronism; resistant hypertension, chronic cardiac failure and hepatic cirrhosis	05/03/2010
36	Olopatadine5mg + Ambroxol30mg tablets	For the management of cough in adult patients only	05/03/2010
37	Methylcobalamin750mcg + Pregabalin75/150mg + Vitamin B61.5mg + Folic acid0.75mg + Benfothiamine7.5mg capsules	For the treatment of painful diabetic neuropathy in adults only	05/03/2010
38	Calcium acetate 435mg + Magnesium carbonate 235mg tablets	For the management of hyperphosphatemia in adults patients with renal failure being treated with dialysis (hemodialysis or peritoneal dialysis)	05/03/2010
39	Dicyclomine2.5mg + Dried Aluminium Hydroxide200mg + Light Magnesium Oxide100mg + Simethicone 20mg per 5ml suspension.	For the treatment of the symptoms of functional gastrointestinal disorders like irritable bowel syndrome, functional dyspepsia, peptic ulcers., GERD which includes smooth muscle spasm, flatulence, abdominal distension,	05/03/2010

		hyperacidity, gastric distress, bloting etc.	
40	Sertaconazole 2% w/v+ Zinc Pyrithione 1% w/v Shampoo	For the treatment in adults patients with dandruff/seborrheic dermatitis of the scalp	05/03/2010
41	Faropenam Sodium Extended Release Tablet 225/300/450 mg	For the Treatment of respiratory tract infections, urinary tract infection, skin and skin structure infections and gynaecological infections	08/03/2010
42	Amlodipine5mg + Ramipril10mg/5mg Tablets (additional strength)	For the treatment of hypertension only	10/03/2010
43	Doxofylline MR Tablet 650 mg	For the treatment of Bronchial Asthma and COPD in Adults	11/03/2010
44	Lidocaine7.5mg + Prilocaine2.5mg per acutation spray	For the treatment of adult male patients with premature ejaculation	12/03/2010
45	Pramipexole Di HCl monohydrate ER Tablet 0.375/0.75/1.5/3/4.5 mg	For the treatment of the sign and symptoms of idiopathic parkinsons disease	13/03/2010
46	Drosperinone 3mg + Ethinyl Estradiol0.02mg tablets	For the treatment of symptoms of premenstrual dysphoric disorders (PMDD) in women (additional indication)	16/03/2010
47	Miglitol 25 mg + Metformin 500mg tablets	Additional Strength	16/03/2010
48	Propranolol 40mg (SR Pellets) + Fluarizine 5mg/10mg capsules	For the prophylaxis of migraine	16/03/2010
49	Citicholine 500mg + Piracetam 400mg Tablets	For the treatment of acute stroke	16/03/2010
50	Diclofenac 50mg + Chlorzoxazone500mg Tablets	For the treatment of acute inflammation conditions associated with spasm in adults only	16/03/2010
51	Mecobalamin 750 mcg + Pyridoxine 1.5mg + Nicotinamide 45 mg + Benfotiamine 150mg Tablets	For the treatment of diabetic neuropathy in adults	16/03/2010
52	Etoricoxib 1%+ Menthol 5% Spray	For the topical treatment of acute musculoskeletal pain	16/03/2010
53	Pantoprazole 40mg + Cinitapride (ER) 3mg Capsules	For the treatment of patients suffering from non-ulcer dyspepsia (NUD) or gastroesophageal reflux disease (GERD)	17/03/2010
54	Atorvastatin 20mg + Ramipril	Additional higher strength	17/03/2010

	2.5mg/5mg Capsules		
55	Lamotrigine Orodispersible Tablet 12.5 mg(additional strength)	Same as Approved	20/03/2010
56	Trabectedin powder for Conc. solution for infusion (Additional Indication)	In combination with pegylated liposomal doxorubicin, it is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer	20/03/2010
57	Lornoxicam 8mg/8mg + Thiocolchicoside 4mg/8mg Tablets	Additional higher strength	23/03/2010
58	Diclofenac sodium SR Tablet 150 mg	For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post operative pain following dental surgery etc.	26/03/2010
59	Magnesium Valproate CR Tablet 200/ 300/400/ 500 mg (additional strength)	Same as Approved	26/03/2010
60	Lidocaine 2.5% w/w+Prilocaine 2.5% w/w Gel	Additional higher Strength	26/03/2010
61	Nicotinic Acid and Laropiprant Modified Release Tablets: Nicotinic Acid.....1000 mg Laropiprant.....20 mg	1. For the treatment of dyslipidaemia, particularly in patients with combined mixed dyslipidaemia (characterised by elevated levels of LDL-cholesterol and triglycerides and low HDL-cholesterol) and in patients with primary hypercholesterolemia (heterozygous familial and non-familial). 2. In combination with HMG-CoA reductase inhibitors (statins), when cholesterol lowering effect of HMG-CoA reductase inhibitor monotherapy is inadequate. It can be used as monotherapy only in patients in whom HMG-CoA reductase inhibitors are considered inappropriate or not tolerated. Diet or other non-pharmacological treatments (e.g. exercise, weight reduction) should be continued during therapy.	26/03/2010
62	Pantoprazole Mouth Dissolving Tablet 20/40 mg	For the treatment of gastric ulcer, duodenal ulcer & gastroesophageal	30/03/2010

		reflux disease (GERD).	
63	Praziquantel 175mg + Pyrantel 504mg + Febental 525mg Tablets	For the treatment of mixed infections with roundworms and tapeworms in dogs	30/03/2010
64	Difluprednate Ophthalmic Emulsion 0.05% w/v	For the treatment of inflammation and pain associated with ocular surgery.	30/03/2010
65	Tolperisone Hcl SR 450mg Tablets	For the relief of painful muscle spasms of the skeletal musculature.	30/03/2010
66	S(-)Metoprolol 25mg/50mg (ER) + Atorvastatin (IR)10mg tablets	For the treatment of patients with both essential hypertension and hypercholesterolemia	04/01/2010
67	Atorvastatin10mg + Ramipril 5mg + Aspirin (EC pellets) 75mg/150mg + Metoprolol (ER tablets) 25mg Capsules	For secondary prophylaxis of ischemic heart disease in patients where use of such combinations in appropriate	05/04/2010
68	Lamotrigine 25mg Modified Release Tablet (Addl. Strength)	Same as Approved	05/04/2010
69	Imatinib Mesylate 100/400mg Tablets (Addl. Indication)	Adjuvant treatment of adult patients following resection of gastro-intestinal stromal tumours (GIST)	05/04/2010
70	Azithromycin SR Granules for Oral Suspension 1gm (Addl. Strength)	Same as Approved	05/04/2010
71	Gemfibrozil Capsule USP & Gemfibrozil Tablet USP 200mg/600mg (Addl. Indication)	For the treatment of other dyslipidemias: (a) Fredrickson Types III and V.(b) Associated with diabetes.(C) Associated with xanthomata.	05/04/2010
72	Ibuprofen 400mg + Chlorzoxazone 500mg Tablets	For the short term treatment of musculoskeletal pain associated with inflammation and spasm in adults only	07/04/2010
73	Doxophylline (SR) 400mg/800mg + Montelukast 10mg/10mg Tablets	For the treatment of bronchial asthma in adults	07/04/2010
74	Dronedarone(as Hydrochloride) film coated tablet 400 mg.	To reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age > 70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter > 50mm or left ventricular ejection fraction [LVEF] < 40%),	08/04/2010

		who are in sinus rhythm or who will be cardioverted.	
75	Dosulepin Hcl Tablet 25mg/75mg (Additional Indication)	For the treatment of chronic pain.	08/04/2010
76	Prasugrel (as Hydrochloride) film coated tablet5 mg / 10mg.	<p>To reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI) as follows:</p> <ul style="list-style-type: none"> • Patients with unstable angina (UA) or non-ST-elevation myocardial infarction (NSTEMI). • Patients with ST-elevation myocardial infarction (STEMI) when managed with primary or delayed PCI. 	13/04/2010
77	Tofisopam uncoated tablet JP... 50/100mg	For the treatment of anxiety and depression.	13/04/2010
78	Zotepine tablet25/50/100mg	For the treatment of schizophrenia	15/04/2010
79	Armodafinil uncoated tablet ..50/150/250mg	To improve wakefulness in patients with excessive sleepiness associated with treated obstructive sleep apnea (OSA), shift work sleep disorder (SWD) or narcolepsy.	23/04/2010
80	Indacaterol (as Maleate) Inhalation Powder Hard Capsules150/300mcg	For maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).	24/04/2010
81	Ranolazine ER Tablets 750mg (Additional Strength)	Same as Approved	24/04/2010
82	Tacrolimus Capsules 3mg (Additional Strength)	Same as approved	24/04/2010
83	Cefixime 100mg/200mg + Ofloxacin 100mg/200mg Tablets	For the treatment of patients with typhoid fever and urinary tract infection in adults	26/04/2010

84	Liquid paraffin 6% + White soft paraffin 15%w/v Cream	For symptomatic relief of dermatological condition associated with dry skin including atopic dermatitis, eczema, pruritus, ichthyosis, xerosis, psoriasis	29/04/2010
85	Levosimendan Injection 2.5mg / ml	For the short term treatment of acutely decompensated chronic heart failure (ADHF) in situations where conventional therapy is not sufficient and in cases where inotropic support is considered appropriate.	30/04/2010
86	Thiocholchicoside SR Tablet 16 mg	As an adjuvant treatment in painful spasms associated with degenerative vertebral disorders and vertebral static problems, torticollis dorsal pain, low back pain, traumatological and neurological disorders.	31/04/2010
87	Telmisartan 40/80 mg+ Indapamide SR 1.5/1.5 mg tablet	For the treatment essential hypertension	05/04/2010
88	one strip of 3 uncoated tablets of artesunate 150mg & one strip of 2 uncoated tablets of FDC of Sulphadoxine IP 500mg + Pyrimethamine IP 25mg	Additional strength	05/04/2010
89	Lapatinib Ditosylate Tablets 250mg (addl. Indication)	In combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.	10/05/2010
90	Pentosan polysulfate Sodium Cpasules 100mg	For the relief of bladder pain or discomfort associated with interstitial cystitis.	11/05/2010
91	Indapamide (SR) 1.5mg/1.5mg +Nebivolol 2.5mg/5mg tablet	For the treatment of hypertension not controlled with monotherapy	12/05/2010
92	Cinitapride (ER) 3mg + Omeprazole (EC) 20mg Capsules	For the treatment of gastirc ulcer,gastroesophageal reflux disease(GERD) & Dyspepsia not responding to omeprazole alone	12/05/2010
93	Timolol Maleate Long Acting Ophthalmic Solution 5mg/ml	For the treatment of elevated intraocular pressure in patient with ocular hypertension or open angle glaucoma.	14/05/2010

94	Telmisartan tablet 20/40/80 mg(Additional indication)	For the prevention of cardiovascular morbidity and mortality in patient 55 years older at high risk of cardiovascular disease	14/05/2010
95	Dexketoprofen Trometamol 25mg + Thiocolchicoside 4mg tablets	For the treatment of acute low back pain and other musculoskeletal painful & inflammatory conditions in adult patients	20/05/2010
96	Troxipide film coated Tablets 50mg /100mg	For the treatment of Gastric ulcers and for amelioration of gastric mucosal lesions (erosion, hemorrhage, redness and edema) in the diseases such as acute gastritis, acute exacerbation stage of chronic gastritis.	20/05/2010
97	Ambrisentan film coated Tablets 5 mg / 10mg	For the treatment of pulmonary arterial hypertension (WHO Group I) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening.	24/05/2010
98	Rosuvastatin Calcium Tablet(Additional Indication)	Risk reduction of MI stroke and arterial evascularisation procedure in patients without clinically evident CHD but with multiple risk factor	24/05/2010
99	Paracetamol SR 1000mg Bilayered tablet	For symptomatic treatment of pain and fever	24/05/2010
100	Tacrolimus PR Caps 0.5/1/5 mg	For Prophylaxis of transplant rejection in adult kidney or liver allograft rejection	24/05/2010
101	Rizatriptan Benzoate orally disintegrating tablet 10 mg(Additional Dosage Form)	Same as Already approved	24/05/2010
102	Ramipril 1.25/ 2.5/5/10 mg(Additional Indication)	For the treatment of non-diabetic overt glomerular or incipient nephropathy	24/05/2010
103	Exenatide Inj. (Additional Indication)	Use in patients with type-2 diabetes mellitus who are using a thiazolidinedione alone or in combination with metformin but have not achieved adequate glycemic control	24/05/2010

104	Temozolomide lyophilised powder 100mg / vial	For the treatment of "Adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment." Children from the age of three years, adolescents and Adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.	24/05/2010
105	Fluticasone Propionate 50mcg/125mcg/250mcg + Salmeterol xinafoate 25mcg/25mcg/25mcg Powder for inhalation	For the maintenance treatment of asthma and for the treatment of COPD associated with chronic bronchitis	25/05/2010
106	Cross linked Hyaluronic Acid 24mg + Lidocaine 3mg Pre-filled syringes	For filling any medium sized depression of the skin via mid dermis injection as well as for lip definition. The presence of lidocaine is meant to reduce the patients pain during the treatment	28/05/2010
107	Aceclofenac 1% w/w + Menthol 5% Spray	For the treatment of acute painful inflammatory conditions in adults only	28/05/2010
108	Metformin SR 500mg/500mg + GliclazideSR 60mg/30mg + Pioglitazone 15mg/15mg 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 glycemic control	28/05/2010
109	3 tablets of artesunate 100mg + 3 tablets of Artesunate 50mg & 2 tablets of FDC of Pyrimethamine 25mg + Sulphadoxine 500mg combipack	Additional strength	28/05/2010
110	Calcium carbonate 600mg +Simethicone 80mg Chewable tablet	To relieve the uncomfortable symptoms of acid indigestion, heart burn, gas or sour stomach	28/05/2010
111	Activated Dimethicone 50mg + Magnesium Hydroxide 250mg+ Dried Aluminium Hydroxide250 mg + Sorbitol (70%)1.25 gm /5ml Solution	For treatment of symptoms of hyperacidity (e.g. heartburn, epigastric discomfort, or their equivalents) that are often associated with dyspepsia, peptic	28/05/2010

		ulcers, gastritis, peptic esophagitis and indicated for relief of flatulence	
112	Aspirin 75mg + Simvastatin 10mg/20mg + Lisinopril 5mg/10mg + Atenolol 25mg/50mg Tablets	For secondary prevention of coronary heart disease/stroke in patients where use of such combination is appropriate	01/06/2010
113	Irsogladine Maleate Tablet 2mg /4mg	For gastric ulcers, improvement of gastric mucosal lesion (erosion, hemorrhage, redness and edema) caused by acute gastritis and acute exacerbation stage of chronic gastritis.	05/06/2010
114	Lacosamide film coated tablet 50mg /100mg /150mg /200mg	As an adjunctive treatment of partial onset seizures in patients > 17 years of age.	10/06/2010
115	Carmustine for inj. 100 mg	Indicated as palliative therapy as a single agent or in established combination therapy with other approved chemotherapeutic agents in the following: 1. Brain tumors—glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumors. 2. Multiple myeloma—in combination with prednisone. 3. Hodgkin's Disease—as secondary therapy in combination with other approved drugs in patients who relapse while being treated with primary therapy, or who fail to respond to primary therapy. 4. Non-Hodgkin's lymphomas—as secondary therapy in combination with other approved drugs for patients who relapse while being treated with primary therapy, or who fail to respond to primary therapy.	10/06/2010
116	Monteleukast Sodium Tablet 10mg; Monteleukast Sodium 4/5mg Chewable Tablet; Monteleukast Sodium Oral granule(Additional	For the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.	12/06/2010

	Indication)		
117	Ramosetron Dispersible Tablet 0.1 mg	For the prevention and treatment of gastrointestinal symptoms(nausea and vomiting) associated with ematogenic cancer chemotherapy	12/06/2010
118	Amitraz 2% w/v pour on solution	For the control of ticks on cattle and ostriches	12/06/2010
119	Flupirtine Maleate Capsules 100mg	For treatment of acute and chronic pain ,i.e, for painful increased muscle tone of the posture and motor muscles, primary headache, tum or pain, dysmenorrhea and pain after traumatologic / orthopaedic operations and injuries.	12/06/2010
120	Lidocaine Patch 350mg (Additional Pack Size)	For the relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.	17/06/2010
121	Oseltamivir Phosphate (Additional indication)	In the treatment of children 6 to 12 months of age during a pandemic influenza outbreak.	19/06/2010
122	Methylcobalamin 1500mcg +Folic acid 0.7mg +Niacinamide 12mg injection	For the treatment of diabetic neuropathy in adults	23/06/2010
123	Methylcobalamin 1500mcg +Pyridoxine 100mg +Nicotinamide 100mg injection	For the treatment of diabetic neuropathy in adults	23/06/2010
124	1 tablet of Tenofovir disoproxil 300mg + Lamivudine 300mg & 2 tablet of Nevirapine 200mg combipack	For the treatment of HIV infection in adults	23/06/2010
125	Vitamin A (oily form) as palmiate 2000IU + Vitamin B1 1mg + Vitamin B2 1mg + Vitamin B6 1.34mg + Vitamin B12 1mcg + Ascorbic acid 33.3mg + Vitamin D3 200IU + Folic acid 0.3mg + Calcium pantothenate 1mg + Niacinamide 15mg + Dibasic calcium phosphate 100mg + Phosphorus 77mg+ Ferrous fumarate 50mg + Copper 0.01mg+ Potassium iodide 0.0015mg + Heavy magnesium oxide 1mg + Manganse sulphate 0.01mg + Potassium	For the treatment of vitamin deficiency states in adults	23/06/2010

	sulphate 1mg + Zinc sulphate 0.15mg Capsule		
126	Ramipril MR Capsules 2.5/5 mg (Additional Strength)	Same As Approved	03/07/10
127	Sitagliptin Phosphate 25/50/100 mg Tablet (Additional Indication)	(i) Use of Sitagliptin Phosphate in combination with Metformin and a PPAR γ agonist as an adjunct to diet & exercise in adult patients with type-2 Diabetes mellitus who are inadequately controlled on combination therapy with Metformin and a PPAR γ agonist. (ii) Use of Sitagliptin Phosphate in combination with insulin, alone or in combination with Metformin.	03/07/10
128	Erlotinib HCl 25/100 mg Tablet (Additional Indication)	As monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum based first line chemotherapy.	03/07/10
129	Gemcitabine HCl injection 2gm/vial (Additional Strength)	Same as Approved	03/07/10
130	Etizolam 0.25 mg tablet (Additional Strength)	Same As Approved	03/07/10
131	Dexketoprofen 1.25% w/w + Linseed Oil 3.0% w/w + Menthol 5% w/w + Methyl Salicylate 10% w/w (12.5mg)	For the topical treatment of acute musculoskeletal pain	06/07/10
132	Cefuroxime Sodium 750/1500mg + Sulbactam Sodium 375/750mg	For the treatment of mild to moderate lower respiratory tract infection	06/07/10
133	HPMC 0.3% + Dextran 0.1% + Glycerin 0.2%	For the temporary relief of burning and irritation due to dryness of the eye and for use as a protection against further irritation. For the temporary relief of discomfort due to minor irritations of the eyes or to exposure to wind or sun	06/07/10

134	Cyanocobalamin 15mcg+Chromium Picolinate USP 250mcg+Folic Acid USP 1500 mcg+Nicotinamide IP100 mg+Pyridoxine 3mg +Selenius Acid USP 100mcg+Zinc Sulfate Monohydrate USP 61.8 mg eq. to 22.5 mg	For Mineral & Vitamins deficiency states in adult patients	06/07/10
135	Methylparaben 0.15% w/w +Propyl paraben 0.05% w/w+Glycerin 20% w/w +CMC 1.74% w/w +Allantoin 0.5% w/w +Benzyl alcohol 0.5% w/w.	For short term treatment of chronic wounds including stage III & IV pressure sores, leg ulcers	06/07/10
136	Clonazepam IR 0.5mg/0.5mg+ Paroxetine CR 12.5/25mg	For the treatment of patients with co-morbid depression and anxiety	08/07/10
137	Nilotinib Capsules 200mg	For the treatment of chronic and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML) in adult patients resistant to or intolerant to prior therapy that included imatinib.	10/07/10
138	Imipenem 50mg + Clistatin 50mg	Treatment of infection caused by susceptible bacteria for the following indication as in neonates and infants (below 3 months of age) 1. Lower respiratory tract infections 2. Urinary tract infections 3. Intra-abdominal infections 4. Bacterial septicemia 5. bone and joint infections 6. Skin and Skin structure infections 7. Bacterial endocarditis	14/07/10
139	Lidocaine Lozenges 100mg (Additional Strength)	Same as Approved	15/07/10
140	Metoprolol succinate ER 25/50 mg+Telmisartan 20/40mg	For the treatment of essential hypertension	16/07/10
141	Etodolac 300/300mg +Thiocolchicoside 4/8mg	For the treatment of patients with acute painful musculoskeletal conditions	19/07/10
142	Celecoxib 100/200mg +Diacerein 50/50mg	For the treatment of adult patients with osteoarthritis of knee and/or hip joints	19/07/10
143	Metoprolol succinate ER 25mg+50mg + Olmesartan 20/20mg	For the treatment of essential hypertension	19/07/10

144	1 tablet of Atazanavir 300mg & 1 tablet of ritonavir Ritonavir 100mg & FDC of Tenofovir Disoproxil fumarate 300mg + Lamivudine 300mg (Each Co-pack contains :- 1 capsule of Atazanavir 300mg & 1 Tablet of Ritonavir 100mg & 1 Tablet of FDC of Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg)	For the treatment of HIV infections in adults	19/07/10
145	Gliclazide 40/80mg+Metformin 500mg+Pioglitazone15mg	Additional strength	19/07/10
146	Lidocaine HCl Ophthalmic Sterile Gel 35 mg/ml	Indicated for ocular surface anaesthesia during ophthalmologic procedures.	30/07/10
147	Naftopidil Tablets 25/50/75mg	For the treatment of dysuria associated with benign prostratic hyperplasia.	30/07/10
148	Metformin 500/850/1000mg+Sitagliptin Phosphate 50/50/50mg (Additional Indication)	A) FDC is indicated as triple combination therapy with a PPAR γ agonist (i.e a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metfomin and a PPAR γ agonist. B) FDC is also indicated as add-on to insulin(i.e triple combination therapy) as an adjucnjt to diet and exercise to improve glycemic contrl in patients when stable dosage of insulin and metformin alone do not provide adequte control.	02/08/10
149	Bimatoprost Eye Drps 0.1mg/ml	for the treatment of hypotrichosis of the eye-lashes by increasing their growth including length, thickness & darkness.	05/08/10
150	S(+) Etodolac 5/10% w/w + Camphor 4% w/w + Menthol 10% w/w + Methyl salicylate 5% w/w + Linseed oil 3% w/w	For the painful & inflammatory conditions associated with joint, tendons, ligaments and muscles	05/08/10
151	Cefpodoxime 100/200mg+Dicloxacillin ER 500/500mg	For the treatment of lower RI, Skin and soft tissue, bone and joint infections and ENT infections in adult patients prone to antibiotic induced diarrhoea	06/08/10
152	Voglibose0.3 + Metformin (SR) 500mg	Additional higher strength	06/08/10

153	Amoxicillin Oral Suspension 200/400 mg per 5ml	in the treatment of infections due to susceptible strains of the designated micro-organisms in the condition of E.N.T infection, skin & skin structure infection, lower respiratory tract infection, genito-urinary tract infection, gonorrhoea, acute uncomplicated (anogenital & urethral) infections.	09/08/10
154	Olmesartan 40mg + Amlodipine 5mg (Additional Strength)	Additional indication: 1. For the treatment of hypertension alone or with other antihypertensive agents 2. To use as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals	09/08/10
155	Doripenem 500 mg powder for injection (Additional Indication)	Complicated intra-abdominal infections and complicated urinary tract infections, including complicated and uncomplicated pyelonephritis and cases with concurrent bacteremia	10/08/10
156	Nadolol tablet USP 20/40/80 mg	in the treatment of angina-pectoris, cardiac arrhythmias & essential hypertension.	20/08/10
157	Fluconazole For Oral suspension 50/200 mg per 5ml (Pack Size : 35ml)	for the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy.	20/08/10
158	Metformin 500/500mg + Repaglinide 1/2mg	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a meglitinide & metformin or who have inadequate glycemic control on a meglitinide alone or metformin	20/08/10
159	Hydroxyzine Hydrochloride SR Tablets 25/50/75mg	For management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine - mediated pruritus.	20/08/10
160	Rosuvastatin 5/10/20mg+Fenofibrate 67/145/160mg	For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function	23/08/10
161	Fexofenadine 120mg + Montelukast 10mg	For treatment of allergic rhinitis in adults only	31/08/10

162	Irinotecan HCl Trihydrate Injection 20 mg/ml (Pack Size 25ml)	for the treatment of metastatic colorectal cancer .	31.08.10
163	Cefixime SR 200mg/400mg + Ofloxacin SR 200mg/400mg Tablet	Additional strength	31.08.10
164	Ademetionine enteric coated Tablets ..200mg/400mg	For the management of intrahepatic cholestasis and liver disease.	01.09.10
165	Memantine HCl ER Tablet 28mg	in the treatment of moderate to severe Alzheimer's disease.	06.09.10
166	Buserelin Acetate injection 1mg/ml (Additional Indication)	indicated for the palliative (initial & maintenance treatment) of patients with hormone-dependent advanced carcinoma of the Prostate gland (Stage D).	08.09.10
167	Etodolac 400mg/400mg + Thiocolchicoside 4mg/8mg tablet	Additional higher strength	09.09.10
168	Montelukast Sodium 10 mg Tablet, Montelukast Sodium 4/5 mg Chewable Tablet and Montelukast Sodium Oral Granules (Additional Indication).	For The relief of perennial allergic rhinitis in adults & pediatrics patients 6 months of age and older.	11.09.10
169	Acyclovir SR Tablet 1200 mg	For the treatment of uncomplicated Herbis Zoster in immunocompetent patients.	11.09.10
170	Lornoxicam 4mg + Eperisone 50mg tablet	For the improvement of myotonic conditions caused by neck shoulder arm syndrome, scapulumeral periarthrititis and low back pain in adult patients only	13.09.10
171	Pirfenidone film coated tablet ...200mg	For the treatment of idiopathic pulmonary fibrosis.	14.09.10
172	Beclomethasone Dipropionate IP 0.025% w/w + Neomycin sulphate IP 0.5% w/w cream	Additional lower strength	15.09.10
173	Amlodipine 5mg/2.5mg + Valsartan 320mg/80mg + HCTZ 12.5mg/12.5mg tablet	Additional strength	21.09.10
174	Paracetamol 500mg/500mg +Thioclchicoside 4mg/8mg tablet	For the treatment of acute inflammation conditions associated with spasm in adults only	21.09.10

175	Ketorolac Tromethamine 0.4% w/v +Moxifloxacin 0.5% w/v Ophthalmic solution	Additional lower strength	21.09.10
176	Nilotinib Capsules 150 mg.	Treatment of newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase.	29/09/10
177	Levocloperastine (as Fendizoate) Suspension eq. to Levocloperastine Hcl 20mg / 5ml.	For the treatment of non productive cough in adult patients	29.09.10
178	Zileuton uncoated bilayered extended release tablet ...600mg	For the prophylaxis and chronic treatment of asthma in adults.	30.09.10
179	Etodolac 400mg + Paracetamol IP 500mg tablet	Additional higher strength	01.10.10
180	Dried Aluminium Hydroxide Gel IP 600mg +Magnesium Hydroxide IP 300mg +Simethicone IP 25mg +Oxetacaine BP 10mg per 5ml syrup	For the treatment of symptoms of functional gastrointestinal disorders like irritable bowel syndrome, functional dyspepsia, peptic ulcer, gastroesophageal reflux disease which include smooth muscle spasms, flatulence, abdominal distension, hyperacidity, gastric distress, bloating etc.	05.10.10
181	S(-) Metoprolol Succinate ER Eq. to S (-) Metoprolol tartarate 25mg/50mg + Clopidogrel (IR) 75mg/75mg tablet	For the treatment of essential hypertension who need antiplatelet therapy especially for prophylaxis of atherombotic event.	07.10.10
182	Exenatide Injection (Additional indication)	Exenatide is a glucagon like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.	09.10.10
183	Bimatoprost Ophthalmic Solution 0.01% w/v (Additional Strength)	Same as approved.	09.10.10

184	Drosperinone + Ethinylestradiol tablets Same as approved	For the treatment of moderate acne vulgaris in adult females, who have no known contraindications to oral contraceptive therapy, and have achieved menarche. It should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control.	09.10.10
185	Etodolac USP 400mg +Tolperisone HCL 150mg tablet	For the treatment of acute inflammation conditions associated with spasm in adults only	11.10.10
186	Citicoline 500mg +Piracetam 400mg per 5 ml syrup	Additional dosage form	11.10.10
187	Thiocolchicoside 0.25% +Methyl salicylate IP 100mg +Menthol IP 50mg +Absolute alcohol IP 50mg per gm gel	For the topical treatment of painful muscles spasms of skeletal musculature	11.10.10
188	Amlodipine Besylate IP Eq. to Amlodipine 10mg/5mg/2.5mg +Telmisartan 80mg/40mg/20mg + HCTZ 25mg/12.5mg/12.5mg tablet	For the treatment of essential hypertension	12.10.10
189	Pregabalin 150mg/75mg +Methylcobalamin 750mcg +Alpha lipoic acid 100mg +Pyridoxine 3mg +Folic acid 1.5mg capsule	For the treatment of painful diabetic neuropathy in adults only	12.10.10
190	Ferrous bisglycinate 60mg + Zinc sulphate monohydrate Eq. to Zinc 14mg + Copper as copper sulphate 1 mg + Selenium as selenomethionine 70mcg + Vitamin B6 IP 10mg + Methylcobalamin 1500mcg + Folic acid 5mg + Fish oil 10/40 (DHA 200mg) 500mg capsule.	For Vitamin and mineral deficiency	13.10.10
191	Combipack of 21 tablets of FDC of Ethinylestradiol IP 0.03 mg + Levonorgestrel IP 0.15 mg and 7 tablets of Ferrous Fumarate IP 75mg (Eq. to 24.375 mg of Ferrous iron)	As contraceptive pill for women	13.10.10
192	Amitriptyline Hydrochloride IP 4% w/w + Ketamine HCL eq. to Ketamine 2% w/w per gm cream.	For the treatment of patients suffering from neuralgia	13.10.10

193	Paracetamol IP 500mg + Phenylephrine HCL IP 5mg +Caffeine (anhydrous) IP 30mg + Diphenhydramine HCL IP 25mg tablet.	For the treatment of fever associated with cold, nasal congestion in adults	13.10.10
194	Levocetirizine dihydrochloride 2.5mg +Montelukast 5mg dispersible tablet	Additional strength	13.10.10
195	Calcium citrate maleate Eq. to elemental calcium 250mg +Vitamin D3 IP 200 IU tablet	For the treatment of calcium and Vitamin D deficiency states	13.10.10
196	Levonorgesterel 100mcg +Ethniyl estradiol IP 20mcg tablet	(Additional indication) For the treatment of moderate acne vulgaris in women more than 18 years of age who have no therapy contraindications to oral contraceptive therapy, desire contraceptiopl, and have achieved menarche	13.10.10
197	Eberconazole 1% w/w + Mometasone Furate USP 0.1% w/w cream	For the treatment of mild to moderate inflammed cutaneous mycoses	13.10.10
198	Lubiprostone Soft Gelatin Capsules8mcg /24mcg	1. For the treatment of chronic constipation in adults. 2. For the treatment of irritable bowel syndrome with constipation (IBS-C) in women > 18 years old.	16.10.10
199	Pazopanib (as Hydrochloride) film coated Tablets...200mg / 400mg	For the treatment of patients with advanced renal cell carcinoma.	16.10.10
200	Eltrombopag (as Olamine) Tablets ...25mg / 50mg	for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts).	16.10.10

201	Tolperisone HCL 150mg + Paracetamol IP 500mg tablet	For the treatment of patients with acute painful musculoskeletal conditions	21.10.10
202	Zaltoprofen film coated tablet ...80mg JP	For anti inflammatory and analgesic activity in rheumatoid arthritis, osteoarthritis, low back pain, peri-arthritis of shoulder, cervicobrachial syndrome, postoperative, post trauma, and post dental extraction.	31.10.10
203	Hyoscine Butylbromide 20 mg tablet (Additional Strength)	Same as Approved.	04.11.10
204	Cerebroprotein Hydrolysate injection (Lyophilised)1050mg / 2100mg (approx) equivalent to nitrogen....30mg / 60mg respectively.	For amelioration of cranial injury, cerebrovascular pathological sequelae and aprosexia in dementia.	04.11.10
205	Clebopride (as Malate) (1)Tablets...0.5 mg Ph. Eur. (2.) Syrup...0.1 mg / ml Ph. Eur. (3.) Injection...1 mg / 2mlPh. Eur.	For the treatment of various disorders associated with altered gastrointestinal motility like non-ulcer dyspepsia (NUD) and / or chronic gastritis, gastroesophageal reflux disease (GERD), nausea and vomiting of organic or functional origin.	04.11.10
206	Tolperisone HCl Mouth Dissolving tablet 50/100 mg (Additional Dosage Form)	Same as Approved.	04.11.10
207	Oxybutynin Gel 100 mg	For the treatment of overactive bladder with the symptoms of urge urinary incontinence, urgency and urinary frequency.	04.11.10
208	Dapoxetine (as Hydrochloride) Tablets ...30mg/60mg	For the treatment of premature ejaculation (PE) in men 18 to 64 years of age.	13.11.10
209	Opipramol dihydrochloride Tablet 50mg/100mg.	For the Treatment of generalised anxiety disorder(GAD) and somatic disturbances.	13.11.10.
210	Ondansetron Rapid Film Oral Strip 4/8 mg	For chemotherapeutic induced nausea and vomiting.	16.11.10
211	Acebrophylline SR Tablet 200 mg	For the treatment of adult patients with chronic obstructive pulmonary disease (COPD) and bronchial asthma.	23.11.10

212	Ammonium Lactate Cream 12% w/w	Indicated For the treatment of Dry,scaly skin(xerosis) and ichthyosis vulgaris and for temporary relief of itching associated with these condition.	03.12.2010
213	Rabeprazole Sodium Powder oral suspension (sachet of 20 mg) (Additional dasage form)	Same as approved	03.12.2010
214	Temsirolimus Concentrate for Infusion for Injection 25mg/ml	For the treatment of advanced renal cell carcinoma	11.12.2010
215	Acetyl Cysteine Eye Drops 5% w/v	Indicated the relief of Dry eye symptoms associated with defecient tear secretion, impaired or abnormal mucus Production.	14.12.2010
216	Clindamycin Palmitate Hcl For Oral Solution 75mg/5ml.	Indicated for the Prophylaxis against alpha-hemolytic(viridans group) sreptococci before dental, oral and upper respiratory tract surgery.	14.12.2010
217	Deferasirox Tablet for Oral Suspension (Additional Sosage Form)	Same as approved	14.12.2010
218	Ramelteon film coated tablets 8mg	For the treatment of insomnia characterized by difficulty with sleep onset.	15.12.2010
219	Memantine ER Tablet 7mg/14mg/21mg. (Additional Strength)	Same as approved	17.12.2010
220	Solution for haemofiltration and haemodialysis (Each unit contains two compartments A & B. Before reconstitution: • 1000ml of electrolyte solution in Compartment A contains: Calcium Chloride. 2H2O5.145gm Magnesium Chloride. 2H2O.... 2.033gm Lactic Acid....5.4gm • 1000ml of buffer solution in Compartment B contains: Sodium Chloride....6.45gm Sodium Bicarbonate....3.090gm)	For treatment of acute kidney disease (renal failure), as substitution solution in continuous haemofiltration and haemodiafiltration and as a dialysis solution in continuous haemodialysis.	23.12.2010
221	Pyridoxine HCL IP 3mg + Nicotinamide IP 100mg + Cyanocobalamin IP 15mcg + Folic acid IP 500mcg + Chromium Picolinate USP 250mcg Tablet	For Mineral & Vitamins deficiency states in adult patients	23.12.2010
222	Rosuvastatin Calcium IP 5mg/10mg + Fenofibrate BP 160mg/160mg tablet	Additional strength	29.12.2010
223	Chlorhexidine gluconate IP 1% w/v + Ethyl Alcohol IP 61% w/v Solution	Surgical hand scrub & healthcare personnel hand wash	29.12.2010

224	Streptococcus faecalis T-110 JPC 30 million + Clostridium butyricum TO-A 2 million + Bacillus mesentericus TO-A JPC 1 million + Lactic acid bacillus (lactobacillus sporogenes) 50 million Capsules	For restoration of intestinal microflora	15-03-2010
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