

**LIST OF APPROVED DRUG FROM 01-01-2012 to Till Date**

<b>S.No</b>	<b>Name Of Drug</b>	<b>Indication</b>	<b>Date of issue</b>
1.	Ornidazole IP 1 % w/w + Povidone Iodine IP (0.5% w/w available Iodine) 5% w/w Ointment	For the prevention and treatment of surgical wound infections in adult patients undergoing surgery	03.01.12
2.	Aceclofenac IP (Sustained released pellets) 200mg/200mg + Thiocolchicoside IP (Sustained released pellets) 8mg/16mg Capsules. (New Dosage Form)	For the treatment of acute inflammation conditions associated with spasm in adults only	04.01.12
3.	Budesonide IP 1mg/0.5mg + Formoterol Fumarate Dihydrate IP eq to Formoterol Fumarate 20mcg/20mcg Respirator suspension. (Additional Indication)	In the regular treatment of patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD) with frequent symptoms and a history of exacerbations.	04.01.12
4.	Diclofenac Sodium IP (Enteric coated granules) 50mg + Eperisone Hcl IP (Tablet) 50mg Hard Gelatin Capsules. (New Dosage Form)	For the treatment of Patients with acute musculoskeletal spasm associated with low back pain	06.01.12
5.	Degarelix for Injection 80mg / 120mg per vial	For the treatment of adult patients with advanced hormone dependent prostate cancer.	19.01.12
6.	Linagliptin film coated Tablet 5mg	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.  Important limitations of use: 1. Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. 2. Has not been studied in combination with insulin.	23.01.12

7.	Eribulin mesylate solution for injection 0.88mg / 2ml vial	For the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments.	27.01.12
8.	Plerixafor Injection 20mg/ml	In combination with Granulocyte Colony Stimulating Factor (G-CSF) to enhance mobilisation of hematopoietic stem cells to the peripheral blood for collection and subsequent autologous hematopoietic stem cells transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma whose cells mobilise poorly.	31.01.12
9.	Cephalexin IP (as monohydrate) 200mg + Kanamycin IP (as monosulphate) 100,000 IU Suspension per 10 gm Intramammary Suspension	For the treatment of clinical mastitis in lactating dairy cows for bacteria susceptible to the combination of cephalexin and kanamycin such as Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus uberis and Escheria coli.	07.03.12
10.	Mucotrol Concentrated Oral Gel Wafer.	For the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiotherapy). Irritation due to oral surgery and traumatic ulcers caused by braces or ill fitting dentures of diseases and for diffuse aphthous ulcers.	07.03.12
11.	Ondansetron Hydrochloride Mouth Melting Strips 4mg	For chemotherapeutic induced nausea and vomiting	29.3.12

12.	Ulinastatin for Injection 50000 IU / 100000 IU	For the treatment of severe sepsis.	03.04.12
13.	Silodosin Tablets 4mg	For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adults only	10.4.12
14.	Paracetamol Bilayer Tablet 1000mg	For symptomatic treatment of pain and fever	11.4.12
15.	Ketoprofen Plaster 30mg (7cm X 10cm)	For the relief of musculoskeletal pain and inflammation	18.4.12
16.	Sterile Solution for Peritoneal Dialysis Each 1000 ml contains: Calcium chloride dihydrate 0.184 g/l + Glycine 0.51 g/l + L-Alanine 0.951 g/l + L- Arginine 1.071 g/l + L- Isoleucine 0.85 g/l + L- Histidine 0.714 g/l + L- Leucine 1.02 g/l + L- Lysine (as Hcl) 0.955 g/l + L-Methionine 0.85 g/l + L- Phenylalanine 0.57 g/l + L-Proline 0.595 g/l + L- Serine 0.51 g/l + L- Threonine 0.646 g/l + L-Tryptophan 0.27 g/l + L-Tyrosine 0.3 g/l + L-Valine 1.393 g/l + Magnesium chloride hexahydrate 0.051 g/l + Sodium chloride 5.38 g/l + Sodium lactate 4.48 g/l	As Nutritional supplements for malnourished renal failure patients (Albumin concentration lower than 35 g/litre) being maintained on peritoneal dialysis.	18.04.12
17.	Sodium Hyaluronate Injection 8mg/vial (6ml Pre-filled syringe for Intra Articular use only)	Indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesic.	23.4.12
18.	Blonanserin Tablet 2mg/4mg/8mg	For the treatment of Schizophrenia in adult patients when first line treatment is ineffective.	24.04.12
19.	Etravirine Tablet 100mg	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents. It should be used only in situations where other treatments have failed or cannot be used because of side	26.04.12

		effects.	
20.	Ticagrelor Tablet 90mg	For the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non ST elevation Myocardial infarction (STEMI) including patients managed medically, and those who are managed with percutaneous those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).	03.05.12
21.	Clenbuterol Hydrochloride Solution for injection 30mcg/ml	For the treatment of equine respiratory diseases in horses where airway obstruction due to bronchospasm and/or accumulation of mucus is contributing factor and improved muco-ciliary clearance is desirable. The product should be used alone or as an adjuvant therapy. The product is of particular value in cases of: - Acute, sub-acute and chronic infections where the presence of mucus and/or micro-organisms may stimulate bronchospasm e.g. Bronchitis, broncholitis and Bronchopneumonia - Acute, sub-acute and chronic respiratory allergies. - Chronic obstructive pulmonary disease (COPD)	01.07.2012
22.	Apixaban Tablets 2.5mg	Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.	03.08.2012

23.	Ethyl esters of iodized fatty acids of poppy seed oil solution for injection 48%.	<p>In Diagnostic Radiology: Lymphography and Diagnosis of liver lesions. (Diagnosis of the spread of malignant lesions, whether hepatic or not, by selective hepatic arterial injection).</p> <p>In Interventional Radiology: Embolization with surgical glues. (In association with surgical glues during vascular embolizations).</p> <p>In Endocrinology: Prevention of iodine deficiency disorders. (This treatment should only be used when other methods of supplementation, particularly iodization of salt and/or drinking water, cannot be undertaken)</p>	22.08.2012
24.	Conivaptan Hydrochloride Injection 20mg/4ml.	For the treatment of euvolemic hyponatremia (e.g. the syndrome of inappropriate secretion of antidiuretic hormone , or in the setting of hypothyroidism, adrenal insufficiency, pulmonary disorders, etc.) in hospitalized patients.	21.08.2012
25.	Colesevelam Hydrochloride Tablets 625mg & Sachets for oral suspension 3.75gm/1.875gm.	Indicated as an adjunct to diet and exercise to reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia as monotherapy or in combination with an hydroxymethylglutaryl-coenzyme A (HMG CoA) reductase inhibitor (statin). Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	29.08.2012

26.	Tolvaptan Tablets 15/30mg	For the treatment of clinically significant hypervolemic and euvolemic hyponatremia [serum sodium < 125mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH).	06.09.2012
27.	Agomelatine Tablets 25mg	For the treatment of major depression in adult patients aged 18 – 65 years only with normal liver functions.	10.09.2012
28.	Almotriptan Tablet 6.25mg/12.5mg	For acute treatment of migraine attacks with a history of migraine with or without aura in adults.	05.10.12
29.	Flupirtine Maleate Sustained Release Tablets 400mg	For the treatment of acute and chronic pain, i.e. for painful increased muscle tone of the posture and motor muscle, Primary Headache, tumor pain, Dysmenorrhea and pain after Traumatology/Orthopedic Operations and injuries	18.10.12
30.	Lacosamide Injection 10mg/ml	As an adjunctive treatment of partial onset seizures in patients >17 years of age.	19.10.12
31.	Vemurafenib Tablet 240mg	For the treatment of patients with unresectable or metastatic melanoma with BRAFV600E mutation as detected by an FDA-approved test.  Vemurafenib is not recommended for use in patients with wild-type BRAF melanoma.	19.10.12
32.	Pitavastatin Tablet 4mg	An adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglyceride TG), and to	23.10.12

		increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia or mixed dyslipidemia.	
33.	Pemetrexed Disodium 500mg/100mg Powder for Injection	As monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has to progressed immediately following platinum based chemotherapy.	30.10.12
34.	Choline Fenofibrate DR Capsule 45mg/135mg & DR Tablet 45mg/135mg.	For treatment of mixed lipidemia in combination with statins, severe hypertriglyceridemia.	01.11.12
35.	Ondansetron Hydrochloride Oral Spray 2mg (Each spray delivers ondansetron-2mg)	For chemotherapeutic induced nausea and vomiting	8.11.12
36.	Trimethoxysilyl Quaternary Ammonium Chloride solution for spray inanimate surfaces for disinfection 0.71%.	Surface protectant and disinfectant for persistent disinfection of all inanimate surfaces. Effective upto 14 days.	16.11.12
37.	Seratrodast Tablets 40mg/80mg	As add-on therapy in bronchial asthma.	30.11.12
38.	Imipenem IP (Sterile) eq to anhydrous Imipenem 1 g + Cilastatin Sodium IP (sterile) eq to Cilastatin 1 g Powder for Injection (Additional strength)	For the treatment of serious lower respiratory tract infections, urinary tract infections, intra-abdominal, bone and joint infection, endocardities and bacterial septicemia	28.06.12
39.	Tacrolimus Capsules 0.25mg	For the prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplant.	3.12.12
40.	Diclofenac Sodium Injection 75mg/2ml	For acute painful conditions in post-operative pain, renal colic and acute exacerbation of gouty arthritis	4.12.12
41.	Megestrol Acetate Oral Suspension 400mg per 10ml (10 & 20mg Sachet)	For the treatment of anorexia, cachexia, or an unexplained, significant weight loss in patients with a diagnosis of cancer or	5.12.12

		acquired immunodeficiency syndrome (AIDS)	
42.	Sildenafil Citrate Injection 0.8mg/ml	For the treatment of pulmonary arterial hypertension (PAH) (WHO Group-1) to improve exercise ability and delay clinical worsening.	5.12.12
43.	Gemcitabine Injection 38mg/ml	<p>Ovarian cancer-Gemcitabine injection in combination with cisplatin is indicated for the treatment of patients with advanced ovarian cancer that has replaced at least 6 months after completion of platinum based therapy.</p> <p>Breast Cancer-Gemcitabine injection in combination with paclitaxel is indicated for the first line treatment of patients with metastatic breast cancer after failure of prior anthracycline containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.</p> <p>Non-small cell lung cancer-Gemcitabine injection is indicated in combination with cisplatin for the first line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (stage IV) non-small cell lung cancer.</p> <p>Pancreatic cancer- Gemcitabine injection is indicated as first-line treatment for patient with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas.</p> <p>Gemcitabine injection is indicated for patients previously treated with 5-EU.</p>	5.12.12
44.	Diclofenac Diethylamine BP 4.64 % w/v Eq. to Diclofenac Sodium IP 4.00 % + Absolute Alcohol IP 10.00 % v/v Topical Solution	For the Treatment of Acute Lower Back Pain	21.12.12