

**Drugs approved from 1st Jan 2014 to 31 december 2014**

| <b>S.No</b> | <b>Drug</b>  | <b>Indication</b>  | <b>Date</b> |
|-------------|--|--|-------------|
| 1           | Tolterodine Tartrate Extended release tablets 2mg/4mg (Additional Dosage Form)   | For the treatment of overactive bladder with symptoms of urge urinary incontinence, urinary incontinence, urgency and frequency.   | 31.01.14    |
| 2           | Bortezomib for injection 3.5mg (Sub-cutaneous route of administration as an alternate to intravenous route) (Additional route of administration) | Same as already approved   | 28.01.14    |
| 3           | Paclitaxel Injection Concentrate for Nanodispersion 100mg and 300mg (Additional Dosage Form)   | For the treatment of Breast cancer after failure of combination therapy metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. | 22.01.14    |
| 4           | Heparin Sodium Topical Solution 1000 IU/ml (Additional Dosage Form)  | For the management of post infusion superficial thrombophlebitis.  | 16.1.2014   |
| 5           | Simethicone Orally disintegrating strip 62.5mg   | For the treatment of flatulence and as adjuvant in hyperacidity.   | 14.11.2010  |
| 6           | Eltrombopag Olamine tablet 25/50mg (Additional Indication)   | Indicated in patients with chronic hepatitis C Virus (HCV) infection for the treatment of thrombocytopenia to: Enable the initiation of interferon based therapy, optimise interferon based therapy.                                     | 07.04.2014  |

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| 7 | Decitabine lyophilised powder for injection<br>50mg/20ml vial (additional indication)  | For the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukemia (AML), according to World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.   | 09.04.2014 |
| 8 | Glycopyrronium bromide inhalation powder hard capsule with inhaler. Each capsule contains 63mcg Glycopyrronium bromide eq. to Glycopyrronium 50 mcg. | Indicated as a once daily maintenance bronchodilator treatment to relieve symptoms of patients with Chronic Obstructive Pulmonary Disease (COPD).  | 01.04.2014 |
| 9 | Micafungin sodium for injection<br>100mg/vial (Additional Strength)  | Treatment of patient with candidemia, acute Disseminated Candidiasis, Candida Peritonitis and abscesses. Treatment of patients with Esophageal Candidiasis, Prophylaxis of Candidia and Aspergillus Infections in patients undergoing Hemopoietic stem cell transplantaion. Treatment of patient with Fungemia, Respiratory mycosis, Gastrointestinal mycosis caused by Aspergillus sp.. | 2.05.2014  |

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| 10 | Apixaban tablets 2.5mg/5mg (Additional Strength & Additional Indication)   | Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), including those with one or more risk factors, such as prior stroke or transient ischemic attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA class ≥ II). Compared to warfarin apixaban also results in less bleeding, including intracranial hemorrhage. | 16.05.2014 |
| 11 | Mometasone furoate nasal spray 50 mcg/actuation (Additional Indication)  | For the treatment of nasal symptoms of seasonal allergic and perennial allergic rhinitis, in adults and pediatric patients 2 years of age and older.   | 21.05.2014 |
| 12 | Micronised Purified Flavonoid 1000mg (MPFF). "Each film coated tablet contains diosmin 900mg and flavonoids expressed as Hesperidine 100 mg of Micronised Purified Flavonoid fraction of Rutaceae 1000mg (MPFF)" | Acute hemorrhoid piles   | 28.11.13   |

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| 13 | <p>Gemcitabine HCl injection ready to use infusion bags<br/> Gemcitabine HCL equivalent to Gemcitabine 10mg per mL (100,120,130,140,150,160,170,180,190 and 200mL)<br/> (Approved as infusion bags)</p> | <p>Ovarian cancer-Gemcitabine injection in combination with carboplatin is indicated for the treatment of patients with advanced ovarian cancer that has replaced at least 6 months after completion of platinum based therapy.<br/> 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.<br/> 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),</p> | 17.06.2014 |
| 14 | Tadalafil Orally Disintegrating Strip 10mg & 20mg (Additional dosage form)  | For erectile dysfunction  | 30.07.2014 |
| 15 | Hydroxychloroquine Sulphate USP 400 mg tablets (Additional Indication)  | As an adjunct to diet and exercise to improve glycemic control of patients on metformine, sulfonylurea combination in patients with Type II Diabetes.   | 28.07.2014 |
| 16 | Nevirapine Extended release tablet 400mg (Additional Strength)  | For use in combination with other anti-retroviral agents for the treatment of HIV-1 infection in adults   | 01.07.2014 |

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| 17 | Artesunate injection. Each combipack contains: "Artesunate for injection 120mg ( Each vial contains Artesunate IP 120mg), Sodium bicarbonate injection IP 5%w/v (Each 2ml ampoule contains: Sodium Bicarbonate IP 5% w/v), Sodium chloride Injection IP 0.9% w/v (Each 10ml ampoule contains: Sodium chloride IP 0.9% w/v)" | Promoted for use in severe malaria including cerebral malaria as a second line in chloroquine resistant malaria cases only.  | 13.11.2013 |
| 18 | Cerebrolysin solution for injection. Each ml contains: Porcine brain derived peptide preparation (Cerebrolysine concentrate) 215.2mg  | For amelioration of cranial injury, cerebrovascular pathological sequelae and aprosexia in dementia.   | 25.07.2014 |
| 19 | Artesunate powder for injection 60mg/vial alongwith 6ml ampoule of phosphate buffer solution (pH 8.0;0.30M)   | For the treatment of severe Falciparum malaria in areas where there is evidence if quinine resistance  | 02.07.2014 |
| 20 | Montelukast sodium chewable tablet 4mg/5mg and Montelukast sodium film coated tablet 10mg.  | As add on therapy in mild to moderate asthma inadequately controlled by inhaled corticosteroids and short active B2 agonist, Exercise induced bronchoconstriction.   | 26.02.2002 |
| 21 | Lactobacillus brevis CD2 Lozenges 400mg (corresponding to not less than 2 billion) of live, lyophilised, lactic acid bacteria, Lactobacillus brevis CD2. (Additional indication)  | Prevention of radiotherapy and chemotherapy induced oral mucositis in cancer patients.   | 9/8/2014   |
| 22 | Rivaroxaban tablet 15/20mg (Additional strength/indication)   | 1. Treatment of deep vein thrombosis and for prevention of recurrent DVT and pulmonary embolism. 2. For the prevention of stroke and systemic embolism in patient with non-valvular arterial fibrillation. | 2.9.14     |

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| 23 | Hydroxychloroquine Sulphate Tablet 300mg<br>(Additional strength/indication)   | Indicated for the treatment of patients with lower body weight i.e 45 to 60kg in Rheumatoid arthritis, Systemic Lupus Erythematosus & Polymorphic Light Eruption | 9/8/2014  |
| 24 | Ginkgo biloba extract Tablet 120mg<br>(Additional strength)                    | For the treatment of dementia, vertigo and tinnitus in adult patients.   | 9/12/2014 |
| 25 | Bendamustine Hydrochloride lyophilised injection 25mg<br>(Additional strength) | Treatment of patients with chronic lymphocytic leukemia  | 19.9.2014 |
| 26 | Metformin ER tablet 750mg<br>(Additional strength)                             | As an adjunct to diet and exercise to improve glycemic control in adult patients with Type II Diabetes.  | 25.9.14   |
| 27 | Sorafenib tosylate tablet 200mg<br>(Additional indication)                     | For the treatment of patients with locally advanced or metastatic differentiated thyroid carcinoma refractory to radioactive iodine.                             | 25.9.14   |
| 28 | Deferasirox Dispersible tablet 100/400mg<br>(Additional indication)            | Treatment of chronic iron overload in patients with non-transfusion dependent thalassemia (NTDT) syndromes aged 10 years and older.                              | 26.9.2014 |

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| 29 | <p>IMATINIB mesilate 100/400mg tablets and 100 mg capsules (Additional indication)</p>  | <p>Treatment of Paediatric patients with newly diagnosed Philadelphia chromosome positive acute Lymphoblastic Leukaemia (Ph+ALL) integrated with chemotherapy</p> | <p>9/9/2014</p>   |
| 30 | <p>Tapentadol Extended release tablet 100/150/200mg (Additional strength)</p>   | <p>For use in in-patients under hospital setting for severe acute pain for a period not exceeding 5 days</p>  | <p>9.12.13</p>    |
| 31 | <p>Olanzapine pamoate Prolonged release powder for suspension for I.M injection (combi pack)<br/> Each combipack contains<br/> a. Vial of Olanzapine pamoate Prolonged release powder for suspension.<br/> Each vial contains: Olanzapine pamoate monohydrate eq to Olanzapine 210mg/300mg/405mg. After reconstitution each mL of suspension contains 150mg.<br/> b. Vial of vehicle: 3mL clear, colourless to slight yellow solution contains:<br/> Manitol IP.... 5.070%w/v<br/> Sodium carboxymethyl cellulose IP.... 0.770% w/v Polysorbate 80 IP .... 0.025%w/v<br/> HCL IP....q.s.<br/> NAOH IP....q.s<br/> Water for injection....q.s. to 100%</p> | <p>For the treatment of schizophrenia</p>   | <p>14.10.14</p>   |
| 32 | <p>Rivastigmine transdermal patch. Each Transdermal patch of 15cm<sup>2</sup> contains Rivastigmine 27mg (Additional indication)</p>  | <p>For the treatment of patients with severe dementia of the Alzheimer's type</p>   | <p>28-10-2014</p> |

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| 33 | Dabigatran Etexilate Mesilate hard gelatin capsule 75/110/150mg<br>(Additional Indication) | 1. Treatment of acute deep vein thrombosis (DVT) and /or pulmonary embolism (PE) and prevention of related death. 2.Prevention of recurrent deep vein thrombosis (DVT) and /or pulmonary embolism (PE) and related death                          | 17.11.14   |
| 34 | Pegaspergase 3,750 IU/5 mL   | Indicated as a component of multi agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who are hypersensitive to asparaginase   | 07 03 2014 |
| 35 | Tulobuterol Transdermal Patch 0.5 mg/ 1.0 mg /2.0 mg                                       | For treatment of patients with Asthma and COPD without co-morbidity   | 24 04 14   |
| 36 | Azacitidine 100 mg / vial  | For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome   | 29 04 14   |
| 37 | Azacitidine  | For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome   | 23 07 14   |
| 38 | Regorafenib film coated tablet 40 mg   | For the “treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-base chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy”. | 01 07 14   |

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| 39 |  | For the treatment of severe chronic obstructive pulmonary disease (COPD)(FEV1 post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.  | 17 07 14 |
| 40 |  |  |          |
| 41 |  |  |          |
| 42 | Roflumilast Tab 500 mcg                  |  |          |
| 43 | Dimethyl Fumarate delayed release        |  |          |
| 44 | 12                                       |  |          |
| 45 |  | For " Relapsing remitting  | 27 08 14 |
| 46 |  | " To improve glycemic control in combination with other glucose lowering medicinal products including insulin when these together with diet and exercise, do not provide adequated glycemic control or as monotherapy as adjunct to diet and exercise to improve glycemic control in adults aged 18 years or older with type 2 Diabetic mellitus." | 27 08 14 |
| 47 |  |  |          |
| 48 |  |  |          |
| 49 |  |  |          |
| 50 | Alogliptin Tablet 6.25 mg/12.5 mg/ 25 mg |  |          |
| 51 |  | For the “ treatment of advanced renal cell carcinoma after failure of one prior systemic therapy”  |          |
| 52 | Axitinib Tablet 1mg/5mg                  |  | 18.09.14 |
| 53 |  | For the treatment of mild to severe acute pancreatitis.  |          |
| 54 | Ulinastatin Injection                    |  | 19.09.14 |
| 55 |  | “Indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type-2 Diabetic Mellitus”.  |          |
| 56 | Canagliflozin Tablet 100/300mg           |  | 17.11.14 |

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| 57 | Levosulpiride 75/150/200 mg (add. Strength)  | 75 mg tablet: For the treatment of gastro intestinal problem like fanatical dyspepsia, nausea, vomiting and diabetic gastroperisis.<br>150/200mg: For the treatment of depression and schizophrenia in adults.  | 9.12.14   |
| 58 | Nitrofurantoin dispersible tablets 50 mg (add. Strength/ dosage form)  | for the treatment of acute uncomplicated urinary tract infections ( acute cystitis) caused by susceptible strains of E.coli or staphylococcus saprophyticus   | 15.12.14  |
| 59 | Methylcobalamin orally disintegrating strips 1500mcg (add. Dosage form/ indication)  | for the treatment of peripheral neuropathy and diabetic neuropathy  | 17.12.14  |
| 60 | Paclitaxel suspension for injection Conc. For nanodispersion 100/300mg (add. Indication)   | management of endometriosis associated pain   | 18.12.14  |
| 61 | Lapatinib tablet 250mg (Additional indication)   | lapatinib in combination with trastuzumab , indicated for the treatment of patients with hormone receptor - negative metastatic breast cancer whose tumours overexpress HER2/neu (ErbB2) and who have progressed on prior trastuzumab therapy in combination with chemotherapy in the metastatic setting. | 22.12.14  |
| 62 | Medroxyprogesterone acetate suspension for injection s.c . Single dose container with 104mg Medroxyprogesterone acetate in 0.65 ml suspension for injection (SAYNA <sup>□</sup> PRESS) (Additional route/ strength/indication) | Indicated for the management of endometriosis-associated pain.  | 18.12.14  |
| 63 | Empty Hydroxy Propyl Methyl Cellulose Capsules   | NA  | 11.1.2011 |