

**Drugs approved from 1st January 2015 till present**

S.NO	Name Of Drug	Indication	Date of Approval
1	Levocetirizine ODS 2.5mg /5mg (Additional dosage form)	For allergic rhinitis and chronic urticaria.	14.01.15
2	Decitabine Injection 30mg/vial (Additional pack size)	1. 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. 2. For the treatment of adult patients aged 65 yrs and above with newly diagnosed de novo or secondary acute myeloid leukemia, according to WHO classification, who are not candidates for standard induction chemotherapy.	13.02.15
3	Meloxicam ODT 7.5mg /15 mg(Additional dosage form)	Non-steroidal anti-inflammatory.	23.02.15
4	Ruxolitinib Tablet 5mg/15mg/20mg (Additional indication)	Treatment of patients with polycythemia vera who are resistant to or intolerant of hydroxyurea.	23.02.15
5	Gadopentetic acid dimeglumine salt injection 469mg/1ml (0.5mmol) (Additional indication)	For use in MRI in adult patients to facilitate visualization of lesions with abnormal vascularity in the body (excluding heart).	23.02.15

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6	Pazopanib Tablet 200mg/400mg (additional indication)	For the treatment of patients with advanced Soft Tissue Sarcoma (STS) who have received prior chemotherapy.	23.02.15
7	Eribulin mesylate solution for injection 0.88mg in 2ml vial (Add. Indication)	For the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.	18.02.15
8	Abiraterone acetate Tablet 250 mg (Additional Indication)	For the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated, with prednisone or prednisolone.	27.03.15
9	Indomethacin Injection 1mg/vial (additional Dosage form)	To close a hemodynamically significant patent ductus arteriosus (PDA) in premature infants weighing between 500g and 1750g when after 48 hrs. usual medical management (e.g. fluid restriction, diuretics, digitalis, respiratory support, etc.) is ineffective. Clear-cut clinical evidence of hemodynamically significant patent ductus arteriosus should be present, such as respiratory distress, a continuous murmur, a hyperactive precordium, cardiomegaly and pulmonary plethora on chest X-ray.	30.04.15
10	Ketorolac ODS 10mg (Additional Dosage form)	For the treatment of short-term management of post-operative pain and musco-skeletal pain.	29.04.15

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11	Tiamulin hydrogen fumarate solution for injection 162 mg/ml (additional Dosage form)	For treatment and prevention of swine dysentery caused by <i>Branchyspira hydodysenteriae</i> .  The product is not appropriate for use for the prevention of disease at the level of herd treatment but should only be used for prevention of swine dysentery in individual animals with a known history of exposure to diseased animals.	17.04.15
12	Montelukast Orally Disintegrating Strips 4mg/5mg/10mg (additional Dosage form)	For the Relief of perennial allergic rhinitis in adults & pediatric patients 6 months of age and older.	29.05.15
13	Apixaban Tablets 2.5/5mg (additional Indication)	Treatment of deep vein thrombosis (DVT) and pulmonary Embolism (PE), and prevention of Recurrent DVT and PE in adult patients.	29.05.15
14	Ruxolitinib 10mg tablet (additional Strength)	1. For the treatment of patients with myelofibrosis including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis  2. Treatment of patients with polycythemia vera who are resistant to or intolerant of hydroxyurea.	29.05.15
15	Lorazepam Orodispersible Tablet 1mg/2mg (additional Dosage form)	For the management of anxiety disorders or for the short term relief of symptoms of anxiety or anxiety associated with depressive symptoms.	29.05.15
16	Brimonidine topical gel 0.33% (Add. Dosage form/indication)	For the topical treatment of persistent (non-transient) facial erythema of rosacea in adults 18 years of age or older.	18.06.15

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17	Rivaroxaban tablet 2.5mg (add. strength)	Rivaroxaban 2.5mg tablet, co-administered with Acetylsalicylic acid (ASA) alone or with ASA plus Clopidogrel or Ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.	13.07.15
18	Lamotrigine ER Tablet 25mg/50mg/100mg/200mg	Add-on therapy for partial and secondary generalised tonic-clonic seizures.	06.08.12
19	Feracrylum 3% solution	For the management of post-operative wounds cuts, Abrasions as a Haemostatic Agent cum anti-septic.	13-02-2002
20	Feracrylum 3% gel	For the management of post-operative wounds cuts, Abrasions as an Haemostatic Agent cum anti-septic.	13-02-2002
21	Arteether injection 150mg/mL	Indicated for the treatment of severe malaria including cerebral malaria and as a second line in chloroquine resistant malaria cases only.	03-12-2010
22	Everolimus dispersible Tablet 0.1mg/0.25mg (additional Indication)	For the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, Everolimus should be used in combination with tacrolimus and corticosteroids.	21-08-15  (Condition: Phase-IV trial duly approved by CDSCO shall be conducted in statistically significant number of patients.)

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23	Everolimus Tablet 0.25 mg/0.5 mg/0.75 mg/1.0 mg (additional Indication)	For the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, Everolimus should be used in combination with tacrolimus and corticosteroids.	21-08-15  (Condition: Phase-IV trial duly approved by CDSCO shall be conducted in statistically significant number of patients.)
24	Cetrorelix Acetate injection 0.25mg/0.5ml in 0.5 ml prefilled syringe.  (Additional pack size)	Prevention of premature ovulation in patients undergoing a controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.	26-08-15
25	Exenatide 2 mg powder and solvent for prolonged release suspension for injection in a prefilled pen (s.c. Injection)  (Additional strength)	For treatment of type 2 diabetes mellitus in combination with Metformin Sulphonylurea Thiazolidinedione Metformin and Sulphonylurea Metformin and Thiazolidinedione In Adults who have not achieved adequate glycemic control on maximally tolerated doses of these oral therapies.	09-09-15
26	Vitamin D3 (Cholecalciferol) Orally disintegrating strips 2000 IU (additional Dosage form)	For the treatment of Vitamin D3 deficiency.	01-10-15
27	Dexamethasone Intravitreal implant 0.7mg (Additional Indication)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.	12-10-15

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28	Zolpidem Tartarate Orally disintegrating Tablet 5mg/10mg (Additional dosage form)	For insomnia.	12-10-15
29	Etodolac i.m injection 400mg/2ml (Additional dosage form)	For the treatment of post operative orthopaedic pain.	14-12-15