



List of approved drugs in 2018

S.No	Name of drug	Indication	Date of issue
1	Tenofovir Alafenamide Hemifumarate Bulk & Emtricitabine 200mg/200mg + Tenofovir Alafenamide 10/25 mg Tablets	In combination with other antiretroviral agents for treatment of Human Immunodeficiency Virus type-1 (HIV-1) infection in adults and adolescents with aged 12 years and older	10.01.2018
2	Clofarabine Bulk & Injection 20 mg/20ml vial	For the treatment of patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This indication is based upon response rate	16.01.2018
3	Denaverine Hydrochloride 40 mg Injection (Vet.)	cattle : Facilitation of parturition in heifers; activation of icattle : Facilitation of parturition in heifers; activation of interrupted parturitions; insufficient opening of the soft birth canal; narrowness of the cervix of first and second degree after correction of uterine torsions; improvement of the conditions for foetotomy; regulation of labour contractions of the uterus Dogs: Activation of Interrupted parturition	16.01.2018

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Sr No	Name of Drug	Indication	Date of approval
1	Hydrocortisone Aceponate 0.584mg/ml Cutaneous Spray Solution (Vet.)	For symptomatic treatment of inflammatory and pruritic dermatosis in dogs.	06.01.17
2	Dexlansoprazole Delayed Release Capsule 30/60mg & Bulk	For the treatment of Healing of all grades of erosive esophagitis (EE). Maintaining healing of EE and relief of heartburn. Relapsed or refractory multiple myeloma	16.01.17
3	Carfilzomib for injection	Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	
4	Dabrafenib 50mg/75mg Capsules (Dabrafenib Mesylate)	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as	18.01.17

		detected by an appropriate test.	
5	Trametinib 0.5mg/2mg Tablets (Trametinib Dimethyl Sulfoxide)	As a monotherapy and in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.	18.01.17
6	Alectinib 150mg Capsules (Alectinib Hydrochloride)	For the treatment of patients with anaplastic lymphoma kinase (ALK)-Positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib.	23.01.17
	Eliglustat 84mg Capsules (Eliglustat Tartrate or Hemitartrate Salt)	For the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an appropriate test.	31.01.17
8	Pasireotide long-acting release 20/40/60mg powder for suspension for injection (Additional Indication) (Pasireotide pamoate)	For the treatment of patients with acromegaly who have had an inadequate response to surgery and/ or for whom surgery is not an option.	14.02.2017
9	Etonogestrel 68 mg implant	For use by women to prevent pregnancy.	15.02.2017
10	Bepotastine Besilate 1.5 %w/v Ophthalmic solution	For the treatment of itching associated with allergic conjunctivitis	22.02.2017
11	Dienogest 2mg Tablets	For the management of Pelvic pain associated with Endometriosis	09.03.2017

12	Eprinomectin 0.5% for beef and dairy cattle (vet.)	It is indicated for the treatment and control of gastrointestinal roundworm (including inhibited <i>Ostertagia ostertagi</i>), lungworm, grubs, sucking and biting lice, chloriopic and sarcoptic-mange mites, and horn flies in beef and dairy cattle of all ages, including lactating dairy cattle.	14.03.2017
13	Bepotastine Besilate 10 mg Tablets	For the treatment of allergic rhinitis	27.03.2017
14	Prucalopride 1mg/2mg Tablet & Bulk (Prucalopride Succinate)	For the treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief	13.04.2017
15	Teriflunomide 14 mg tablets	For the treatment of patients with relapsing form of multiple sclerosis	13.04.2017
16	Pomalidomide 1mg/2mg/3mg/4mg Capsules & Bulk	In combination with dexamethasone, for patient with patient multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	01.05.2017
17	Sofosbuvir 400 mg +Velpatasvir 100 mg Tablet	For the treatment of adult patients with -chronic Hepatitis C virus, Genotype 1,2,3,4,5 or 6 infection. -Without cirrhosis or with compensated cirrhosis -With decompensated with chronic for use in combination with Ribavirin.	04.05.2017
18	Velpatasvir Bulk		04.05.2017
19	Osimertinib 40 mg/80 mg Film coated Tablets	For the treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer	29.05.2017

	(Osimertinib Mesylate)	(NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy	
20	Argatroban Hydrate Bulk & Injection 250 mg/2.5 ml	For prophylaxis or treatment of thrombosis in adult patients with Heparin induced thrombocytopenia (HIT). As an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention (PCI)	30.05.2017
21	Fluralaner chewable tablets 112.5 mg/250 mg/500mg/1000mg/1400 mg	For the treatment of tick and flea infestations on dogs for 12 weeks. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile Ixodes ricinus, and flea) killing activity for 12 weeks. Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. the onset of effect is within 8 hours of attachment for fleas and 12 hours of attachment for tick The product effectively controls environmental flea population in area to which treated dogs have access. The product can be used as part of an treatment strategy for the control of Flea Allergy Dermatitis (FAD)	30.05.2017
22	Fluticasone Furoate (100 mg mcg) and Vilanterol Trifenatate (25 mcg) powder for inhalation	Indicated for the maintenance treatment of the airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/ or emphysema and to reduce exacerbation of COPD in patients with an exacerbation history.	29.06.2017
23	Mirabegron Prolonged Release Tablet 25 mg /50 mg	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder	12.07.2017

		(OAB) Syndrome	
24	Delamanid 50 mg tablet	For the use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability	02.08.2017
25	Mirabegron Prolonged Release Tablet 25 mg /50 mg & Bulk	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome	18.08.2017
26	Efonidipine Hydrochloride Ethanolate Bulk & Tablets 10 mg/20mg/40mg	Indicated for the management of Hypertension Renal parenchymal hypertension Angina	28.08.2017
27	Brivaracetam Film Coated Tablets 50mg/75mg/100mg	As adjunctive therapy in the treatment of partial -onset seizures in patients 16 years of age and older with epilepsy	07.09.2017
28	Treosulfan Bulk & injection 5g/vial	For the conditioning treatment prior to haematopoietic stem-cell transplantation	26.09.2017
29	Ribociclib 200 mg Film coated	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of post menopausal women with the hormone receptor (HR)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer	27.09.2017
30	Dienogest Bulk & 2mg Tablet	For the management of Pelvic pain associated with Endometriosis	28.09.2017
	Apremilast bulk & film coated tablets	for treatment of patients with moderate to severe plaque psoriasis who are	

31	10 mg/20 mg/30 mg	candidate for phototherapy or systemic therapy	13.10.2017
32	Arbekacin bulk & Injection 200mg/4ml	Treatment of following infections caused by Methicillin resistant Staphylococcus aureus (MRSA)", sepsis pneumonia	20.10.2017
33	Benestermycin Intra-mammary suspension (vet.)	For the treatment of subclinical mastitis at drying off, and the prevention of new bacterial infections of the udder during the dry period in dairy cows, caused by bacteria susceptible to penicillin and framycetin	03.11.2017
34	Midostaurin 25 mg Capsules	In combination with standard induction and consolidation chemotherapy followed by single agent in maintenance of therapy for adult patients with newly diagnosed with acute myeloid leukemia (AML) who are FLT-3 Mutation positive. For the treatment of adult patients with advanced systemic mastocytosis (Advanced SM)	09.11.2017
35	Tenofovir Alafenamide Fumarate bulk & 25 mg capsules	For the treatment of chronic Hepatitis B virus infection in adults with compensated liver disease	10.11.2017
36	Arteolane Maleate and Piperaquine phosphate Dispersible tablets (37.5 mg +187.5 mg	Indicated in children aged 6 months to 12 years for the treatment of : Acute uncomplicated Plasmodium falciparum malaria infection Acute uncomplicated Plasmodium Vivax malaria infection	24.11.2017
37	Macitentan Bulk and Tablets 10 mg	Macitentan is an endothelin receptor antagonist (ERA)I indicated for the treatment of Pulmonary arterial hypertension (PAH, WHO group I) to delay disease progression	07.12.2017