

## List of new drugs approved in the year 2019 till date

S.No	Name of drug	Indication	Date of issue
1	Fenspiride hydrochloride film coated extended release tablet 80 mg and Fenspiride hydrochloride bulk	1. Acute Rhinosinusitis 2. Moderate persistent asthma as an add-on therapy	04.02.2019
2	Bilastine tablets 20 mg and Bilastine Bulk	For symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria in adults	06.02.2019
3	Iguratimod film coated tablets 25mg and Iguratimod Bulk	For the treatment of active rheumatoid arthritis symptoms	18.02.2019
4	Fingolimod Capsules 0.5mg and Fingolimod hydrochloridebulk	For the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.	25.03.2019
5	Remogliflozin etabonate bulk and Remogliflozin etabonate film coated tablets 100 mg	Indicated in adults aged 18 years and older with type2 diabetes mellitus to improve glycemic control as:- <ul style="list-style-type: none"> <li>• Monotherapy when diet and exercise alone do not provide adequate glyceamic control.</li> <li>• Add on therapy with metformin, together with diet and exercise, when these do not provide adequate glyceamic control.</li> </ul>	26.04.2019
6	Concentrate of Proteolytic enzyme enriched in Bromelain topical gel	Indicated for removal of eschar in adults with deep partial-and full-thickness thermal burns	17.05.2019
7	Menotrophin injection 600 IU/ml, 1 ml & 2 ml multi dose vial (Highly purified)	Menotropin is indicated for the treatment of female and male infertility in the following conditions:  Anovulation , including Polycystic Ovarian Disease (PCOD), in women who have been unresponsive to the treatment with	17.06.2019

		<p>Clomiphene citrate.</p> <p>Women undergoing controlled ovarian hyperstimulation to induce the development of multiple follicles for Assisted Reproductive Technologies (ART).</p> <p>Hypogonadotropic hypogonadism in men.</p>	
8	Rifapentine 150mg film coated tablet	<p>“For the treatment of latent tuberculosis infection caused by Mycobacterium tuberculosis in adults and children 2 years and older who are at high risk of progression to tuberculosis disease (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin test, HIV-infected patients, or those with pulmonary fibrosis on radiograph). Active tuberculosis disease should be ruled out before initiating treatment for latent tuberculosis infection.</p> <p>Rifapentine Tablets 150mg must always be used in combination with isoniazid as a 12-week once-weekly regimen for the treatment of latent tuberculosis infection”.</p>	08.07.2019
9	FDC of Bictegravir, Emtricitabine and Tenofovir alafenamide 50mg/200mg/25mg tablets	<p>For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per ml) on a stable antiretroviral regimen for at least 3 month with no history of treatment failure and no known substitutions associated with resistance to Bictegravir, Emtricitabine and Tenofovir alafenamide.</p>	09.08.2019
10	Levomilnacipran ER capsules 20mg/40mg/80mg/120mg	For treatment of major depressive disorder	13.08.2019
11	Bosutinib bulk and Bosutinib tablets 100mg,	For the treatment of adult patients with: 1) Newly diagnosed chronic phase (CP)	09.09.2019

	400mg, 500mg	Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+CML) 2) Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+CML with resistance or intolerance to prior therapy.	
12	Algard - R-82 (octyldecyl dimethyl ammonium chloride 6.510 w/w + Dioctyl dimethyl ammonium chloride 2.604% w/w + Didecyl dimethyl ammonium chloride 3.906% w/w + Alkyl dimethyl benzyl ammonium chloride 8.680% w/w	Surface disinfectant for persistent disinfection of all inanimate surfaces (Against pathogens as annexed)	09.09.2019
13	Algard HWS-256 (didecyl dimethyl ammonium chloride 10.14% w/w + n-Alkyl dimethyl benzyl ammonium chloride 6.76% w/w	Surface disinfectant for persistent disinfection of all inanimate surfaces (Against pathogens as annexed)	09.09.2019
14	Safinamide methane sulphonate bulk drug and Safinamide tablets 50, 100mg	For the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other Parkinson's disease (PD) medicinal products in mid to late stage fluctuating patients.	09.09.2019
15	Droxidopa bulk drug and Droxidopa capsules 200mg/300mg	For the treatment of orthostatic dizziness, light headedness or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's Disease multiple system atrophy (MSA) and pure autonomic failure), dopamine beta-hydroxylase deficiency and non-diabetic autonomic neuropathy.	24.09.2019
16	Acalabrutinib 100mg capsules	For the treatment of patients with mantle cell lymphoma (MCL) who have received atleast one prior therapy	18.10.2019
17	Abemaciclib 50mg, 100mg, 150mg and 200mg film coated tablets	(i) Abemaciclib is indicated for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase	18.11.2019

		<p>inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.</p> <ul style="list-style-type: none"> <li>• In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone- releasing hormone (LHRH) agonist.</li> </ul> <p>(ii) As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.</p>	
18	Ripasudil hydrochloride hydrate bulk drug and Ripasudil Eye drops 0.4% w/v	To treat glaucoma and ocular hypertension when other medicines for glaucoma have insufficient effect or cannot be used.	20.11.2019
19	Diperoxochloric acid concentrate and Diperoxochloric acid topical solution	Indicated for wound healing in diabetic neuropathic ulcers of skin and subcutaneous tissues reduction	20.11.2019
20	Endoxifen citrate bulk and Endoxifen tablets 8 mg	For the acute treatment of manic episodes with or without mixed features of Bipolar I disorder	10.12.2019
21	Azelnidipine bulk and Azelnidipine tablets 16 mg	For the treatment of Stage II Hypertension	10.12.2019
22	Genopep bulk and Genopep 0.05% w/w cream	Indicated for treatment of burn wound, antimicrobial therapy, scar prevention/reduction	11.12.2019
23	Alalevonadifloxacin mesylate bulk and Levonadifloxacin tablets 500mg	<p>Indicated in adults (<math>\geq 18</math> years of age) for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) including diabetic foot infections and concurrent bacteraemia caused by susceptible isolates of the following:</p> <p>Gram-positive organisms:- Staphylococcus aureus (methicillin-resistant, methicillin-susceptible, quinolone-resistant, quinolone-susceptible isolates), Streptococcus pyogenes, Enterococcus faecalis, Streptococcus dysgalactiae ssp. dysgalactiae, Streptococcus agalactiae.</p>	13.12.2019

24	Midodrine hydrochloride bulk drug	-	26.12.2019
25	Lorlatinib film coated tablets 25mg and 100 mg	For the treatment of ALK fusion gene-positive unresectable advanced and/or recurrent non-small cell lung cancer with resistance or intolerance to ALK tyrosine kinase inhibitor(s)	26.12.2019
26	Levonadifloxacin L-arginine tetrahydrate bulk and Levonadifloxacin injection 800mg/100ml	Indicated in adults ( $\geq 18$ years of age) for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) including diabetic foot infections and concurrent bacteraemia caused by susceptible isolates of the following: Gram-positive organisms:- Staphylococcus aureus (methicillin-resistant, methicillin-susceptible, quinolone-resistant, quinolone-susceptible isolates), Streptococcus pyogenes, Enterococcus faecalis, Streptococcus dysgalactiae ssp. dysgalactiae, Streptococcus agalactiae.	30.12.2019