

## List of new drugs approved in the year 2020 till date

S.No	Name of drug	Indication	Date of issue
1	Cidofovir dihydrate bulk drug and Cidofovir injection 75 mg/ ml (5 ml single use vial)	Cidofovir is indicated for the treatment of CMV retinitis in adults with acquired immune deficiency syndrome (AIDS) and without renal dysfunction. It should be used only when other medicinal products are considered as unsuitable.	03.01.2020
2	Dacomitinib tablet 15mg, 30mg and 45mg	For the first line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations	03.01.2020
3	Alpelisib film coated tablets 50mg, 150mg, 200mg	Alpelisib is a kinase inhibitor indicated in combination with Fulvestrant for the treatment of postmenopausal women, and men, with Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.	03.01.2020
4	Isavuconazolesulfate 100mg capsules	Indicated for patients 18 years of age and older for the treatment of Invasive Aspergillosis and Invasive Mucormycosis	14.02.2020
5	Azelnidipine tablets IP 8 mg	For the treatment of Stage I Hypertension	04.03.2020
6	Riboflavin Ophthalmic Solution 0.1%	It is intended to treat keratoconus and corneal ectasia following refractive surgery	11.03.2020
7	Pixantrone 29mg powder for concentrate for solution for infusion	Indicated as 3rd line and 4th line therapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non-Hodgkins B- Cell Lymphomas (NHL)	11.03.2020
8	FDC of Bilastine 20mg and Montelukast 10mg tablets	Indicated for the treatment of allergic rhinitis in adults.	11.03.2020
9	Obeticholic acid bulk drug and Obeticholic acid 5mg/10mg tablets	For the treatment of primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with	11.03.2020

		ursodeoxycholic acid (UDCA) in adult with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA	
10	Isavuconazole (as Isavuconazoniumsulfate) 200mg powder for concentrate for solution for infusion	Indicated for patients 18 years of age and older for the treatment of Invasive Aspergillosis and Invasive Mucormycosis	11.03.2020
11	Polymyxin B for injection 500000 IU	<p>Polymyxin B sulfate is a drug of choice in the treatment of infections of the urinary tract, meninges, and blood stream, caused by susceptible strains of Ps. Aeruginosa. It may also be used as subconjunctival infection in the treatment of infections of the eye caused by susceptible strains of Ps. aeruginosa. It may be indicated in serious infections caused by susceptible strains of the following organisms,</p> <ol style="list-style-type: none"> <li>1. H. influenzae, specifically meningeal infections</li> <li>2. Escherichia coli, specifically urinary tract infections</li> <li>3. Aerobacter aerogenes, specifically bacteremia</li> <li>4. Klebsiella pneumoniae, specifically bacteremia</li> </ol>	30.03.2020
12	Sucroferric oxyhydroxide bulk and Sucroferric oxyhydroxide chewable tablet 500mg	Phosphate binder indicated for the control of serum phosphorous levels in patients with chronic kidney disease on dialysis	18.04.2020
13	Hydrogen peroxide 0.5% w/w wipes	Cleans, disinfects and deodorizes hard non-porous inanimate environmental surfaces	29.04.2020
14	Centhaquine citrate bulk and Centhaquine citrate injection 1.0mg/vial	Add on resuscitative agent for hypovolemic shock	14.05.2020
15	Hydrogen peroxide 0.5% w/w spray	Cleans, disinfects and deodorizes hard non-porous inanimate environmental surfaces	28.05.2020
16	Remdesivir Injection 5 mg/mL and Remdesivir lyophilised powder for Injection 100 mg	For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with severe disease, in light of Covid 19 outbreak, for restricted emergency use in the country.	01.06.2020

17	Lymphoseek 50mcg kit (each kit contains : Tilmanocept 50mcg, Glycine 0.1mg, Sodium ascorbate 0.1mg, Trehalose dihydrate 16mg, stannous chloride dihydrate 0.015mg, sodium hydroxide q.s, hydrochloric acid q.s, Nitrogen q.s, water for injection q.s)	Indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity. This medicinal product is for diagnostic only.	04.06.2020
18	Favipiravir bulk and Favipiravir film coated tablet 200mg	For the treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak, for restricted emergency use in the country.	19.06.2020
19	Remdesivir bulk drug	-	20.06.2020
20	Pretomanid bulk and Pretomanid tablets 200mg	Indicated as part of a combination regimen with Bedaquiline and Linezolid, in adults for the treatment of pulmonary extensively drug resistant (XDR), or treatment intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)	15.07.2020
21	Favipiravir film coated tablet 400mg	For the treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak for restricted emergency use in the country	22.07.2020
22	n-alkyl dimethyl benzyl ammonium chloride 0.105% w/w spray	Cleans, disinfects, deodorizes hard, non-porous inanimate environmental surfaces	31.07.2020
23	Defetilide bulk and Dofetilide capsules 125mcg, 250mcg, 500mcg	<p><b>Maintenance of Normal Sinus Rhythm (Delay in AF/AFL Recurrence)</b></p> <p>Dofetilide is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/ atrial flutter [AF/AFL]) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm. Because Dofetilide can cause life threatening ventricular arrhythmias, it should be reserved for patients in whom atrial fibrillation/atrial flutter is highly symptomatic.</p> <p>In general, antiarrhythmic therapy for atrial fibrillation/atrial flutter aims to prolong the time in normal sinus rhythm. Recurrence is expected in some patients.</p> <p><b>Conversion of Atrial Fibrillation/Flutter</b></p>	31.07.2020

		<p>Dofetilide is indicated for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm.</p> <p>Dofetilide has not been shown to be effective in patients with paroxysmal atrial fibrillation.</p>	
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