

## List of new drugs approved in the year 2021 till date

S.No	Name of drug	Indication	Date of issue
1	Avanafil bulk and Avanafil tablets 50mg/100mg/200mg	For the treatment of erectile dysfunction	26.02.2021
2	Omidenepag isopropyl ophthalmic solution 0.002% w/v	For the treatment of glaucoma and ocular hypertension	12.03.2021
3	Ozenoxacin bulk and Ozenoxacin cream 1% w/w	Indicated for the topical treatment of impetigo due to staphylococcus aureus or streptococcus pyogenes in adult and pediatric patients 2 months of age and older	15.04.2021
4	2-Deoxy-D-Glucose bulk and 2-Deoxy-D-Glucose 2.34g & 5.85g sachet	As an adjunct therapy only in moderate to severe Covid-19 patients	01.05.2021
5	Capmatinib 150mg and 200mg film coated tablets	Capmatinib is a kinase inhibitor indicated for the treatment of adult patient with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal epithelial transition (MET) exon 14 skipping.	12.05.2021
6	Rucaparib camsylate bulk and Rucaparib tablets 200mg/300mg	<p>Ovarian cancer</p> <ul style="list-style-type: none"> <li>• For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.</li> <li>• For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.</li> </ul> <p>Prostate cancer</p> <ul style="list-style-type: none"> <li>• For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic) associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a</li> </ul>	12.05.2021

		taxane-based chemotherapy.	
7	Trientine Tetrahydrochloride bulk and Trientine Tetrahydrochloride capsules 333 mg (Each capsule contains Trientine tetrahydrochloride 333mg equivalent to Trientine 167mg base)	For the treatment of Wilson's disease (hepatolenticular degeneration) in patients intolerant to Penicillamine. It should be used when continued treatment with Penicillamine is no longer possible because of intolerable or life endangering side effects.	08.06.2021
8	Rucaparib tablets 250mg	<p>Ovarian cancer</p> <ul style="list-style-type: none"> <li>• For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.</li> <li>• For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBYCA.</li> </ul> <p>Prostate cancer</p> <ul style="list-style-type: none"> <li>• For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic) associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.</li> </ul>	18.06.2021
9	Vigabatrin bulk and Vigabatrin powder for oral solution 500mg	<p>For the treatment of</p> <ol style="list-style-type: none"> <li>1) Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments; Vigabatrin for Oral Solution, USP, 500 mg is not indicated as a first line agent.</li> <li>2) Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom</li> </ol>	18.06.2021

		the potential benefits outweigh the potential risk of vision loss.	
10	Cangrelor tetra sodium bulk and Cangrelor for injection 50mg/vial	Indicated as an adjunct to percutaneous coronary intervention (PCI) to reduce the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients who have not been treated with a P2Y12 platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor	21.06.2021
11	Rifapentine bulk and FDC of Isoniazid and Rifapentine (300mg/300mg)	Indicated for treatment of latent tuberculosis, caused by Mycobacterium tuberculosis (For use in NTEP only)	28.06.2021
12	Lemborexant tablets 5mg/10mg	Treatment for insomnia	01.07.2021
13	Cetilistat bulk and Cetilistat 120 mg tablets	For the treatment of Obesity (limited to patients with both type 2 diabetes mellitus and dyslipidaemia, and with a BMI $\geq$ 25 kg/m <sup>2</sup> in spite of dietary treatment and /or exercise therapy)	09.07.2021
14	Benzonatate bulk and Benzonatate capsules 100mg	For the treatment of refractory cough	15.07.2021
15	Cariprazine hydrochloride bulk and Cariprazine capsules 1.5mg/3mg/4.5mg and 6mg	For the treatment of Schizophrenia in adults. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults	16.07.2021
16	Gadoteridol 279.3 mg/ml for injection	For intravenous use in magnetic resonance imaging (MRI) in adults and pediatric patients over 2 years of age for whole body MRI including the head, neck, liver, breast, musculoskeletal system and soft tissue pathologies	29.07.2021
17	Darolutamide 300mg film coated tablets	For the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC)	13.08.2021
18	Tetracosactide BP bulk and Tetracosactide injection BP 250 mcg/ml	Diagnostic test for the investigation of adrenocortical insufficiency	13.08.2021
19	Cabozantinib (S) - Maleate bulk and Cabozantinib tablets 20mg, 40mg and 60mg	(1) For the treatment of patients with advanced renal cell carcinoma (RCC). (2) For the treatment of patients with	10.09.2021

		Hepatocellular Carcinoma (HCC) who have been previously treated with sorafenib.	
20	Tipiracil hydrochloride bulk and FDC of 1) Trifluridine 15mg + Tipiracil 6.14mg and 2) Trifluridine 20mg + Tipiracil 8.19mg	Indicated for the treatment of i) adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy  ii) Adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/ neu-targeted therapy.	16.09.2021
21	Selumetinib 10mg & 25mg capsule	Indicated for the treatment of Pediatric patients 3 years of age and older with neurofibromatosis type 1 (NF1) and who have symptomatic, inoperable plexiform neurofibromas (PN)	17.09.2021
22	Biapenem sterile bulk and Biapenem for injection 300mg	Complicated urinary tract infections	17.09.2021