

## List of new drugs approved in the year 2022 till date

S.No	Name of drug	Indication	Date of issue
1	Triamcinolone Hexacetone injectable suspension 20mg/ml	For intraarticular, intra-synovial or periarticular use in adults and adolescents for the symptomatic treatment of subacute and chronic inflammatory joint diseases including rheumatoid arthritis and Juvenile Idiopathic Arthritis (JIA), Osteoarthritis and post-traumatic arthritis, Synovitis, tendinitis, bursitis and epicondylitis.	20.01.2022
2	Gimeracil bulk & Oteracil potassium bulk and Tegafur 15mg/20mg, Gimeracil 4.35mg/5.8mg and Oteracil 11.8mg/15.8mg capsules	indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin.	01.02.2022
	Topiroxostat tablets 20mg, 40mg and 60mg and bulk	Gout, hyperuricemia.	04.02.2022
3	Nitric oxide nasal spray	For treatment of adult high risk patients with mild Covid-19 having risk of progression of the disease.	08.02.2022
4	Vericiguat tablets 2.5mg/ 5mg/ 10mg	Indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%	25.02.2022
5	Inosine pranobex bulk and Inosine pranobex 500mg tablet	As add on therapy for treatment of mild Covid-19 patients with co-morbidities and moderate Covid-19 patients, in light of Covid 19 outbreak for restricted emergency use in the country	02.03.2022
6	Desidustat bulk and Desidustat tablets 25mg and 50mg	For treatment of Anemia in adult patients with chronic kidney disease (CKD) not on Dialysis and on Dialysis	03.03.2022
7	Lumacaftor bulk, Ivacaftor bulk & Lumacaftor and Ivacaftor tablets 100mg/125mg and 200mg/125mg	Indicated for the treatment of cystic fibrosis (CF) in patient age 2 years and older who are homozygous for the F508del mutation in the CFTR gene.	11.03.2022
8	Liothyronine sodium bulk and Liothyronine sodium tablets 5mcg & 20 mcg	To treat some of the more severe conditions in which the thyroid does not produce enough thyroxine and balance the effect of medicines used to treat an	04.04.2022

		overactive thyroid.	
9	Polyhexamethylene guanidine hydrochloride 1.000 lit	For surface disinfection	06.04.2022
10	Finerenone 10mg/20mg film coated tablets	Indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 Diabetes (T2D)	11.04.2022
11	Sugammadex sodium bulk and Sugammadex injection 100mg/ml (single dose vial for bolus injection, IV)	Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults undergoing surgery	18.04.2022
12	Nirmatrelvir bulk and Combipack of Nirmatrelvir 300mg tablets (2x150mg tablets) and Ritonavir tablets 100mg	For treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death, in light of Covid 19 outbreak for restricted emergency use in the country	21.04.2022
13	Aviptadil bulk and Aviptadil injection (Each ml vial contains Aviptadil 15 mcg)	For treatment of patients with severe COVID-19 with Acute Respiratory Distress Syndrome (ARDS), in light of Covid 19 outbreak for restricted emergency use in the countr0079	29.04.2022
14	Bempedoic acid bulk and Bempedoic acid tablet 180 mg	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.  Limitation of use: The effect of the drug on cardiovascular morbidity and mortality has not been established.	09.05.2022
15	rdESAT-6 bulk; rCFP-10 bulk and rdESAT-6 and rCFP-10 (Cy-Tb) injection - Each vial (10 dose vial, single dose of 0.1ml) contains: rdESAT-6:0.05 mcg; rCFP-10: 0.05 mcg	For detection of Latent TB for population of 18 years and above	09.05.2022
16	Pralsetinib Capsule 100mg	• Indicated for the treatment of adult patients with metastatic rearranged during transfection (RET)fusion-positive non-small cell lung cancer.,.	26-05-2022

		<ul style="list-style-type: none"> <li>• Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy.</li> <li>• Indicated for the treatment of adult and pediatric patients 12years of age and older with ladvanced or metastatic RET-fusion positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).</li> </ul>	
17	Nitisinone Capsules 2/5/10 mg and bulk	Indicated for the treatment of herediarty tyrosinemia type -1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.	09-06-2022
18	Tepotinibe film coated tablet 250 mg	Each film coated tablet contains Tepotinibe hydrocholridehydrate 250 mg equiv. to Tepotinibe 225 mg	12-08-2022
19	Lobeglitazone Sulfate Tablet 0.5mg and Lobeglitazone Sulfate bulk	<p>Indicated for treatment of adult type 2 diabetes mellitus patients:</p> <ul style="list-style-type: none"> <li>o as monotherapy <ul style="list-style-type: none"> <li>• who are inadequately controlled by diet &amp; exercise for whom metformin is inappropriate because of contraindications or intolerance</li> </ul> </li> <li>o as dual oral therapy in combination with <ul style="list-style-type: none"> <li>• who are inadequately controlled by diet &amp; exercise and taking metformin despite maximal tolerated dose of metformin monotherapy</li> <li>• who are inadequately controlled by diet &amp; exercise and taking a sulphonylurea at maximal tolerated dose of sulphonylurea monotherapy in which metformin is inappropriate because of contraindications or intolerance</li> </ul> </li> </ul>	16-09-2022
20	Idelalisib 150 mg and 100 mg Tablets and Idelalisib bulk	<p>Idelalisib is a kinase inhibitor indicated for the treatment of patients with:</p> <ul style="list-style-type: none"> <li>• Relapsed chronic lymphocytic leukemia (CLL), in combination with</li> </ul>	14-10-2022

		<p>rituximab, in patients for whom rituximab alone would be considered</p> <p>appropriate therapy due to other co-morbidities. • Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.</p> <p>• Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.</p> <p>Limitation of use:</p> <p>Idelalisib is not indicated and is not recommended for first-line treatment of any patient.</p> <p>Idelalisib is not indicated and is not recommended in combination with bendamustine and/or rituximab for the treatment of FL.</p>	
21	FDC of Bempedoic acid 180 mg+ Ezetimibe 10 mg tablet	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.	07-11-2022
22	Naftifine HCL USP cream 2% w/w and Naftifine HCL USP Bulk	Indicated for the treatment of superficial fungal infection of the skin (tinea corporis and Tinea cruris)	09-11-2022
23	Entrectinib Capsules 100mg and 200mg	Adult patients with metastatic non small cell lung cancer (NSCLC) whose tumors are ROS1-positive. Adult and pediatric patients 12 years of age and older with solid tumors that: 1. have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation. 2. are metastatic or where surgical resection is likely to result in severe morbidity and 3. have progressed	18-11-2022

		following treatment or have no satisfactory alternative therapy.	
24	Sitagliptin Fentanil Phaohate Tablet 35 mg, 70 mg, 140 g	As an adjunct top diet and exercise to improve glycemic control In adults with Type-2 Diabetes Mellitus.	29-11-2022
25.	Imeglimin Hydrochloride Tablet 500 mg /1000mg and bulk drug	Type 2 diabetes mellitus	06-10-2022
26	Imeglimin Hydrochloride Tablet 1000mg and bulk drug	Type 2 diabetes mellitus	18-11-2022
27	Apalutamide 60 mg Tablet and bulk drug	For treatment of patients with metastatic castration-resistant prostate cancer (M-CRPC) and non metastatic, castration resistant prostrate cancer (NM-CRPC)	18-11-2022
28	Icatibant Acetate Injection, 30 mg/3ml(10mg/ml) and Icatibant Acetate Bulk drug	Indicated for treatment of acute attacks of hereditary angioedema(HAE) in adults 18 years of age and older	02- 12-2022
29	Lobeglitazone Sulfate Tablet 0.5mg and Metformin HCL extended release 500 mg Tablets and Lobeglitazone Sulfate Tablet 0.5mg and Metformin HCL extended release 1000 mg	As an adjuant to diet and exercise – in patients who have inadequate glycemic control with maximum tolerated dose of metformin alone or in patients who are already receiving combination therapy of lobeglitazone and metformin	30-12-2022
30.	Sodium Glycerophosphate 4.32g/20ml solution for infusion	For the treatment of patients, severly ,malnourished hypophosphotamea due to refeeding syndrome.	30-12-2022
31	Gilteritinib 40 mg film coated tablet	Indicated as monotherapy of adult patients who have replased or refractory acute myeloid leukaemia (AML) with as FLT3 mutation.	30-12-2022