

**List of New Drugs approved in the year 2025 till date**

<b>S.No.</b>	<b>Name of New Drug</b>	<b>Indication</b>	<b>Date of Approval</b>
1.	Tafamidis Bulk Drug	Not applicable as it is a bulk drug	16.01.2025
2.	Letermovir Bulk Drug &Letermovir Tablets 240mg and 480 mg	Letermovir is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). It is also indicated for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative[D+/R-])	17.01.2025
3.	Fexuprazan hydrochloride Bulk Drug and Fexuprazan hydrochloride Tablets 40mg	Indicated for the treatment of erosive esophagitis(EE).	10.02.2025
4.	Edoxaban Tosylate Monohydrate Bulk Drug	Not applicable as it is a bulk drug	11.02.2025
5.	Edoxaban Tablets 15mg, 30mg and 60mg	In prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf) with one or more risk factors, such as congestive heart failure, hypertension, age $\geq$ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack(TIA). For the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT and PE in adults.	20.02.2025
6.	Sodium Zirconium Cyclosilicate powder for Oral Suspension (LOKELMA) 5g/10g	Indicated for the treatment of Hyperkalaemia in adult patients.	05.03.2025
7.	Rimegepant Oral disintegrating tablets (ODT) 75 mg	For Acute treatment of migraine with or without aura in adults with a previous insufficient response to triptans.	27.03.2025
8.	Doravirine Bulk Drug and Doravirine Tablets 100mg	Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults	

		and pediatric patients weighing at least 35 kg with no prior antiretroviral treatment history only (treatment naïve)	28.03.2025
9.	Tucatinib hemiethanolate bulk drug & Tucatinib tablets 50 mg and 150 mg	Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.	08.04.2025
10.	Zanubrutinib capsules 80 mg	It is indicated for the treatment of adult patients with: <ol style="list-style-type: none"> <li>1. Mantle cell lymphoma (MCL) who have received at least one prior therapy.</li> <li>2. Waldenstrom's macroglobulinemia (WM)</li> <li>3. Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.</li> <li>4. Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL).</li> <li>5. Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.</li> </ol>	08.04.2025
11.	Linacotide Bulk Drug & Linacotide Capsule 72 mcg & Linacotide Capsule 145 mcg	Indicated in adults for the treatment of Chronic idiopathic constipation.	21.04.2025
12.	Siponimod Hemifumarate Bulk Drug & Siponimod Tablets 0.25 mg/1mg/2mg	For the treatment of patients with secondary progressive multiple sclerosis (SPMS) with active disease as evidenced by relapses or imaging features of inflammatory activity.	09.05.2025
13.	Ivosidenib 250 mg film coated tablet	It is indicated <ol style="list-style-type: none"> <li>1. In combination with Azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-</li> </ol>	14.05.2025

		<p>1(IDH1) R132 mutation who are not eligible to receive standard Induction chemotherapy.</p> <p>2. As a monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy.</p>	
14.	Tegoprazan Tablet 50 mg	<p>Indicated for:</p> <ul style="list-style-type: none"> <li>• Erosive Gastroesophageal Reflux Disease</li> <li>• Non-erosive Gastroesophageal Reflux Disease</li> <li>• Gastric Ulcer</li> </ul>	28.05.2025
15	Tegoprazan Tablet 25 mg	Maintenance of healed Erosive Gastroesophageal Reflux disease	08.07.2025
16	FDC of Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg+ 1 mg+ 0.5mg)	Indicated for the management of heavy menstrual bleeding associated with uterine Leiomyomas(Fibroids) in premenopausal women.	16.07.2025
17.	Lutetium Lu-177 Vipivotide Tetraxetan solution for injection or infusion 1000MBq/m L – reg.	Lutetium (Lu-177) Vipivotide Tetraxetan is indicated for the treatment of adult patients with prostate-specific membrane antigen(PSMA)- positive metastatic castration-resistant prostate cancer (m CRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.	23.07.2025
18.	Stamicis 1mg kit for Radiopharmaceutical Preparation	<p>After radiolabelling with sodium pertechnetate(<sup>99m</sup>Tc) solution, the solution of technetium(<sup>99m</sup>Tc) sestamibi obtained is indicated for:</p> <ul style="list-style-type: none"> <li>• <b>Myocardial perfusion scintigraphy</b> for detection and localization of coronary artery disease (angina pectoris and myocardial infraction).</li> <li>• <b>Assessment of global ventricular function.</b> First –pass technique for determination of</li> </ul>	23.07.2025

		<p>ejection fraction and/or ECG-triggered, gated SPECT for evaluation of left ventricular ejection fraction, volumes and regional wall motion.</p> <ul style="list-style-type: none"> <li>• <b>Scintimammography for the detection of suspected breast cancer</b> when mammography is equivocal, inadequate or indeterminate.</li> <li>• <b>Localization of hyperfunctioning parathyroid tissue</b> in patients with recurrent or persistent disease in both primary and secondary hyperparathyroidism, and in patients with both primary hyperparathyroidism scheduled to undergo initial surgery of the of the parathyroid glands.</li> </ul>	
19.	Upadacitinib Bulk Drug and Upadacitinib Extended Release Tablets 15mg,30mg and 45mg	For the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.	19.08.2025
20.	Pitolisant Bulk drug and Pitolisant Tablets 4.45 mg and 17.8 mg	For treatment of excessive day time sleepiness (EDS) or cataplexy in adult patients with narcolepsy	27.08.2025
21.	Etrasimod Tablets 2mg	Etrasimod is indicated for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (US) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.	16.09.2025
22.	Erdafitinib Tablets 3 mg, 4 mg and 5 mg.	Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.	01.10.2025

		Limitations of Use: Erdafitinib is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.	
<b>23</b>	Erdafitinib Bulk Drug	Not applicable as it is a bulk drug	08.10.2025
<b>24</b>	Vorasidenib Tablets 10 mg/ 40 mg	Vorasidenib is indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, subtotal resection, or gross total resection.	15.10.2025