

**NEW DRUGS APPROVAL LIST FROM SND DIVISION
(FROM 01/01/2024 TO 30/04/2024)**

S.No.	Drug	Indication	Date of Approval
1	Zolpidem Sublingual Spray 3.85% w/v (Additional Dosage Form)	For the short-term treatment of insomnia.	12.01.2024
2	Dydrogesterone Extended Release Tablets 30mg	Indicated “For the treatment of Endometriosis”.	12.01.2024
3	Imeglimin Hydrochloride Sustained Release Tablets 500mg/1000mg (Additional Dosage Form)	Indicated for the treatment of type 2 diabetes mellitus inadequately controlled with diet and exercise alone.	18.01.2024
4	Empagliflozin Tablets 10mg /25 mg (Additional Indication)	To reduce the risk of sustained decline in eGFR (only for patients with eGFR 30-90 ml/min/1.73m2), end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression.	18.01.2024
5	Pegaspargase Injection 1500 IU/2ml vial	Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who are hypersensitive to asparaginase. Pegaspargase Injection as First-Line chemotherapeutic agent for treatment of patients with acute lymphoblastic leukemia (ALL)	06.02.2024
6	Ferric Carboxymaltose Injection (50mg iron/ml) (Additional Indication)	For the treatment of iron deficiency in children and adolescents aged > 1 years when oral iron preparations are ineffective or cannot be used	15.02.2024
7	Tadalafil Oral Jelly 20 mg (Orange Flavour) (Additional Dosage Form)	It is indicated for the treatment of erectile dysfunction in adult men.	16.02.2024
8	Bisoprolol Fumarate Tablets USP 3.75 mg/7.5mg (Additional Strength)	Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides	16.02.2024
9	Sterile dehydrated Human Amnion Chorion Membrane (12x6cm2)	Indicated for the treatment of acute and chronic non-healing wounds.	28.02.2024
10	Hydroxyurea Oral Suspension 100 mg/ml (Additional Dosage Form)	It is indicated for the prevention of vaso-occlusive complications of Sick Cell Disease in patients over 2 years of age .	07.03.2024
11	Tacrolimus Lipid Tablets 3 mg (Additional strength)	For treatment of active rheumatoid arthritis in adult patients for whom disease modifying anti-rheumatic drug (DMARD) therapy is ineffective or inappropriate.	21.03.2024

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12	Nicoumalone Tablets IP 1.5mg/2.5mg/3.5mg (Additional Strength)	For the prevention and treatment of thromboembolic diseases such as venous thrombosis, atrial fibrillation with embolization, pulmonary embolism and as an adjunct in the treatment of coronary occlusion.	22.03.2024
13	Esmolol Hydrochloride Topical Gel 14% w/w	For the treatment of Diabetic foot ulcer.	24.04.2024
14	Alfuzosin Prolonged Release Tablets IP 10mg	For the treatment of sign & symptoms of Benign Prostatic Hyperplasia (BPH).	30.04.2024