

List of drugs approved from SND Division from 01.01.2021 to 02.02.2021

S. No	Drug Name	Composition	Indication	Date of Approval
1	Atropine Sulfate Ophthalmic Solution USP 0.01% w/v (Additional Strength)	Each ml Contains: Atropine Sulfate.....0.1 mg Polyhexamethylene biguanide Hydrochloride.....0.05mg (As Preservative)	It is indicated to control the progression of myopia in children of 5 years and above "WARNING: To be sold by retail on the prescription of Ophthalmologist only" With the Condition to conduct phase IV Clinical trial to assess long term safety of the product.	12-01-2021
2	Colistimethate Sodium For Injection IP 3 MIU/ 4.5 MIU (Additional Strength)	(i) Colistimethate Sodium for Injection IP 3 MIU Each Vial contains Colistimethate Sodium.....300 0000 IU (ii) Colistimethate sodium for Injection IP 4.5 MIU Each Vial Contains: Colistimethate Sodium.....4500 000 IU	For the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contraindicated or may be ineffective because of bacterial resistance. "WARNING: To be sold by retail on the prescription of a Medical Specialist only"	15-01-2021
3	Dapagliflozin Tablets 10 mg Additional Indication	Each film-coated tablets contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin..... 10 mg	For the treatment of patients of Chronic Kidney Disease (CKD) up to Stage III (eGFR of greater than or equal to 30ml/min/1.73m ²) "WARNING: To be sold by retail on the prescription of Nephrologist only"	03-02-2021

4	Brivaracetam Oral Solution Solution 10mg/ml Additional Dosage Foam	Each ml contains: Brivaracetam10mg/ml	As adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy	03-02-2021
5	Drospirenone Tablets 4 mg Additional Strength	Drospirenone..... 4 mg	Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy	15-02-2021
6	Apomorphine Hydrochloride 5 mg/ml solution for infusion in 20ml vial Apomorphine Hydrochloride 10 mg/ml solution for injection in 3ml cartridge Additional pack size & strength	Apomorphine Hydrochloride solution for infusion in 20ml vial Each ml contains: Apomorphine Hydrochloride..... ... 5mg/ml Apomorphine Hydrochloride solution for injection in 3ml cartridge Each ml contains: Apomorphine Hydrochloride..... 10 mg/ml	For the treatment of disabling motor fluctuations (“on-off” phenomena) in patients with Parkinson’s disease which persist individually titrated treatment with Levodopa (with a peripheral decarboxylase inhibitor) and/or other dopamine agonists. “WARNING: To be sold by retail on the prescription of Neurologists only”	16-02-2021
7	Thyroxine Sodium Tablets 88 mcg / 200mcg Additional Strength	Each uncoated tablet contains: Thyroxine Sodium.....8 8 mcg / 200 mcg	For the treatment of hypothyroidism	22-02-2021
8	Brivaracetam injection 50mg/5ml (10mg/ml) Additional dosage form & New route of administration	Each ml Contains: Brivaracetam....10mg	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy	24-02-2021