

List of drugs approved from SND Division from 01.01.2019 to 31.12.2019.

S. No	Drug Name	Composition	Indication	Date of Approval
1	Donepezil Hydrochloride Orally Disintegrating Strips (Additional dosage form)	Each Orally Disintegrating Strips Contains: Donepezil Hydrochloride 5/10 mg	For the treatment of mild to moderate severe Alzheimer's Dementia. With the condition:- To be sold by retail on the prescription of Neurologists only.	11.01.2019
2	Tapentadol Hydrochloride capsule 50mg (New dosage form)	Each capsule contains: Tapentadol Hydrochloride 50mg	For relief of moderate to severe acute pain in adults 18 years of age or older.	30.01.2019
3	Midodrine Hydrochloride tablet 2.5mg, 5mg and 10mg (Additional strength)	Each tablet contains: Midodrine Hydrochloride 2.5mg, 5mg and 10mg	It is indicated in the treatment of symptomatic orthostatic hypotension. With the condition:- To be sold by retail on the prescription of Cardiologists only.	20.02.2019
4	Ribociclib film coated tablet 200mg (Additional indication)	Ribociclib succinate 254.40mg eq. To Ribociclib 200mg	Ribociclib in combination with an aromatase inhibitor for the treatment of pre/peri-menopausal or post-menopausal women, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2(HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. With the condition: To be sold by retail on the prescription of an Oncologist only.	13.03.2019
5	Azacitidine for injection 150mg/vial (Additional strength)	Each vial contains: Azacitidine. 150mg Lyophilized powder for injection (for subcutaneous or Intravenous use)	For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome. With the condition: to be sold by retail on the prescription of an Oncologist only.	25.03.2019
6	Lenvatinib capsule 4mg/10mg (Additional Indication)	Each capsule contains: Lenvatinib mesylate 4.90mg eq. To Lenvatinib 4mg., Lenvatinib mesylate 12.25 mg eq. To Lenvatinib 10mg.	For the first line treatment of patients with unresectable hepatocellular carcinoma. With the condition: to be sold by retail on the prescription of an Oncologist only.	26.03.2019

7	Primidone tablet 50mg (Additional Strength)	Each uncoated tablet contains: Primidone USP 50mg	It is indicated for the management of grand mal and psychomotor (temporal lobe) epilepsy. It is also of value in the management of focal or jacksonian seizures, myoclonic jerks and akinetic attacks. Management of essential tremor. With the condition: To be sold by retail on the prescription of an Neurologist only.	15.04.2019
8	Amisulpride orodispersible tablet 50/100/200/300/400mg (New dosage form)	Each uncoated Oro dispersible tablet contains: Amisulpride 50/100/200/300/400mg	For acute and chronic schizophrenic disorders, in which positive and negative symptoms are prominent, including patients characterised by predominant negative symptoms. With the condition: To be sold by retail on the prescription of a Psychiatrist only.	03.05.2019
9	Progesterone solution for Injection 25mg/1.119ml vial (Add. Dosage form and add. route of administration)	Each vial (1.119 ml) contains: Progesterone 25mg (22.35mg/ml) (For subcutaneous or intramuscular use only)	It is indicated in adults for luteal support as part of an Assisted Reproductive Technology (ART) treatment program in infertile women who are unable to use or tolerate vaginal preparations. With the condition: To be sold by retail on the prescription of Gynaecologists only.	17.05.2019
10	Azilsartan medoxomil tablet 20/40/80mg (Additional lower Strength)	Each uncoated tablet contains: Azilsartan Kamedoxomil equivalent to Azilsartan medoxomil 20/40/80mg	Indicated for the treatment of hypertension in adult patients either alone or in combination with other antihypertensive agents. With the condition: To be sold by retail on the prescription of a Cardiologist only.	27.05.2019
11	Everolimus Tablet 0.25mg/0.5mg/0.75mg/1.0mg (Additional indication)	Each film coated tablet contains: Everolimus 0.25mg/0.5mg/0.75mg/1.0mg	Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and Corticosteroids. With the condition: To be sold by retail on the prescription of Cardiologist only.	27.05.2019

12	Diclofenac sodium 2% Topical Solution (New route of administration)	Each 1 gram of solution contains: Diclofenac sodium 20mg	For the treatment of pain of osteoarthritis of the knees.	03.06.2019
13	Artesunate for injection 120mg with phosphate buffer 0.3M (Additional strength)	Each combi pack contains: a) Artesunate for injection 120mg Each vial contains: Artesunate IP 120mg b) Phosphate Buffer 0.3M (12ml) Each ampoule contains: Anhydrous Disodium Hydrogen Phosphate BP 4.0% w/v Potassium dihydrogen phosphate BP 0.2% w/v	Indicated for the treatment of severe falciparum malaria in areas where there is evidence of quinine resistance	26.06.2019
14	Tranexamic acid injection IP 100mg/ml (Additional Indication)	Each ml contains: <i>Tranexamic acid</i> IP 100 mg/ml	Indicated for short term use in prophylaxis and treatment in patients at high risk of per-and post-operative hemorrhage following: a) Prostatectomy. b) Conisation of the cervix. c) Surgical procedures and extractions in hemophiliacs	26.07.2019
15	Rivaroxaban tablets 2.5mg (Add. Indication)	Rivaroxaban tablets 2.5mg	Rivaroxaban 2.5mg tablet, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events. With the condition:- To be sold by retail on the prescription of Cardiologists only.	30.07.2019
16	Olaparib 100 mg and 150 mg tablet (Additional Indication)	Olaparib 100 mg and 150 mg tablet	for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in	30.07.2019

			complete or partial response to first-line platinum-based chemotherapy With the condition:- To be sold by retail on the prescription of Oncologist only.	
17	Tapentadol Hydrochloride 25.000 milligram (mg) Capsules (Additional Lower Strength)	Tapentadol Hydrochloride 25.000 milligram (mg) Capsules	For relief of moderate to severe acute pain in adults 18 years of age or older	30.07.2019
18	Leuprolide 22.50mg depot Injection Powder for prolonged-release suspension for injection (Depot injection for I.M. use only) (Add. strength)	Each vial contains : Leuprolide acetate 22.5mg	Treatment of advanced Prostatic cancer. With the condition:- To be sold by retail on the prescription of Oncologist only.	07.08.2019
19	Clobazam Tablets IP 2.5mg & 7.5mg (Add. lower strength).	Each tablet contains: Clobazam 2.5mg & 7.5mg	As an adjunctive therapy in patients with refractory epilepsy. With the condition:- To be sold by retail on the prescription of Neurologist/Psychiatrist only.	07.08.2019
20	Sildenafil for oral suspension 10mg/ml (Add. Indication)	Each ml of reconstituted suspension contains: Sildenafil citrate IP equivalent to Sildenafil 10mg	For the treatment of pulmonary arterial hypertension (WHO Group I) in adults to improve exercise ability and delayed clinical worsening. With the condition:- To be sold by retail on the prescription of Cardiologist only.	09.08.2019
21	Pantoprazole dual-release gastro- resistant tablet 80mg (New Dosage form)	Each dual-release gastro-resistant tablet contains: Pantoprazole sodium equivalent to Pantoprazole 80mg	For the treatment of moderate to severe refractory Gastro-oesophageal reflux disease (GERD) for 4 weeks only.	02.09.2019

22	Pirfenidone tablet 400 mg (Add. Strength)	Each film coated tablet contains : Pirfenidone 400mg	For the treatment of idiopathic pulmonary fibrosis. With the condition:- To be sold by retail on the prescription of Pulmonologist only.	02.09.2019
23	Olopatadine HCl ophthalmic solution 0.7% w/v (Add. strength)	Each ml contains: Olopatadine HCl 0.7% w/v Benzalkonium chloride 0.015%w/v	For the treatment of ocular itching associated with allergic conjunctivitis. With the condition:- To be sold by retail on the prescription of Ophthalmologist only.	06.09.2019
24	Ibrutinib hard gelatin capsule 140mg (Add. indication)	Each capsule contains: Ibrutinib 140mg	For the treatment of patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL). With the condition:- To be sold by retail on the prescription of Oncologist only.	11.09.2019
25	Ibrutinib hard gelatin capsule 140mg (Add. indication)	Each capsule contains: Ibrutinib 140mg	For the treatment of patients with Waldenstrom's macroglobulinemia	11.09.2019
26	Desonide Ointment 0.05% (Add. Dosage form)	Desonide topical ointment 0.05%	for sub-acute to chronic steroid responsive dermatoses.	26.09.2019
27	Atorvastatin calcium tablet 30/60 mg (Add. Strength)	Each film coated tablet contains : Atorvastatin calcium equivalent to Atorvastatin 30/60 mg	1. As an Adjunct to Diet to Reduce Elevated Total Cholesterol and Triglyceride Levels in Patients with Primary Hypercholesterolemia and Mixed Dyslipidemia (Type IIa and IIb). 2. In adult patients with type II diabetes and without clinically evident coronary heart disease to reduce the risk of myocardial infarction and stroke. 3. To reduce the risk of stroke in adult patients without clinically evident coronary	27.09.2019

			heart disease but multiple risk factors for coronary heart disease With the condition:- To be sold by retail on the prescription of Cardiologist only.	
28	Desloratadine tablets 10mg (Additional strength)	Each film coated tablet contains : Desloratadine 10mg	For the treatment of Chronic Idiopathic Urticaria in patients who have not responded to the standard 5mg dose of Desloratadine.	27.09.2019
29	Diclofenac sodium Rectal Solution 25 % w/v with applicator (Add. dosage form)	Each ml contains: Diclofenac sodium 25%w/v Each Squirt (0.2ml) delivers: Diclofenac Sodium 50 mg	Mild to moderate pain in adults.	27.09.2019
30	Perampanel tablets 2mg /4mg/6mg/8mg/10mg/12mg (Additional indication)	Each film coated tablet contains : Perampanel 2mg /4mg/6mg/8mg/10mg/12mg	For the adjunctive treatment of primary generalized tonic-clonic seizures in patients with epilepsy aged 12 years and older. With the condition:- To be sold by retail on the prescription of Neurologist only.	27.09.2019
31	Ribociclib Film Coated Tablet 200mg (Additional Indication)	Ribociclib Succinate 254.40 mg equivalent to Ribociclib 200 mg	Indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER-2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine based therapy or in women who have received prior endocrine therapy. Warning: To be sold by retail on the prescription of oncologist only.	04-10-2019
32	Cinidipine Tablet 20 mg (Additional Strength)	Each Film Coated Tablets contain Clinidipine 20mg	For the treatment of mild to moderate hypertension	11-10-2019

33	Glycopyrronium Solution Inhalation Solution 25mcg (For nebulisation) (Add. Dosage form)	Each 2ml contains Glycopyrrolate equivalent to Glycopyrronium 25mcg in isotonic solution	For the long term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema	14-11-2019
34	Cefpodoxim Proxetil Sustained Release Tablet 200/400mg (Add. Dosage form)	Each film coated sustained release Tablet contains: Cefpodoxime Proxetil, Equivalent to Cefpodoxime 200mg & 400mg	Acute bronchitis, exacerbations of chronic bronchitis, pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis and acute otitis.	03.12.2019
35	Ivermectin Topical lotion 0.5% w/w	Each ml contains: Ivermectin 0.5% w/w	For the topical treatment of head lice infestation in patients 6months of age and older.	03.12.2019
36	Lenvatinib Capsules 4mg and 10mg (Additional Indication)	Each capsule contains Lenvatinib mesylate 4.90 mg equivalent to Lenvatinib 4mg and Lenvatinib mesylate 12.25mg equivalent to Lenvatinib 10 mg.	In combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. Warning: To be sold by prescription of a "Oncologist" only.	04.12.2019
37	Bilastine Oral Solution 2.500 mg/ml (Add. Dosage form)	Each ml contains: Bilastine 2.5000 mg	Symptomatic treatment of allergic rhino- conjunctivitis (seasonal and perennial) and urticaria. Bilastine is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.	10.12.2019
38	Pregabalin Extended Release Tablets 82.50 mg and 165mg	Each film coated Extended Release Tablet contains: Pregabalin 82.50 mg/165 mg	For treatment of peripheral neuropathic pain in adults.	12.12.2019
39	Clobetasol Propionate Topical Foam 0.5% w/w (Add.dosage form)	Contains: Clobetasol Propionate 0.05% w/w Phenoxyethanol 1.0% w/w	Treatment of Inflammatory and pruritic manifestation of corticosteroid responsive dermatoses in patients 12 years of age or older.	16.12.2019

40	Clobetasol Propionate Cream, 0.025% w/w (Add.Strength)	Each gram of cream contains: Clobetasol Propionate 0.25mg	Indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.	16.12.2019
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