

List of drugs approved from SND Division from 01.01.2020 to 31.03.2020

S. No	Drug Name	Composition	Indication	Date of Approval
1	Betahistine Dihydrochloride Orally Disintegrating Strips 16mg /24 mg (New Dosage form)	Each Orally Disintegrating Strips contains: Betahistine Dihydrochloride16mg/24 mg	Indicated in the treatment of Menier's syndrome, Characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss	02-01-2020
2	Posaconazole Gastro-Resistant Tablet 100 mg (Modified Release dosage form)	Each-Gastro-Resistant Tablet Contains: Posaconazole.....100mg	For Prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy. Posaconazole Gastro Resistant tablets are indicated in patients 13 years of age and older Warning: To be sold by retail on the prescription of Specialist only.	03-01-2020
3	Pirfenidone tablet 600 mg (Additional strength)	Each Film coated Tablet contains: Pirfenidone....600mg	For the Treatment of idiopathic pulmonary fibrosis Warning: To be sold by retail on the prescription of Pulmonologist only.	08-01-2020
4	Saroglitazar Tablet 2mg/4 mg (Additional indication)	Each uncoated tablet contains: Saroglitazar..... 2/4 mg	Type 2 Diabetes mellitus-as an add-on therapy to metformin	13-01-2020
5	Enzalutamide Soft Capsule 40 mg (Additional indication)	Each soft capsules contains Enzalutamide...40 mg	In the treatment of adult men with metastatic castration-resistant prostate cancer who are	23-01-2020

			asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated Warning: To be sold by retail on the prescription of Oncologist only.	
6	Canagliflozin 100 mg and 300 mg Tablet (Additional Indication)	Each film coated tablet contains: Canagliflozin 100mg/300mg	To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.	17-02-2020
7	Norethisterone Acetate Controlled Release Tablet 10 mg (Additional Dosage form & Indication)	Each film coated controlled release tablet contains: Norethisterone Acetate 10mg	To arrest bleeding in women with dysfunctional uterine bleeding due to hormonal imbalance.	24-02-2020
8	Lidocaine Hydrochloride 2% Solution (Additional Dosage Form)	Each ml contains: Lidocaine Hydrochloride 20mg	Indicated in adults: • For the production of topical anesthesia of irritated or inflamed mucous membranes of the mouth and pharynx. • For reducing gagging during the taking of X-ray pictures and dental impressions.	25-02-2020
	Saroglitazar Tablets 4mg (Additional Indication)	Each uncoated tablet contains: Saroglitazar 4 mg	Noncirrhoic Non-Alcohol Steatohepatitis	02-03-2020
	Itraconazole Capsule 200 mg (Additonal Strength)	Each capsule contains: Itraconazole 200 mg	For the treatment of onychomycosis of the toenail due to Trichophyton rubrum or T. mentagrophytes in non-immunocompromised patients Warning: To be sold by retail on the prescription of a Specialist only.	03-03-2020
	Nepafenac Ophthalmic suspension 0.3% w/v (Additional Indication)	Each ml contains: Nepafenac 3mg	Reeducation in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients Warning: To be sold by	03-03-2020

			retail on the prescription of a Opthamologists only.	
	Bisoprolol Fumarate tablet 1.25 mg (Additional strength)	Each film coated tablet contains: Biosoprolol Fumarate 1.25 mg	For the treatment of congestive heart failure (CHF)	04-03-2020
	Pirfenidone Tablets 267 & 801 mg (Additional Strength)	Each film coated tablet contains: Pirfenidone 267mg/801 mg	For the treatment of idiopathic pulmonary fibrosis Warning: To be sold by retail on the prescription of a Pulmonologist only.	04-03-2020
	Pegaspargase Injection 3750 IU/5ml (Additional Indication)	Each 5ml vial contains: Pegaspargase Injection 2750 IU	Injection as first-Line chemotherapeutic agent for treatment of patients with acute Lymphoblastic Leukemia (ALL) Warning: To be sold by retail on the prescription of a Oncologist only.	04-03-2020
	Norethisterone Acetate Controlled Release Tablet 15 mg (Additional Strength)	Each film coated controlled release tablet contains Norethisterone Acetate 15 mg	To arrest bleeding in women with Heavy Menstrual Bleeding (HMB)/abnormal Uterine Bleeding (AUB) due to hormonal imbalance Warning: To be sold by retail on the prescription of a Gynaecologist/Obstertrician only.	09-03-2020
	Estriol Tablets 1mg/2mg (Additional strength)	Each uncoated Tablet contains: Estriol 1mg/2mg	Estrogen deficiency symptoms due to menopause Warning: To be sold by retail on the prescription of a Gynaecologist only.	09-03-2020
	Busulfan Injection 60 mg/10ml (Additional Strength)	Each 10 ml vial contains: Buslfan 60mg	In combination with cyclophosphamide as a conditioning regimen prior to allogenic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia Warning: To be sold by retail on the prescription of a Oncologist only.	09-03-2020
	Ulipristal Acetate Tablet 30 mg (Additional strength & indication)	Each film coated tablet contains Ulipristal acetate 30 mg	Emergency contraception within 120 hrs (5 days) of unprotected sexual intercourse or contraceptive failure Warning: To be sold by retail on the prescription of a Gynaecologist only.	11-03-2020

	Canagliflozin Tablet 100/300 mg (Additional Indication)	Each film coated tablet contains: Canagliflozin 100/300 mg	To reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria 300mg/day	11-03-2020
	Nintedanib Soft Gelatin Capsules 100/150 mg (Additional Indication)	Each soft gelatin capsule contains: Nintedanib Ethanesulfonate equivalent to Nintedanib 100/150 mg	For the treatment of systemic sclerosis associated interstitial Lung Disease (SSc-ILD) Warning: To be sold by retail on the prescription of a Pulmonologist only.	20-03-2020