

**List of drugs approved from SND Division from 01.01.2020 to 29.05.2020**

<b>S. No</b>	<b>Drug Name</b>	<b>Composition</b>	<b>Indication</b>	<b>Date of Approval</b>
1	Betahistine Dihydrochloride Orally Disintegrating Strips 16mg /24 mg <b>(New Dosage form)</b>	Each Orally Disintegrating Strips contains:  Betahistine Dihydrochloride .....16mg/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 <b>(Modified Release dosage form)</b>	Each-Gastro-Resistant Tablet Contains: Posaconazole.....100 mg	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  <b>Warning: To be sold by retail on the prescription of Specialist only.</b>	03-01-2020
3	Pirfenidone tablet 600 mg <b>(Additional strength)</b>	Each Film coated Tablet contains: Pirfenidone....600mg	For the Treatment of idiopathic pulmonary fibrosis  <b>Warning: To be sold by retail on the prescription of Pulmonologist only.</b>	08-01-2020

4	Saroglitazar Tablet 2mg/4 mg <b>(Additional indication)</b>	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 <b>(Additional indication)</b>	Each soft capsules contains Enzalutamide...40 mg	In the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated  <b>Warning: To be sold by retail on the prescription of Oncologist only.</b>	23-01-2020
6	Canagliflozin 100 mg and 300 mg Tablet <b>(Additional Indication)</b>	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 <b>(Additional Dosage form &amp; Indication)</b>	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 <b>(Additional Dosage Form)</b>	Each ml contains:  Lidocaine Hydrochloride 20mg	<b>Indicated in adults:</b> • 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
9	Saroglitazar Tablets 4mg	Each uncoated tablet contains:	Noncirrhoic Non-Alcohol Steatohepatitis	02-03-2020

	<b>(Additional Indication)</b>	Saroglitazar 4 mg		
10	Itraconazole Capsule 200 mg <b>(Additional Strength)</b>	Each capsule contains: Itraconazole 200 mg	For the treatment of onychomycosis of the toenail due to <i>Trichophyton rubrum</i> or <i>T. mentagrophytes</i> in non-immunocompromised patients  <b>Warning: To be sold by retail on the prescription of a Specialist only.</b>	03-03-2020
11	Nepafenac Ophthalmic suspension 0.3% w/v <b>(Additional Indication)</b>	Each ml contains: Nepafenac 3mg	Reeducation in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients  <b>Warning: To be sold by retail on the prescription of a Ophthalmologists only.</b>	03-03-2020
12	Bisoprolol Fumarate tablet 1.25 mg <b>(Additional strength)</b>	Each film coated tablet contains: Biosoprolol Fumarate 1.25 mg	For the treatment of congestive heart failure (CHF)	04-03-2020
13	Pirfenidone Tablets 267 & 801 mg <b>(Additional Strength)</b>	Each film coated tablet contains: Pirfenidone 267mg/801 mg	For the treatment of idiopathic pulmonary fibrosis  <b>Warning: To be sold by retail on the prescription of a Pulmonologist only.</b>	04-03-2020
14	Pegaspargase Injection 3750 IU/5ml <b>(Additional Indication)</b>	Each 5ml vial contains: Pegaspargase Injection 3750 IU	Injection as first-Line chemotherapeutic agent for treatment of patients with acute Lymphoblastic Leukemia (ALL)  <b>Warning: To be sold by retail on the prescription of a Oncologist only.</b>	04-03-2020
15	Norethisterone Acetate Controlled Release	Each film coated controlled release tablet	To arrest bleeding in women with Heavy	09-03-2020

	Tablet 15 mg <b>(Additional Strength)</b>	contains Norethisterone Acetate 15 mg	Menstrual Bleeding (HMB)/abnormal Uterine Bleeding (AUB) due to hormonal imbalance  <b>Warning: To be sold by retail on the prescription of a Gynaecologist/Obstetrician only.</b>	
16	Estriol Tablets 1mg/2mg <b>(Additional strength)</b>	Each uncoated Tablet contains: Estriol 1mg/2mg	Estrogen deficiency symptoms due to menopause  <b>Warning: To be sold by retail on the prescription of a Gynaecologist only.</b>	09-03-2020
17	Busulfan Injection 60 mg/10ml <b>(Additional Strength)</b>	Each 10 ml vial contains: Busulfan 60mg	In combination with cyclophosphamide as a conditioning regimen prior to allogenic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia  <b>Warning: To be sold by retail on the prescription of a Oncologist only.</b>	09-03-2020
18	Ulipristal Acetate Tablet 30 mg <b>(Additional strength &amp; indication)</b>	Each film coated tablet contains Ulipristal acetate 30 mg	Emergency contraception within 120 hrs (5 days) of unprotected sexual intercourse or contraceptive failure  <b>Warning: To be sold by retail on the prescription of a Gynaecologist only.</b>	11-03-2020
19	Canagliflozin Tablet 100/300 mg <b>(Additional Indication)</b>	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	11-03-2020

			albuminuria 300mg/day	
20	Nintedanib Soft Gelatin Capsules 100/150 mg  <b>(Additional Indication)</b>	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)  <b>Warning: To be sold by retail on the prescription of a Pulmonologist only.</b>	20-03-2020
21	Oxaliplatin Injection 50 mg/vial & 100 mg/val  <b>(Additional Dosage Form)</b>	Each Vial contains: Sterile Solution of Oxaliplatin 50mg and 100mg	For the treatment of advanced colorectal cancer.  <b>Warning: To be sold by retail on the prescription of an oncologist only.</b>	29-04-2020
22	Metformin Hydrochloride Prolonged Release Tablets 500mg  <b>(Additional Indication)</b>	Each Prolonged Release Tablets contains: Metformin Hydrochloride 500mg	For the treatment of Polycystic Ovary Syndrome (PCOS) with established insulin resistance  <b>WARNING: To be sold by retail on the prescription of a RMP only</b>  In the package insert - Special warnings and precautions: Pregnancy: "There are no adequate and well-controlled studies in pregnant women with Metformin and Metformin should not be used during pregnancy unless clearly needed"	05-05-2020
23	Olaparib 100 mg and 150 mg Tablets  <b>(Additional Indication)</b>	Each Film coated tablet contains: Oloaparib... 100mg/150 mg.	Olaparib is indicated as monotherapy for the Maintenance treatment of adult patients with germline BRCA-mutated metastatic	06-05-2020

			<p>adenocarcinoma of the pancreas whose disease has not progressed on first-line platinum-based chemotherapy</p> <p><b>“WARNING: To be sold by retail on the prescription of Oncologist only”</b></p>	
24	<p>Bortezomib For injection 2.5mg/ml <b>(Additional Pack Size)</b></p>	<p>Each Vial Contains: Bortezomib 2.5 mg</p>	<ul style="list-style-type: none"> <li>• For the treatment of patients with multiple myeloma</li> <li>• For the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.</li> </ul> <p><b>WARNING: To be sold by retail on the prescription of Oncologist only” which shall be in red box;</b></p>	12-05-2020