

## LIST OF DRUGS APPROVED FROM SND TILL 31 May 2021

S. No	Drug Name	Composition	Indication	Date of Approval
1	Atropine Sulfate Ophthalmic Solution USP 0.01% w/v  <b>(Additional Strength)</b>	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  <b>"WARNING: To be sold by retail on the prescription of Ophthalmologist only"</b>  <b>With the Condition to conduct phase IV Clinical trial to assess long term safety of the product.</b>	12-01-2021
2	Colistimethate Sodium For Injection IP 3 MIU/ 4.5 MIU  <b>(Additional Strength)</b>	(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.  <b>"WARNING: To be sold by retail on the prescription of a Medical Specialist only"</b>	15-01-2021
3	Dapagliflozin Tablets 10 mg  <b>Additional Indication</b>	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 <sup>2</sup> )  <b>"WARNING: To be sold by retail on the prescription of Nephrologist only"</b>	03-02-2021

4	Brivaracetam Oral Solution Solution 10mg/ml  <b>Additional Dosage Foam</b>	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	03-02-2021
5	Drospirenone Tablets 4 mg  <b>Additional Strength</b>	Each for uncoated Tablets 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  <b>Additional pack size &amp; strength</b>	Apomorphine Hydrochloride solution for infusion in 20ml vial Each ml contains: Apomorphine Hydrochloride..... ... 5mg  Apomorphine Hydrochloride solution for injection in 3ml cartridge Each ml contains: Apomorphine Hydrochloride..... 10 mg	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.  <b>"WARNING: To be sold by retail on the prescription of Neurologists only"</b>	16-02-2021
7	Thyroxine Sodium Tablets 88 mcg / 200mcg  <b>Additional Strength</b>	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)  <b>Additional dosage form &amp; New route of administration</b>	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

9	<p>Aripiprazole powder and solvent for prolong-release suspension for injection 300mg/vial and 400 mg/vial</p> <p><b>(Modified Dosage Form)</b></p>	<p>Each vial contains: Aripiprazole.....300mg / 400mg (Supplied along with solvent/diluent)</p>	<p>Maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole</p> <p><b>“WARNING: To be sold by retail on the prescription of an Psychiatrist only”</b></p>	01-03-2021
10	<p>Rebamipide Ophthalmic Suspension 2% w/v with Stabilized Oxychloro complex (as preservative)</p>	<p>Each ml contains: Rebamipide.....2.0 %w/v Stabilized Oxychloro Complex.....0.01% w/v (As Preservative)</p>	<p>Indicated for the treatment of dry eye signs and symptoms</p>	01-03-2021
11	<p>Pancreatin Tablets USP 200 mg</p> <p><b>(Additional Strength/New dosage form/New Indication)</b></p>	<p>Each uncoated tablet Contains: Pancreatin ...200mg Equivalent to Lipase .....10,440 USP units Amylase.....39,150 USP units Protease.....39150 USP units</p>	<p>Indicated in combination with a proton pump inhibitor in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy</p>	01-03-2021
12	<p>Pemetrexed for injection 100mg/500mg</p> <p><b>(Additional Indication)</b></p>	<p>Each vial contains: Pemetrexed Disodium equivalent to Pemetrexed ...100mg/500mg</p>	<p>In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations</p> <p><b>"WARNING: To be sold by retail on the prescription of oncologist only"</b></p>	08-03-2021

13	Ibuprofen solution for infusion 400mg/100ml  <b>(New Dosage Form)</b>	Each ml contains: Ibuprofen .....4mg	Indicated in adults for the short-term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified when other routes of administration are not possible	08-03-2021
14	Cholecalciferol oral drops 800IU/ml  <b>(Additional Strength/New dosage Form)</b>	Each ml contains: Cholecalciferol .....800IU	For the treatment of vitamin D3 deficiency	08-03-2021
15	Osimertinib Tablets 40mg and 80mg  <b>(Additional Indication)</b>	Each film-coated tablets contains: Osimertinib (as mesylate).....40mg/80mg	Osimertinib as monotherapy is indicated for: The adjuvant treatment after complete tumour resection in patients with nonsmall cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations  <b>"WARNING: To be sold by retail on the prescription of oncologist only"</b>	09-03-2021
16	Dolutegravir Dispersible Tablets 10mg  <b>(Additional Dosage Form)</b>	Each Tablet contains: Dolutegravir sodium equivalent to Dolutegravir 10mg	In combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus type1 (HIV-1) infection in adults (treatment-naive or-experienced) and in pediatric patients (treatment-naive or -experienced but integrase strand transfer inhibitor [INSTI]-naive) aged at least 4 weeks and weighing at least 3 kg  <b>"WARNING: To be sold by retail on the prescription of a Specialist only"</b>	23-03-2021

17	Sildenafil Citrate Oral Spray 12.5% w/v  (Additional Dosage Form)	Each Spray (0.2ml) delivers Sildenafil citrate equivalent to Sildenafil.....2 5mg	For the treatment of Erectile Dysfunction in men  “ <b>WARNING: To be sold by retail on the prescription of an Urologist, Psychiatrist and Endocrinologist only</b> ”	26-03-2021
18	Dexamethasone Tablets 6 mg  (Additional Strength)	Each film coated tablet contains : Dexamethasone .....6 mg	<p>Dexamethasone is indicated for treatment of variety of disorders in which systemic glucocorticoids are indicated including:</p> <ul style="list-style-type: none"> <li>• Neurology: Cerebral oedema (only with symptoms of intracranial pressure evidenced by computerised tomography) caused by a primary or metastatic brain tumour, craniotomy or head injury.</li> <li>• Dermatology: Initial treatment of extensive, severe, acute, skin diseases responding to glucocorticoids, e.g. erythroderma, pemphigus vulgaris.</li> <li>• Autoimmune disorders/rheumatology: Initial treatment of autoimmune disorders like systemic lupus erythematosus, in acute gouty arthritis ,acute arthritis carditis, ankylosing spondylitis ,psoriatic arthritis , Severe progressive course of active rheumatoid arthritis Severe systemic course of juvenile idiopathic arthritis (Still's disease).</li> </ul>	06-04-2021

			<ul style="list-style-type: none"> <li>• Haematological disorder: Idiopathic thrombocytopenic purpura in adults.</li> <li>• Oncologists only- for steroid responsive neoplastic disease like leukemias and lymphomas in adults only.</li> </ul>	
19	Betahistine Hydrochloride Orally Disintegrating tablet 8 mg/16mg/24 mg  <b>(New Dosage Form)</b>	Each Uncoated Orally Disintegrating Tablet Contains: Betahistine Hydrochloride mg/16mg/24mg Excipients q.s.	Indicated for the symptomatic treatment of vertigo caused due to conditions including Menier's syndrome.	06-04-2021
20	Pegaspargase powder for solution for injection/infusion  <b>(New Dosage Form &amp; Indication)</b>	Each vial contains: Pegaspargase .....3750 U (After reconstitution each ml contains 750U of Pegaspargase)	Indicated as a component of anti-neoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients	09-04-2201
21	<b>Drospirenone Tablets 4mg</b>  <b>(New Dosage Form)</b>	Each Film Coated Tablet Contains: Drospirenone .....4mg	Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy	22-04-2021

22	<p>Baricitinib Tablets 1mg, 2mg, &amp; 4 mg</p> <p><b>(Additional Strength &amp; Additional Indication)</b></p>	<p>Each Film Coated Tablet Contains: Baricitinib....1 mg/2mg/4 mg</p>	<p>Baricitinib, in combination with Remdesivir, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)</p> <p><b>“WARNING: To be sold by retail on the prescription of specialist for use in Hospital/ Institutional set up only”</b></p>	01-05-2021
23	<p>Remdesivir Injection 100mg/20 ml</p> <p><b>(without Cyclodextrin)</b></p>	<p>Each ml Contains- Remdesivir...5 mg</p>	<p>For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalized with moderate to severe disease</p> <p><b>“WARNING: To be sold by retail on the prescription of specialist for use in Hospital/ Institutional set up only”</b></p>	06-05-2201
24	<p>Favipiravir Oral suspension 100mg/ml</p> <p><b>(New Dosage Form)</b></p>	<p>Each ml contains: Favipiravir..... ....100mg</p>	<p>For the treatment of patients with mild to moderate Covid-19 disease</p> <p><b>“Warning To be sold on prescription of medical specialist”</b></p>	19-05-2021
25	<p>Posaconazole Delayed-Release Tablets</p> <p><b>(Additional Indication)</b></p>	<p>Each Delayed-Release Tablets contains: Posaconazole ..... 100mg</p>	<p>• For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to Itraconazole and/or</p>	28-05-2021

			<p>fluconazole for prophylaxis of invasive Aspergillus and Candida infections in patients, 13 years of age and older, 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.</p> <ul style="list-style-type: none"> <li>• Zygomycosis (Mucormycosis) in patients with diseases refractory to other therapy ,or or patients who are intolerant to other therapy</li> </ul> <p><b>“Warning To be sold on prescription of medical specialist”</b></p>	
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