

**Website Update 01-01-2021 to 31-12-2021**

<b>S. No</b>	<b>Drug Name</b>	<b>Composition</b>	<b>Indication</b>	<b>Date of Approval</b>
1	Atropine Sulfate Ophthalmic Solution USP 0.01% w/v  <b>(Additional Strength)</b>	Each ml Contains: Atropine Sulfate.....0. .....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.....30 00000 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.....1 0 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.....88 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	<p>Sildenafil Citrate Oral Spray 12.5% w/v</p> <p><b>(Additional Dosage Form)</b></p>	<p>Each Spray (0.2ml) delivers Sildenafil citrate equivalent to Sildenafil.....25mg</p>	<p>For the treatment of Erectile Dysfunction in men</p> <p><b>“WARNING: To be sold by retail on the prescription of an Urologist, Psychiatrist and Endocrinologist only”</b></p>	26-03-2021
18	<p>Dexamethasone Tablets 6 mg</p> <p><b>(Additional Strength)</b></p>	<p>Each film coated tablet contains : Dexamethasone .....6 mg</p>	<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 erythematoses, 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> <li>• Haematological disorder: Idiopathic thrombocytopenic purpura in adults.</li> <li>• Oncologists only- for steroid responsive neoplastic disease</li> </ul>	06-04-2021

			like leukemias and lymphomas in adults only.	
19	<p>Betahistine Hydrochloride Orally Disintegrating tablet 8 mg/16mg/24 mg</p> <p><b>(New Dosage Form)</b></p>	<p>Each Uncoated Orally Disintegrating Tablet Contains: Betahistine Hydrochloride mg/16mg/24mg Excipients q.s.</p>	<p>Indicated for the symptomatic treatment of vertigo caused due to conditions including Menier's syndrome.</p>	06-04-2021
20	<p>Pegaspargase powder for solution for injection/ infusion</p> <p><b>(New Dosage Form &amp; Indication)</b></p>	<p>Each vial contains: Pegaspargase .....3750 U (After reconstitution each ml contains 750U of Pegaspargase)</p>	<p>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</p>	09-04-2201
21	<p><b>Drospirenone Tablets 4mg</b></p> <p><b>(New Dosage Form)</b></p>	<p>Each Film Coated Tablet Contains: Drospirenone .....4mg</p>	<p>Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy</p>	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....1mg/2 mg/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>	01-05-2021

			<b>“WARNING: To be sold by retail on the prescription of specialist for use in Hospital/ Institutional set up only”</b>	
23	Remdesivir Injection 100mg/20 ml  <b>(without Cyclodextrin)</b>	Each ml Contains- Remdesivir...5mg	For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalized with moderate to severe disease  <b>“WARNING: To be sold by retail on the prescription of specialist for use in Hospital/ Institutional set up only”</b>	06-05-2201
24	Favipiravir Oral suspension 100mg/ml  <b>(New Dosage Form)</b>	Each ml contains: Favipiravir.....100mg	For the treatment of patients with mild to moderate Covid-19 disease  <b>“Warning To be sold on prescription of medical specialist”</b>	19-05-2021
25	Posaconazole 100 MG Delayed-Release Tablets  <b>(Additional Indication)</b>	Each Delayed-Release Tablets contains:  Posaconazole.....100mg	<ul style="list-style-type: none"> <li>• For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to Itraconazole and/or 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</li> </ul>	28-05-2021

			<p>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>	
26	<p>Posaconazole Gastro-Resistant Tablets 300 mg</p> <p><b>(Additional Strength)</b></p>	<p>Each Gastro-Resistant Tablet Contains:</p> <p>Posaconazole.....300 mg</p>	<p>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.</p> <p>Posaconazole Gastro Resistant Tablets are indicated in patients 13 years of age and older.</p> <p><b>"WARNING: To be sold by retail on the prescription of a Medical Specialist only"</b></p>	07-06-2021
27	<p>Ulinastatin for injection 200000 IU (Liquid)</p> <p><b>(Additional Strength)</b></p>	<p>Each vial Contains: Ulinastatin .....</p> <p>.....200000 IU</p>	<ul style="list-style-type: none"> <li>• For the treatment of severe sepsis.</li> <li>• For the treatment of mild and severe acute pancreatitis.</li> </ul>	24-06-2021
28	<p>Imatinib Oral Solution 80 mg/ml</p> <p><b>(New Dosage Foam)</b></p>	<p>Each ml contains: Imatinib (As mesilate).....80mg</p>	<p>1. Treatment of adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy.</p>	24-06-2021

			<p>2. Treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy.</p> <p>3. Adjuvant treatment of adult patients following resection of gastro-intestinal stromal tumors (GIST), and 4. Treatment of CML in blast crisis, accelerated phase or in chronic phase after failure of interferon alpha therapy.</p> <p><b>“WARNING: To be sold by retail on the prescription of oncologist only”</b></p>	
29	<p>Clozapine Tablet 12.5 mg</p> <p><b>(Additional Strength)</b></p>	<p>Each uncoated tablet contains: Clozapine 12.5 mg</p>	<p>Indicated in the management of schizophrenic patients</p> <p><b>“WARNING: To be sold by retail on the prescription of Neurologist only”</b></p>	29-06-2021
30	<p>Sorafenib Tablets 400mg</p> <p><b>(Additional Strength)</b></p>	<p>Each film coated tablets contains : Sorafenib Tosylate eq. to Sorafenib...400 mg</p>	<p>For the treatment of hepatocellular carcinoma, advanced renal cell carcinoma and locally advance or metastatic differentiated thyroid carcinoma refractory to radioactive iodine</p> <p><b>“WARNING: To be sold by retail on the prescription of Oncologist only”</b></p>	30-06-2021
31	<p>Favipiravir Powder for Oral suspension 800mg</p> <p><b>(Additional Dosage Form)</b></p>	<p>Each sachet contains: 1.5g of Favipiravir powder contains:  Favipiravir.....800mg Excipients.....q.s</p>	<p>For the treatment of patients with mild to moderate Covid-19 disease</p> <p><b>“WARNING: To be sold on the prescription of medical specialist”</b></p>	06-07-2021

32	<p>Heparin Sodium Topical Solution 1000 IU/ml</p> <p><b>(Additional Indication)</b></p>	<p>Each ml contains :  Heparin Sodium .....1000 IU/ml  Absolute Alcohol.....10.0 0% v/v  Topical Solution base.....q.s.</p>	<p>For Prevention of infusion associated phlebitis</p> <p><b>"WARNING: To be sold by retail on the prescription of Specialists only"</b></p>	09-07-2021
33	<p>Pemetrexed for injection 1000mg (Lyophilized)</p> <p><b>(Additional Strength)</b></p>	<p>Each vial contains:  Pemetrexed Disodium heptahydrate equivalent IP to Pemetrexed .....1000mg</p>	<p>1. Indicated as a monotherapy for the maintenance treatment of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First line treatment Should be a platinum doublet with gemcitabine, paclitaxel or docetaxel. 2. In combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.</p> <p>3. As monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.</p> <p>4. As monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has to progressed immediately following platinum based chemotherapy.</p>	16-07-2021

			<b>"WARNING: To be sold by retail on the prescription of oncologist only"</b>	
34	Acetyl Salicylic Acid Effervescent Tablets 500 mg  <b>(Additional Dosage Foam)</b>	Each Effervescent tablet contains: Acetyl Salicylic Acid ... 500 mg	Analgesic & Anti pyretic	16-07-2021
35	Pentosan polysulfate sodium sterile solution for intravesical instillation 10 mg/ml (30ml)  <b>(Additional Dosage form &amp; Route of administration)</b>	Each ml contains: Pentosan Polysulfate Sodium .....10mg	For intravesical treatment of the bladder pain syndrome/interstitial cystitis  <b>"WARNING: To be sold by retail on the prescription of a Specialist only"</b>	16-07-2021
36	Amikacin Injection 750mg/3ml & 1000 mg/4ml  <b>(Additional pack size /Additional Strength)</b>	Amikacin Injection IP 750 mg Each 3ml Contains: Amikacin Sulphate IP Equivalent to Amikacin .....750 mg Water for Injections IP..... q.s Methylparaben IP.....0.04w/v Propylparaben IP.....0.01w/v (As preservatives) (Suitable buffering agent and antioxidant added) Amikacin Injection IP 1000 mg Each 4ml Contains: Amikacin Sulphate IP Equivalent to Amikacin .....1000 mg Water for Injections IP..... q.s Methylparaben	Amikacin Injection is indicated in the treatment of serious infections due to Amikacin sensitive organisms  <b>"WARNING: To be sold by retail on the prescription of a Specialist only"</b>	23-07-2021

		IP.....0.04w/v Propylparaben IP.....0.01w/v (As preservatives) (Suitable buffering agent and antioxidant added)		
37	Riboflavin Sodium Phosphate IP eq. to Riboflavin 0.1 % w/v with Hypromellose Ophthalmic Solution in PFS (Pack Size is 3.0ml)  <b>(Additional Pack Size)</b>	Each ml contains: Riboflavin Sodium Phosphate IP Eq. to Riboflavin .....0.1% w/v Hypromellose I.P.....1.1%w/v	To treat keratoconus and corneal ectasia following refractive surgery	27-07- 2021
38	Amorolfine Lotion 0.25% w/v  <b>(Additional Dosage Form)</b>	Each ml contains: Amorolfine Hydrochloride Equivalent to Amorolfine.....0.25 % w/v	For the treatment of dermatomycosis caused by dermatophytes, cutaneous candidiasis and pityriasis versicolor  <b>"WARNING: To be sold by retail on the prescription of an Dermatologist only"</b>	29-07- 2021
39	Silodosin Tablet 8 mg  <b>(Additional Dosage Form)</b>	Each film coated tablets contains : Silodosin...8 mg	For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adults only  <b>"WARNING: To be sold by retail on the prescription of a Urologist only"</b>	30-07- 2021
40	Remdesivir Injection 100mg/20ml (5mg/ml)  <b>(with Hydroxypropyl Betadex as Excipient)</b>	Each ml contains: Remdesivir...5mg  Hydroxypropyl Betadex (As excipient)...300mg	For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalized with moderate to severe disease, in light of Covid 19 outbreak, for restricted emergency use in the country.  <b>"Warning : To be Sold by retail on the prescription of</b>	05-08-2021

			<b>specialist for use in Hospital/Institutional set up only”</b>	
41	Bilastine Tablets 40mg  <b>(Additional Strength)</b>	Each film-coated tablet contains : Bilastine .....40mg.	For the treatment of Chronic Spontaneous Urticaria  <b>The firm should conduct an active PMS study. Accordingly, the firm should submit active PMS protocol for review by the committee</b>  <b>"WARNING: To be sold by retail on the prescription of Dermatologist only”</b>	06-08-2021
42	Enzalutamide Hard Gelatin Capsules 80mg  <b>(Additional Indication)</b>	Each Hard Gelatin Capsule contains : Enzalutamide ..... .80mg	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>	06-08-2021
43	Triptorelin powder for Injection 3.75 mg/vial  <b>(Additional Indication)</b>	Each pack contains: One vial of Triptorelin pamoate for injection Each single dose vial contains: (Sterile Lyophilized) Triptorelin pamoate equivalent to Triptorelin ..... 3.75 mg Excipients.....q.s.	Indicated for the adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of hormone receptor-positive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy”.  <b>“WARNING: To be sold by retail on the prescription of Oncologist only”</b>	06-08-2021

44	<p>Lorlatinib tablets 25/100 mg</p> <p><b>(Additional Indication)</b></p>	<p>Each film-coated tablets contains: Lorlatinib..... ...25mg/100mg</p>	<p>Lorlatinib is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) positive</p> <p><b>“WARNING: To be sold by retail on the prescription of oncologist only”</b></p>	06-08-2021
45	<p>Palbociclib and Capsules and Palbociclib Tablets 75/100/125 mg</p> <p><b>(Additional Indication)</b></p>	<p>Each Hard Gelatin Capsule contains: Palbociclib..... 75mg/100mg/125mg Each Film-Coated Tablets contains: Palbociclib..... 75mg/100mg/125mg</p>	<p>“Palbociclib is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy and with Fulvestrant in patients who have received prior therapy for Male patients”</p> <p><b>“WARNING: To be sold by retail on the prescription of oncologist only”</b></p>	
46	<p>Itraconazole Capsule 130 mg <b>(Supra-bioavailable formulation)</b></p> <p><b>(Additional Strength, Modified Dosage form)</b></p>	<p>Each Capsule Contains: Itraconazole..... 130 mg</p>	<p>Itraconazole 130 mg Capsule is indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:</p> <ul style="list-style-type: none"> <li>• Blastomycosis, Pulmonary and Extra pulmonary</li> <li>• Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis.</li> <li>• Aspergillosis, pulmonary and extra-pulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy</li> </ul> <p><b>The package insert should contain the following caution</b> <b>“This Itraconazole Capsules 130mg is not interchangeable or substitutable with other Itraconazole products due to the differences in dosing between Itraconazole capsule</b></p>	09-08-2021

			<p><b>130 (Supra bioavailable formulation) and other Itraconazole products</b></p> <p><b>"WARNING: To be sold by retail on the prescription of a Specialist only"</b></p>	
47	<p>Progesterone Solution for Injection (50mg/2.237ml)</p> <p><b>(Additional Strength)</b></p>	<p>Each Vial (2.237ml) Contains: Progesterone ..... 50mg (22.35 mg/ml) Water for Injections IP.....q.s.</p>	<p>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.</p> <p><b>"WARNING: To be sold by retail on the prescription of a Gynecologists only"</b></p>	17-08-2021
48	<p>Estradiol 1.53 mg/actuation, Transdermal spray, solution</p> <p><b>(Additional dosage form and Additional Indication)</b></p>	<p>Each actuation delivers Estradiol Ph. Eur.....1.53 mg (Equivalent to 1.58mg Estradiol hemihydrate) Ethanol 96% USP .....0.09 ml ( Octisalate USP and Ethanol 96% used as excipients )</p>	<p>Hormone Replacement Therapy (HRT) for Estrogen deficiency symptoms in Peri / postmenopausal women (in women at least 6 months since last menses or surgical menopause, with or without a uterus). The experience in treating women older than 65 years is limited</p> <p><b>Firm should conduct active Post Marketing Surveillance study to assess the safety and efficacy. Firm should submit the results of the PMS study within one year from date of approval.</b></p> <p><b>"WARNING: To be sold by retail on the prescription of Gynecologists only"</b></p>	17-08-2021
49	<p>Posaconazole Gastro Resistant Tablets 300 mg</p> <p><b>(Additional Indication)</b></p>	<p>Each Gastro Resistant Tablets Contains: Posaconazole..... .300 mg</p>	<p>For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole. For prophylaxis of invasive Aspergillus and Candida infections in patients, 13 years of age and older, who are at high</p>	17-08-2021

			<p>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. Zygomycosis (Mucormycosis). in patients with disease refractory to other therapy, or patients who are intolerant of other therapy</p> <p><b>"WARNING: To be sold by retail on the prescription of a Medical Specialist only"</b></p>	
50	<p>Mesalazine Prolonged Release Granules 1gm &amp; 2gm</p> <p><b>(Additional dosage form &amp; strengths)</b></p>	<p>(i) Mesalazine Prolonged Release Granules 1gm Each Sachet Contains: Mesalazine ..... 1gm</p> <p>Excipients .....q.s</p> <p>(as film coated granules)</p> <p>(ii) Mesalazine Prolonged Release Granules 2gm Each Sachet Contains: Mesalazine ..... 2gm</p> <p>Excipients ..... q.s</p> <p>(as film coated granules)</p>	<p>Chronic inflammatory bowel disease (Ulcerative Colitis and Crohn's disease)</p>	17-08-2021
51	<p>Cyclosporine Ophthalmic Solution 0.09% w/v</p> <p><b>(Additional dosage &amp; Additional Indication)</b></p>	<p>Each ml contains: Cyclosporine IP.....0.09 mg Aqueous Buffered Vehicle.....q.s</p>	<p>Indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).</p> <p><b>Firm required to conduct Phase IV clinical trial. Accordingly firm should submit phase IV protocol</b></p>	23-08-2021

			<b>“WARNING: To be sold by retail on the prescription of Ophthalmologist only”</b>	
52	Azacitidine Tablets 300 mg  <b>(New Dosage form &amp; Additional Indication)</b>	Each film coated tablet contains: Azacitidine IP .....300 mg	For continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRI) following intensive induction chemotherapy and are not able to complete intensive curative therapy  <b>“WARNING: To be sold by retail on the prescription of Oncologist only”</b>	23-08-2021
53	Moxifloxacin Ophthalmic Solution 0.5% w/v  <b>(Additional Indication)</b>	Each ml of Ophthalmic Solution contains: Moxifloxacin Hydrochloride equivalent to Moxifloxacin base.....5 mg	Indicated for sterilization during the perioperative period of ophthalmic surgery  <b>“WARNING: To be sold by retail on the prescription of Ophthalmologists only”</b>  <b>The firm should submit protocol for active PMS Study</b>	02-09-2021
54	Minoxidil Topical Solution 2% and 5%  <b>(Additional Indication)</b>	Minoxidil Topical Solution 2% Each ml contains: Minoxifil IP 20mg Alcohol (95%) IP equivalent to absolute alcohol 63% v/v  Minoxidil Topical Solution 5% Each ml	For the treatment of androgenic alopecia in females (female pattern hair loss)  <b>“WARNING: To be sold by retail on the prescription of a Dermatologist only”</b>	02-09-2021

		contains: Minoxifil IP 50mg Alcohol (95%) IP equivalent to absolute alcohol 40% v/v		
55	<p>Pemetrexed Solution for Infusion 5mg/ml, 6mg/ml, 6.5mg/ml, 7mg/ml, 7.5mg/ml, 8mg/ml, 8.5mg/ml, 9mg/ml, 10mg/ml &amp; 11mg/ml (100ml ready to use infusion bag)</p> <p><b>(Additional Dosage Form)</b></p>	<p>Each ml Contains: Pemetrexed Disodium Heptahydrate Equivalent to Pemetrexed...5mg Sodium Chloride .....9mg Water for Injections .....q. s.</p> <p>Pemetrexed Disodium Heptahydrate Equivalent to Pemetrexed 6mg Sodium Chloride ..... 9mg Water for Injections..... .....q. s.</p> <p>Pemetrexed Disodium Heptahydrate Equivalent to Pemetrexed 6.5mg Sodium Chloride .....9mg Water for Injections .....q. s.</p> <p>Pemetrexed Disodium Heptahydrate Equivalent to Pemetrexed.....7mg Sodium Chloride .....9mg Water for Injections .....q. s.</p> <p>Pemetrexed Disodium Heptahydrate Equivalent to Pemetrexed 7.5mg Sodium Chloride</p>	<p>1. <b>Malignant pleural mesothelioma:</b></p> <ul style="list-style-type: none"> <li>In combination with Cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma.</li> </ul> <p>2. <b>Non-Small Cell Lung Cancer (NSCLC):</b></p> <ul style="list-style-type: none"> <li>In combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology. • As a monotherapy for the second-line treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology. • As a monotherapy for the maintenance treatment of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.</li> <li>In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous Non-Small Cell Lung Cancer (NSCLC), with</li> </ul>	03-09-2021

		<p>.....  9mg Water for  Injections  .....q. s</p> <p>Pemetrexed  Disodium  Heptahydrate  Equivalent to  Pemetrexed.....8mg  Sodium Chloride  .....  9mg Water for  Injections  .....q. s.</p> <p>Pemetrexed  Disodium  Heptahydrate  Equivalent to  Pemetrexed 8.5mg  Sodium Chloride  .....9  mg Water for  Injections  .....q. s.</p> <p>Pemetrexed  Disodium  Heptahydrate  Equivalent to  Pemetrexed.....9mg  Sodium Chloride  .....9  mg Water for  Injections  .....q. s.</p> <p>Pemetrexed  Disodium  Heptahydrate  Equivalent to  Pemetrexed 10mg  Sodium Chloride  .....9mg  Water for Injections  .....q. s.</p> <p>Pemetrexed  Disodium  Heptahydrate  Equivalent to  Pemetrexed 11mg  Sodium Chloride  .....9mg</p>	<p>no EGFR or ALK genomic  tumor aberrations.</p> <p><b>"WARNING: To be sold by  retail on the prescription  of an oncologist only"</b></p>	
--	--	--	---	--

		Water for Injections .....q. s.		
56	Tofacitinib Tablets 5mg  <b>(Additional Indication)</b>	Each Film coated tablets contains: Tofacitinib citrate equivalent to Tofacitinib..... 5mg	In treatment of adult patient with moderately to severely active Ulcerative Colitis (UC), who have an inadequate response and who are intolerant to TNF blockers  <b>“WARNING: To be sold by retail on the prescription of Rheumatologist, Gastroenterologist, Hepatologist or “Specialist in internal Medicine only”</b>	13-09- 2021
57	Prucalopride Orally Disintegrating Strips 1/2 mg  <b>(Additional Dosage Form)</b>	Each Orally Disintegrating Strips Contains: Prucalopride succinate is equivalent to Prucalopride..... .....1 mg/2 mg	For the treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief	27-09- 2021
58	Itraconazole 100 mg Capsule <b>(Supra- bioavailable formulation)</b>  <b>(Additional strength, Modified Dosage form)</b>	Each Hard Gelatin Capsule Contains: Itraconazole..... ..... .....100 mg	for the treatment of Systematic aspergillosis, candidiasis, cryptococcosis, sporotrichosis, paracoccidiodomycosis, blastomycosis and other rarely occurring systemic or tropical mycosis  <b>The package insert should contain the following caution “This Itraconazole Capsules 100mg is not interchangeable or substitutable with other Itraconazole products due to the differences in dosing between Itraconazole capsule 100 (Supra bioavailable formulation) and other Itraconazole products”.</b>	28-09- 2021

			<p>Firm should present package insert mentioning the effect of Proton pump inhibitor, oral antacids, alcohol, other drugs interaction which may affect the bioavailability of the drug etc. before launch of the product in the market. The package insert should also include details of results of the BE study conducted in the country</p> <p>Firm should present package insert mentioning the effect of Proton pump inhibitor, oral antacids, alcohol, other drugs interaction which may affect the bioavailability of the drug etc. The package insert should also include details of results of the BE study conducted in the country</p> <p><b>"WARNING: To be sold by retail on the prescription of a Specialist only"</b></p>	
59	<p>Itraconazole Capsule 65 mg <b>(Supra-bioavailable formulation)</b></p> <p><b>(Additional Strength, Modified dosage form)</b></p>	<p>Each Capsule Contains: Itraconazole..... 65 mg</p>	<p>Itraconazole 65 mg Capsule (Supra-bioavailable formulation) is indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:</p> <ul style="list-style-type: none"> <li>• Blastomycosis, Pulmonary and Extra pulmonary</li> <li>• Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis.</li> <li>• Aspergillosis, pulmonary and extra-pulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy</li> </ul> <p><b>The package insert should contain the following caution</b></p>	08-10-2021

			<p><b>“This Itraconazole Capsules 65mg (Supra-bioavailable formulation) is not interchangeable or substitutable with other Itraconazole products due to the differences in dosing between Itraconazole capsule 65 (Supra bioavailable formulation) and other Itraconazole products</b></p> <p><b>"WARNING: To be sold by retail on the prescription of a Specialist only”</b></p>	
60	<p>Remdesivir Injection 100mg/ml (1ml/vial) (Single dose vial)</p> <p><b>(Additional Strength)</b></p>	<p>Each ml contains: Remdesivir .....100 mg Alcohol .....20% w/v Benzyl alcohol.....5%w/v</p>	<p>For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised 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>	08-10-2021
61	<p>Azacitidine Tablets 200mg</p> <p><b>(Additional Strength)</b></p>	<p>Each film coated tablet contains: Azacitidine IP .....200 mg</p>	<p>For continued treatment of patients with acute myeloid leukemia (AML) who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy</p> <p><b>"WARNING: To be sold by retail on the prescription of Oncologist only”</b></p>	14-10-2021
62	<p>Empagliflozin Tablets 10/25mg</p> <p><b>(additional Indication)</b></p>	<p>Each Film coated tablets contains: Empagliflozin ..... ..... 10/25mg</p>	<p>To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction</p>	25-10-2021

63	Clobazam Mouth Dissolving Tablets 2.5 mg  <b>(Additional Dosage Form)</b>	Each uncoated mouth dissolving tablet contains: Clobazam 2.5 mg	As an adjunctive therapy in patients with refractory epilepsy  <b>"WARNING: To be sold by retail on the prescription of Neurologist/Psychiatrist only"</b>	01-11-2021
64	Pegylated Liposomal Irinotecan 4.3mg/ml  <b>(Additional Dosage Form)</b>	Each vial contains: Pegylated Liposomal Irinotecan.....4.3 mg/ml	Treatment of metastatic adenocarcinoma of the pancreas, in combination with 5-fluorouracil (5- FU) and leucovorin (LV), in adult patients who have progressed following gemcitabine based therapy  <b>"WARNING: To be sold by retail on the prescription of Oncologist only"</b>	01-11-2021
65	Amantadine Extended Release Tablets 129 mg and 193 mg  <b>(Additional Dosage Form)</b>	Each extended release film coated tablets contains: Amantadine Hydrochloride equivalent to Amantadine .....12 9 mg and 193 mg	For the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients  <b>Firm should conduct a Phase-IV Clinical Trial protocol before the Committee prior to launch of the product in the market</b>  <b>"WARNING: To be sold by retail on the prescription of a Neurologist only"</b>	01-11-2021
66	Gemcitabine Hydrochloride Injection 10mg/ml (220 ml ready to use infusion bag)  <b>(Additional Pack Size)</b>	Each ml contains: Gemcitabine Hydrochloride equivalent to Gemcitabine .....10mg/ml	<ul style="list-style-type: none"> <li>• Ovarian cancer – Gemcitabine injection in combination with carboplatin is indicated for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum based therapy.</li> <li>• Breast cancer – Gemcitabine injection in combination with paclitaxel is indicated for the first line treatment of patients with metastatic breast cancer after failure of prior anthracycline containing adjuvant</li> </ul>	02-11-2021

			<p>chemotherapy, unless anthracyclines were clinically contraindicated.</p> <ul style="list-style-type: none"> <li>• Non-small cell lung cancer – Gemcitabine injection is indicated in combination with cisplatin for the first line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer.</li> <li>• Pancreatic cancer – Gemcitabine injection is indicated as first line treatment for patient with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. Gemcitabine injection is indicated for patients previously treated with 5-FU</li> </ul> <p><b>"WARNING: To be sold by retail on the prescription of an Oncologist only"</b></p>	
67	<p>Baricitinib Tablets 2 mg &amp; 4 mg</p> <p><b>(Additional Indication)</b></p>	<p>Each Film Coated Tablet Contains: Baricitinib.....2 mg/4 mg</p>	<p>Baricitinib for treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or 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>	15-11-2021
68	<p>Faropenem Sodium for Oral Suspension 100mg/5ml</p> <p><b>(Additional Dosage Form)</b></p>	<p>Each 5ml of reconstituted suspension Contains: Faropenem Sodium equivalent to Faropenem..... ...100mg</p>	<p>For the treatment of superficial and deep skin infections like chronic pyoderma, Pharyngitis/laryngitis and ENT infections like Otitis media, Tonsillitis, Sinusitis, Acute tracheo-bronchitis, Bacterial pneumonia, UTIs like cystitis, Pyelonephritis, Lymphangitis/Lymphadenitis,</p>	24-11-2021

			Teeth Periodontitis, Scarlet fever and Whooping cough	
69	Teriparatide Injection solution for injection in a pre-filled pen 600 mcg/2.4 ml  <b>(Synthetic Origin)</b>	Each ml contains: Teriparatide (Synthetic Origin).....250 mcg Mannitol ....45.4 mg Glacial Acetic Acid .....0.41mg Sodium Acetate Anhydrous ....0.1mg Metacresol....3.0 mg (as Preservative) Sodium Hydroxide IP q.s. for pH adjustment Hydrochloric Acid IP q.s. for pH adjustment Water for Injections IP q.s. to 1.0ml	1. For the treatment of men and postmenopausal women with osteoporosis who are at a high risk of fracture. It increases bone mineral density (BMD) and reduces the risk of vertebral and non-vertebral fractures.  2. It is also indicated for the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture  <b>Firm shall submit Phase IV clinical trial study protocol within three months of approval</b>	25-11-2021
70	Calcium Polystyrene Sulphonate Suspension 15g/60ml  <b>(Additional Dosage Form)</b>	Each 60ml contains: Calcium Polystyrene Sulphonate..... 15g Excipients.....q.s	For the treatment of hyperkalaemia associated with oliguria, anuria or dialysis	30-11-2021
71	Ethambutol Dispersible Tablets 100 mg  <b>(Additional Dosage Form)</b>	Each uncoated dispersible tablet contains: Ethambutol Hydrochloride..... 100 mg	For the management of Mycobacterium Tuberculosis	07-12-2021
72	Bedaquiline Tablets 20 mg  <b>(Additional Strength)</b>	Each tablets contains 20mg of Bedaquiline (equivalent to 24.18mg of Bedaquiline fumarate)	Indicated in adult ( $\geq 18$ years) and paediatric patients (5 years to less than 18 years of age and weighing at least 15 kg) as part of combination therapy of pulmonary tuberculosis (TB)	16-12-2021

			<p>due to multi-drug resistant Mycobacterium tuberculosis</p> <p><b>The drug is approved for conditional access i.e it shall be used under National Tuberculosis Elimination Programme (NTEP) framework for conditional access through the PMDT program for treatment of MDR-TB patients only</b></p> <p><b>“WARNING: For use in National Tuberculosis Elimination programme (NTEP)”</b></p>	
73	<p>Gliclazide Extended Release Tablets 90 and 120 mg</p> <p><b>(Additional Strength &amp; Additional Indication)</b></p>	<p>Each Extended Release Tablets Contains: Gliclazide .....90 and 120 mg</p>	<p>Treatment of Non-insulin dependent Diabetes mellitus (Type II) in association with dietary measures in adults only</p> <p><b>The firm should submit protocol for active post marketing surveillance (PMS) for Gliclazide Extended release Tablet 90/120mg within 3 months of granting approval to manufacture and market Gliclazide Extended Release Tablet 90/120mg</b></p>	22-12-2021
74	<p>Etoricoxib Tablets 30mg</p> <p><b>(Additional Strength)</b></p>	<p>Each film-coated Tablets contains: Etoricoxib .....30mg</p>	<p>For the treatment of Symptomatic relief of Osteoarthritis and rheumatoid arthritis, acute gouty arthritis, acute pain associated with dental surgery, primary dysmenorrhea</p>	22-12-2021
75	<p>Faropenem Sodium for Syrup 50mg/5ml</p> <p><b>(Additional Dosage form)</b></p>	<p>Each 5ml of reconstituted syrup contains: Faropenem Sodium hydrate equivalent to Faropenem..... ...50mg</p>	<p>For the treatment of upper and lower respiratory tract infection, urinary tract infection and skin structure infection</p>	22-12-2021

76	17-β estradiol gel 0.06%w/w metered pump  <b>(Metered-pump presentation and Additional Indication)</b>	Each dose of 1.25g (1 pump) contains: 17-β estradiol .....0.06%w/w	1. Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women.  2. Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. The experience treating women older than 65 years is limited.  <b>“WARNING: To be sold by retail on the prescription of Gynecologists only”</b>	23-12-2021
77	Phenylephrine Injection 50mcg/ml  <b>(Additional Strength)</b>	Each ml contains: Phenylephrine Hydrochloride .....50 mcg Water for Injections ..... Q.S	Treatment of Hypotension during spinal, epidural or general anaesthesia  <b>“WARNING: To be sold by retail on the prescription of a Specialist only”</b>	23-12-2021
78	Pregabalin Oral Solution 20 mg/ml  <b>(Additional Dosage Form)</b>	Each ml contains: Pregabalin ..... 20 mg	For the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and Fibromyalgia	27-12-2021
79	Medroxyprogesterone Acetate Sustained Release (SR) Tablets 30mg  <b>(Additional Dosage Form)</b>	Each Uncoated Sustained Release Tablet Contains: Medroxyprogesterone Acetate IP.....30mg	Mild to Moderate Endometriosis	27-12-2021
80	Carfilzomib for Injection 10mg/Vial  <b>(Additional Strength)</b>	Each Vial contains: Carfilzomib ..... ..... 10mg	1. In combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.  2. As a single agent for the treatment of patients with	31-12-2021

			<p>relapsed or refractory multiple myeloma who have received one or more lines of therapy</p> <p><b>"WARNING: To be sold by retail on the prescription of Oncologist only"</b></p>	
--	--	--	--	--