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S.No	Drug Name	Composition	Indication	Date of Approval
1	Pegaspargase injection 3750 IU per vial	Each vial contains: Pegaspargase 3750 IU per vial	As a component of multi agent chemotherapeutic regiment for the treatment of patients with acute lymphoblastic leukaemia who are hypersensitive to L-Asparaginase.	04-01-2018
2	Cefditoren Pivoxil dry powder for suspension 100mg/5ml (Additional Indication)	Each 5ml reconstituted suspension contains: Cefditoren Pivoxil equivalent to Cefditoren 100mg	For the treatment of mild to moderate infection also in children's of (2 months to 12 years of age) which are caused by susceptible strains of the designated microorganisms in the condition listed below: • Acute Bacterial Exacerbation of Chronic Bronchitis • Community-Acquired pneumonia • Pharyngitis/Tonsillitis • Uncomplicated Skin and skin – structure infection	04-01-2018
3	Eltrombopag olamine tablets 12.5mg (additional strength & indication)	Each film coated tablet contains: Eltrombopag olamine equivalent to Eltrombopag olamine as free acid 12.5mg	**1. Chronic ITP : for Adults** For the treatment of thrombocytopenia in patients with chronic immune (idiopathic) Thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts). **For Paediatric patients aged 1 year and above:** Thrombocytopenia in paediatric patients 1 year and older with immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy (lt should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts).	06-02-2018

			2. For the treatment of patients with chronic Hepatitis C virus (HCV) infection for the treatment of thrombocytopenia to: Enable the initiation of interferon based therapy, optimize interferon based therapy. **With the condition: to be sold by retail on the prescription of Haematologist only**	
4	Alectinib Capsules 150mg (additional indication)	Each hard gelatin capsule contains: Alectinib 150mg equivalent to Alectinib hydrochloride 161.3mg	First-line treatment of patients with Anaplastic Lymphoma Kinase (ALK) - positive locally advanced or metastatic non-small cell lung cancer (NSCLC). **With the condition: to be sold by retail on the prescription of Oncologist only.**	05-03-2018
5	Fulvestrant 250mg/5ml injection (additional indication)	Each 5ml pre-filled syringe contains: Fulvestrant 250mg ethanol (96%)-10% w/v	For the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy **With the condition: to be sold by retail on the prescription of Oncologist only.**	20-03-2018
6	Bendamustine hydrochloride injection 90mg/ml (0.5ml vial & 2.0 ml vial) (additional indication)	Each ml contains: Bendamustine hydrochloride 90mg ethanol 4.33% w/v	Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment. **With the condition: to be sold by retail on the prescription of Oncologist/Specialist only.**	23-03-2018
7	Methotrexate injection prefilled syringe 15mg/0.3ml, 20mg/0.4ml and 25mg/0.5ml (Additional strength & indication)	Each 0.3ml prefilled syringe ml contains: Methotrexate 15mg Each 0.4ml prefilled syringe ml contains: Methotrexate 20mg Each 0.5ml prefilled syringe ml contains: Methotrexate 25mg	It is indicated in treatment of 1. Active rheumatoid arthritis in adult patients. 2. Polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drug (NSAIDs) has been inadequate, 3. Severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids and severe psoriatic arthritis in adult patients. 4. Mild to moderate Crohn's disease either alone or in combination with	09-03-2018

			corticosteroids in adult patients refractory or intolerant to thiopurines.	
8	Sildenafil power for oral suspension 10mg/ml (Additional dosage form)	Each ml of reconstituted suspension contains: Sildenafil citrate equivalent to 10mg, Sodium benzoate 4.375mg	**Adults:** Treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. **Paediatric population:** Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease. **With the condition: to be sold by retail on the prescription of Cardiologist only.**	20-03-2018
9	Dydrogesterone tablet 10mg (additional indication)	Each film coated tablet contains: Dydrogesterone 10mg	Luteal support as part of an Assisted Reproductive Technology (ART) treatment. **With the condition: to be sold by retail on the prescription of Gynaecologist only.**	06-04-2018
10	Febuxostat tablet 60mg & 20mg (Additional Strength)	Each film coated tablet contains: Febuxostat 60mg & 20mg	For the treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (including a history, or presence of tophus and / or gouty arthritis)	06-04-2018
11	Posaconazole injection 300mg/16.7ml (18mg/ml) (additional strength & dosage form)	Each injection contains: Posaconazole 300mg/16.7ml	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. **With the condition: to be sold by retail on the prescription of Specialist only.**	13-04-2018
12	Teriflunomide tablet 7mg (Add. Lower strength)	Each film coated tablet contains: Teriflunomide 7mg	For the treatment of patients with relapsing form of multiple sclerosis. **With the condition:** to be sold by retail on the prescription of Neurologist only.	07.05.2018
13	Apremilast film	Each film coated tablet contains: Apremilast-	For the treatment of adult patients with Active psoriatic Arthritis.	11.05.2018

	coated tablet 10/20/30mg (Additional Indication)	10mg, 20mg,30mg		
14	Aripiprazole tablet 2mg (additional strength)	Each uncoated tablet contains: Aripiprazole-2mg	For the treatment of Schizophrenia in adolescent patients (13 to 17 years of age) **With the condition:** to be sold by retail on the prescription of Psychiatrist only.	11.05.2018
15	Dextromethorphan HBr Lozenges 10mg (Add. dosage form & strength)	Each lozenges contains: Dextromethorphan HBr-33.33% Complex 30mg eq. to Dextromethorphan HBr 10mg	Cough suppressant for the relief of acute non-productive (dry, tickly) cough associated with respiratory tract infection in adult patients only.	11.05.2018
16	Voglibose Orally Disintegrating Strips 0.2mg (Modified dosage form)	Each Orally Disintegrating Strips contains: Voglibose 0.2mg & 0.3mg	For improvement of parandial hyperglycaemia in diabetes mellitus, when only diet and/or exercise or oral hypoglycaemic drugs or insulin preparation in addition to diet and/or exercise do not result in adequate glycemic control.	11.05.2018
17	Tranexamic acid tablet 1000mg (Additional strength)	Each film coated tablet contains: Tranexamic acid-1000mg.	For the treatment of menorrhagia	21.05.2018
18	Eltrombopag Olamine Tablet 75mg (Additional strength)	Each film coated tablet contains: Eltrombopag Olamine as free acid-75mg	1. For the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.(It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts). 2. Indicated in patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia to: a. Enable the intiation of interferon based therapy. b. Optimize interferon based therapy	29.05.2018

			3. For the treatment of patients with severe aplastic anaemia (SAA) who have had an insufficient response to immunosuppressive therapy 4. For the treatment of thrombocytopenia in paediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts). **With the condition:** to be sold by retail on the prescription of Hematologist only.	
19	Thyroxine Sodium Tablet 37.5 mcg (Additional strength)	Each uncoated tablet contains: Thyroxine Sodium eq. to Anhydrous Thyroxine Sodium. 37.5 mcg.	1. As replacement or supplemental therapy in patients of any age or state (including pregnancy) with hypothyroidism of any etiology except transient hypothyroidism during the recovery phase of sub-acute thyroiditis resultng from thyroid dysfunction, primary atrophy or partial or total absence of the thyroid gland or from the effects of surgery, radiation or drugs with or without the presence of goiter, including sub-clinical hypothyroidism; secondary (pituitary) hypothyroidism and tertiary (hypothalamic) hypothyroidism. 2. As a pituitary TSH suppressant in the treatment or prevention of various types of euthyroidgoites, including thyroid nodules, sub-acute or chronic lymphocytic thyroiditis (Hashimoto's) multi-nodular goiter and in conjuction with surgery and radioactive iodine therapy in the management of thyrotropin-dependent well differentiated papillary or follicular carcinoma of the thyroid.	08.06.2018
20	Dabrafenib	Each Hard Gelatin Capsule contains:	Dabrafenib in combination with Trametinib for the treatment of adult patients with	08.06.2018

	Hard Gelatin Capsule 50mg,& 75mg (Additional indication)	Dabrafenib Mesylate eq. to Dabrafenib 50mg & 75mg	advanced non-small cell lung cancer with BRAF V600 mutation. **With the condition:** to be sold by retail on the prescription of Oncologist only.	
21	Trametinib Tablet 0.5mg & 2mg (Additional indication)	Each Film coated tablet contains: Trametinib 0.5mg & 2mg	Trametinib in combination with Dabrafenib for the treatment of adult patients with advance non-small cell lung cancer with a BRAF V 600 mutation. **With the condition:** to be sold by retail on the prescription of Oncologist only.	08.06.2018
22	Azacitidine for injection 50mg/vial (Additional strength)	Each vial contains: Azacitidine. 50mg Lyophilized power 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 Oncologist only.	22.06.2018
23	Nilotinib Capsules 50mg (Additional strength & add. indication)	Each Capsule contains: Nilotinib 50mg	1. Paediatric patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukaemia (CML) in the chronic phase. 2. Paediatric patients with chronic phase Philadelphia Chromosome Positive (CML) with resistance or intolerance to prior therapy including imatinib. **With the condition:** to be sold by retail on the prescription of Oncologist only.	22.06.2018
24	Fulvestrant 250mg/5ml	Each 5ml pre-filled syringe contains:	In combination with Palbociclib for the treatment of hormone receptor (HR)-	13.07.2018

	injection (additional indication) (for IM use only)	Fulvestrant USP 250mg Ethanol (96%) BP-10% w/v	positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy". **With the condition: to be sold by retail on the prescription of Oncologist only.**	
25	Ganciclovir Sodium powder for Infusion 500mg (additional indication) (for IV use only)	Each vial contains: Ganciclovir 500mg (In the form of the sodium salt)	For the treatment of cytomegalovirus (CMV) disease in immunocompromised individuals and for the prevention of CMV disease in patients with drug-induced immunosuppression following organ transplantation or cancer chemotherapy. **With the condition: to be sold by retail on the prescription of a Specialist only.**	13.07.2018
26	Nepafenac Ophthalmic Suspension 0.3%w/v (Additional strength)	Each ml contains: Nepafenac 3.0mg	For the treatment of pain and inflammation associated with cataract surgery. **With the condition: to be sold by retail on the prescription of Ophthalmologist only.**	13.07.2018
27	Tadalafil Orally Disintegrating Strip 5mg (Additional strength)	Each Orally Disintegrating Strip contains: Tadalafil 5mg	For the treatment of Erectile Dysfunction	13.07.2018
28	Delamanid Tablets 50mg (additional indication)	Each film coated tablet contains: Delamanid 50mg	In exceptional cases and after a careful benefit/risk assessment Delamanid treatment can be initiated in children >6 years of age, for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. **With the condition: For the use in Revised National Tuberculosis Control Program (RNTCP).**	27.07.2018 .