

**Manufacturing and Marketing permission issued from SND Division from 01.01.2018
to 20.04.2018.**

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: <ul style="list-style-type: none"> • 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	<p>1. Chronic ITP : for Adults</p> <p>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).</p> <p>For Paediatric patients aged 1 year and above:</p> <p>Thrombocytopenia in paediatric patients 1 year and older with 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</p>	06-02-2018

			<p>attempt to normalize platelet counts).</p> <p>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.</p> <p>With the condition: to be sold by retail on the prescription of Haematologist only</p>	
4	Alectinib Capsules 150mg (additional indication)	Each hard gelatin capsule contains: Alectinib 150mg equivalent to Alectinib hydrochloride 161.3mg	<p>First-line treatment of patients with Anaplastic Lymphoma Kinase (ALK) - positive locally advanced or metastatic non-small cell lung cancer (NSCLC).</p> <p>With the condition: to be sold by retail on the prescription of Oncologist only.</p>	05-03-2018
5	Fulvestrant 250mg/5ml injection (additional indication)	Each 5ml pre-filled syringe contains: Fulvestrant 250mg ethanol (96%)-10% w/v	<p>For the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy</p> <p>With the condition: to be sold by retail on the prescription of Oncologist only.</p>	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	<p>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.</p> <p>With the condition: to be sold by retail on the prescription of Oncologist/Specialist only.</p>	23-03-2018
7	Methotrexate injection pre-filled syringe 15mg/0.3ml, 20mg/0.4ml and 25mg/0.5ml (Additional strength indication) &	<p>Each 0.3ml pre-filled syringe ml contains: Methotrexate 15mg</p> <p>Each 0.4ml pre-filled syringe ml contains: Methotrexate 20mg</p> <p>Each 0.5ml pre-filled syringe ml contains: Methotrexate 25mg</p>	<p>It is indicated in treatment of</p> <ol style="list-style-type: none"> 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 	09-03-2018

			alone or in combination with 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	<p>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.</p> <p>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.</p> <p>With the condition: to be sold by retail on the prescription of Cardiologist only.</p>	20-03-2018
9	Dydrogesterone tablet 10mg (additional indication)	Each film coated tablet contains: Dydrogesterone 10mg	<p>Luteal support as part of an Assisted Reproductive Technology (ART) treatment.</p> <p>With the condition: to be sold by retail on the prescription of Gynaecologist only.</p>	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	<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>With the condition: to be sold by retail on the prescription of Specialist only.</p>	13-04-2018