

**Manufacturing and Marketing permission issued from SND Division from
01.01.2018 to 31.12.2018.**

| S.No | Drug Name | Composition | Indication | Date of Approval |
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| 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 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: 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 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> | 06-02-2018 |
| 4 | Alectinib | Each hard gelatin | First-line treatment of patients with Anaplastic | 05-03-2018 |

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| | Capsules 150mg (additional indication) | capsule contains: Alectinib 150mg equivalent to Alectinib hydrochloride 161.3mg | 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. | |
| 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 corticosteroids in adult patients refractory or intolerant to thiopurines. | 09-03-2018 |
| 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 | 20-03-2018 |

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| | | | the prescription of Cardiologist only. | |
| 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 coated tablet 10/20/30mg (Additional Indication) | Each film coated tablet contains: Apremilast-10mg, 20mg,30mg | For the treatment of adult patients with Active psoriatic Arthritis. | 11.05.2018 |
| 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 |

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| 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 | <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a. Enable the initiation of interferon based therapy. b. Optimize interferon based therapy 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). <p>With the condition: to be sold by retail on the prescription of Hematologist only.</p> | 29.05.2018 |
| 19 | Thyroxine Sodium Tablet 37.5 mcg (Additional strength) | Each uncoated tablet contains: Thyroxine Sodium eq. to Anhydrous Thyroxine Sodium. 37.5 mcg. | <ol style="list-style-type: none"> 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 resulting 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 | 08.06.2018 |

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| | | | lymphocytic thyroiditis (Hashimoto's) multi-nodular goiter and in conjunction with surgery and radioactive iodine therapy in the management of thyrotropin-dependent well differentiated papillary or follicular carcinoma of the thyroid. | |
| 20 | Dabrafenib Hard Gelatin Capsule 50mg, & 75mg (Additional indication) | Each Hard Gelatin Capsule contains: Dabrafenib Mesylate eq. to Dabrafenib 50mg & 75mg | Dabrafenib in combination with Trametinib for the treatment of adult patients with advanced non-small cell lung cancer with BRAF V600 mutation. With the condition: to be sold by retail on the prescription of Oncologist only. | 08.06.2018 |
| 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 injection (additional indication) (for IM use only) | Each 5ml pre-filled syringe contains: Fulvestrant USP 250mg Ethanol (96%) BP-10% w/v | In combination with Palbociclib for the treatment of hormone receptor (HR)-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. | 13.07.2018 |
| 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 |

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| 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 |
| 29 | Osimertinib Film coated tablet 40mg and 80mg (Additional indication) | Each film coated tablet contains: Osimertinib 40mg, 80mg | As first-line treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) whose tumors have Epidermal Growth Factor Receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitutions mutations. With the condition: To be sold by retail on the prescription of Oncologist only. | 03.08.2018 |
| 30 | Nicotine Polacrilex Orally disintegrating strips 2mg & 4mg (New dosage form) | Each Orally disintegrating strips contains: Nicotine Polacrilex eq. to Nicotine 2mg, 4mg | To reduce the withdrawal symptoms, including nicotine craving, associated with quitting the smoking and quitting chewed tobacco and gutkha containing tobacco | 17.08.2018 |
| 31 | Zolmitriptan Orally disintegrating strips 2.5mg & 5mg (Additional Dosage form) | Each Orally disintegrating strips contains: Zolmitriptan 2.5mg & 5mg | For Acute treatment of migraine with or without aura in adults. | 10.08.2018 |

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| 32 | Ethyl esters of Iodized fatty acids of Poppy Seed Oil solution for injection (Lipodol Ultra Fluid 10ml) (Additional Indication) | Each ampoule (10ml) contains: Ethyl esters of Iodized fatty acids of Poppy Seed Oil Iodine content 48% i.e. 480mg iodine per ml | Conventional Trans-Arterial Chemo-Embolization (cTACE) of Hepatocellular Carcinoma (HCC) in adults. | 06.09.2018 |
| 33 | Methylcobalamin nasal spray 250mcg/spray (New Dosage form) | Each 0.1ml contains: Methylcobalamin 500mcg Benzalkonium chloride (As preservative) 0.02% w/v | Treatment of Vitamin B12 deficiency in patients without having neurological involvement. | 28.09.2018 |
| 34 | Apomorphine Hydrochloride injection 10mg/ml (2ml and 5ml Ampoule) (subcutaneous use only) (Add. Dosage form and add. indication) | Each ml contains: Apomorphine hydrochloride 10mg | Treatment of disabling motor fluctuations (“on-off” phenomena) in patients with Parkinson’s disease which persist despite individually titrated treatment with levodopa (with a peripheral decarboxylase inhibitor) and/or other dopamine agonists. With the condition: to be sold by retail on the prescription of Neurologist only. | 28.09.2018 |
| 35 | Carfilzomib for Injection 30mg/vial (Lyophilized injection) (Additional Strength) | Each vial contains: Carfilzomib 30mg | <ul style="list-style-type: none"> Carfilzomib for injection is indicated 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. Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. With the condition: to be sold by retail on the prescription of Oncologist only. | 28.09.2018 |
| 36 | Nilotinib hard Capsules 150mg & 200mg (Additional indication) | Each Capsule contains: Nilotinib 150mg & 200mg | <ol style="list-style-type: none"> Treatment of Paediatric patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukaemia (CML) in the chronic phase. Treatment of 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. | 18.10.2018 |
| 37 | Dasatinib film coated tablet 20mg, 50mg, 70mg and | Each film coated tablet contains: Dasatinib 20mg, 50mg, 70mg and 100mg | Treatment of Paediatric patients with Philadelphia Chromosome Positive Chronic myeloid leukemia (Ph+ CML) in chronic phase. | 18.10.2018 |

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| | 100mg (Additional indication) | | With the condition: to be sold by retail on the prescription of Oncologist only. | |
| 38 | Nifedipine Extended Release Tablet 60mg (Add. strength and indication) | Each Extended release film coated tablet contains: Nifedipine 60mg | <ul style="list-style-type: none"> • Vasospastic Angina, • Chronic stable Angina (Classical effort-Associated Angina), • Hypertension. With the condition: to be sold by retail on the prescription of Cardiologist only. | 18.10.2018 |
| 39 | Levetiracetam injection 500mg/100ml, 1000 mg/100ml, and 1500mg/100ml. (Infusion bottle) (Additional dosage form) | Each 100 ml Infusion bottle contains: Levetiracetam in 0.82% sodium chloride (500mg/100ml) Levetiracetam in 0.75% sodium chloride (1000mg/100ml) Levetiracetam in 0.54% sodium chloride (1500mg/100ml) | As adjunctive therapy in adult (16 years and older) with the following types of seizures when oral administration is temporarily not feasible. <ul style="list-style-type: none"> • Partial onset seizures, • Myoclonic seizures in patients with juvenile myoclonic epilepsy, • Primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy With the condition: to be sold by retail on the prescription of Neurologist only. | 27.10.2018 |
| 40 | Nepafenac Ophthalmic Suspension 0.3% w/v (Additional Indication) | Each ml contains: Nepafenac 3.0mg | For the treatment of post-operative pain and inflammation associated with cataract surgery. With the condition: to be sold by retail on the prescription of Ophthalmologist only. | 09.11.2018 |
| 41 | Ibuprofen soft gelatine capsules 400mg. (New Dosage form) | Each soft gelatin capsule contains Ibuprofen 400mg | For chronic arthritic disorder and painful musculoskeletal conditions. | 20.11.2018 |
| 42 | Everolimus tablets 2.5 mg (Additional Indication) | Each tablets contains: Everolimus 2.5 mg | Treatment of patients with Progressive neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced or metastatic disease, Treatment of patients with Advanced Renal Cell Carcinoma (RCC). With the condition: To be sold by retail on the prescription of Oncologist only. | 05.12.2018 |
| 43 | Clonazepam Mouth Dissolving tablets 0.25/0.5/1.0/2.0mg (New Dosage Form) | Each uncoated mouth dissolving tablet contains: Clonazepam 0.25/0.5/1.0/2.0 mg | Treatment of seizure disorders (Petit mal and its variant, akinetic and myoclonic seizures), Panic disorder & add-on therapy in acute mania. With the condition: To be sold by retail on the prescription of Neurologists or Psychiatrist only. | 10.12.2018 |

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| 44 | Divalproex Sodium Oral Solution 250mg/5ml (Additional Strength) | Each 5 ml Contains: Divalproex 250mg | Monotherapy and adjunctive therapy in the treatment of patients with 'complex partial seizures that occur either in isolation or in association with types of seizures for adult patients only. | 21.12.2018 |
| 45 | Ivermectin Cream 1.0% w/w (New Dosage form) | Each Gram Contains: Ivermectin 1.0% w/w | Treatment of inflammatory lesions of rosacea. With the condition: To be sold by retail on the prescription of Dermatologist only. | 21.12.2018 |