



Kingdom of Saudi Arabia  
Saudi Food & Drug Authority

# Saudi Drug Updates (SDU)

Nov 2024 A monthly electronic bulletin published by the drug sector

## SFDA Drug Approvals

| Application Type | Drug Type       | Trade Name | Active Ingredient(s)                                                                                 | Dosage form                                        | Strength (s) | SFDA Approved Indication(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Approval Date |
|------------------|-----------------|------------|------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| New indication   | Biological Drug | CUVITRU    | Human normal immunoglobulin (SCIg)                                                                   | Solution for injection                             | 200 mg       | <p>Indicated for Replacement therapy (Subcutaneous administration (SCIg)) in adults, and children and adolescents (0-18 years) in:</p> <ul style="list-style-type: none"><li>- Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF) or serum IgG level of &lt;4g/l.</li></ul> <p>*PSAF = failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines</p> | 02/10/2024    |
| New indication   | Biological Drug | Pentaxim   | Diphtheria toxoid30 IU,Tetanus toxoid 40 IU,Pertussis toxoid 25 ug, Filamentous haemagglutinin25 ug, | Powder and suspension for suspension for injection |              | Booster dose at 11 months of age.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 06/10/2024    |

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|                  |                 |          | Poliomyelitis virus (inactivated) type 1 (Mahoney strain) 40 DAgU,<br>Poliomyelitis virus (inactivated) type 2 (MEF-1 strain) 8 DAgU,<br>Poliomyelitis virus (inactivated) type 3 (Saukett strain) 32 DAgU,<br>Polysaccharide of Haemophilus influenzae type b 10 ug |                                       |                           |                                                                                                                                                                                                                                                                            |            |
| New indication   | Biological Drug | HYQVIA   | Human normal immunoglobulin                                                                                                                                                                                                                                          | Solution for infusion                 | 100 mg                    | Indicated for <u>immunomodulatory therapy in adults, children, and adolescents (0 to 18 years) in:</u><br><br>Chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy after stabilization with IVIg.                                               | 08/10/2024 |
| New indication   | Biological Drug | Jemperli | Dostarlimab                                                                                                                                                                                                                                                          | Concentrate for solution for infusion | 500 mg                    | Indicated in combination with carboplatin and paclitaxel for the treatment of adult patients with mismatch repair deficient (dMMR)/ microsatellite instability high (MSI H) primary advanced or recurrent endometrial cancer (EC) and who candidates for systemic therapy. | 15/10/2024 |
| New indication   | New Drug        | Kyprolis | Carfilzomib                                                                                                                                                                                                                                                          | Powder for solution for injection     | 61.8 mg                   | Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received to three lines of therapy in combination with Isatuximab and dexamethasone.                                                                                   | 17/10/2024 |
| New indication   | New Drug        | CIBINQO  | Abrocitinib                                                                                                                                                                                                                                                          | Film-coated tablet                    | 200 mg<br>100 mg<br>50 mg | New Age Group:<br><br>Indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.                                                                                            | 21/10/2024 |
| New Registration | Biological Drug | Tremfya  | Guselkumab                                                                                                                                                                                                                                                           | Solution for injection                | 100 mg/ml                 | Indicated for                                                                                                                                                                                                                                                              | 21/10/2024 |

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|                  |                 |           |                                                          |                                            |                                               | <ul style="list-style-type: none"> <li>- Treatment of adult patients with moderately to severely active Crohn’s disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment.</li> <li>- Treatment of adult patients with moderately to severely active Ulcerative Colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor.</li> </ul>                      |            |
| New Registration | Biological Drug | Tremfya   | Guselkumab                                               | Solution for injection                     | 200 mg                                        | <p>Indicated for</p> <ul style="list-style-type: none"> <li>- Treatment of adult patients with moderately to severely active Crohn’s disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic treatment.</li> <li>- Treatment of adult patients with moderately to severely active Ulcerative Colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor.</li> </ul> | 21/10/2024 |
| New Registration | Biological Drug | Epysqli   | Eculizumab                                               | Concentrate for solution for infusion      | 300 mg                                        | Indicated for Paroxysmal nocturnal haemoglobinuria (PNH)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 21/10/2024 |
| New Registration | Biological Drug | Erwinase  | Crisantaspase (L-asparaginase from Erwinia chrysanthemi) | Powder for solution for injection/infusion | 10000 U/ml                                    | Indicated in combination with other chemotherapeutic agents to treat patients, principally children, with acute lymphoblastic leukaemia who have developed hypersensitivity (clinical allergy or silent inactivation) to E. coli asparaginase or pegylated asparaginase obtained from E. coli.                                                                                                                                                                                                                                                      | 21/10/2024 |
| New Registration | Biological Drug | Enrylaze  | Recombinant crisantaspase                                | Solution for injection/infusion            | 10 mg/0.5 mL                                  | Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL) in adult and paediatric patients (1 month and older) who developed hypersensitivity or silent inactivation to E. coli-derived asparaginase.                                                                                                                                                                                                                                            | 21/10/2024 |
| New Registration | Biological Drug | MenQuadfi | Meningococcal (Serogroup A) Polysaccharide 10            | Solution for injection                     | Meningococcal (Serogroup A) Polysaccharide 10 | Indicated for active immunization of individuals from the age of 12 months and older against invasive meningococcal                                                                                                                                                                                                                                                                                                                                                                                                                                 | 28/10/2024 |

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|                  |              |           | ug, Meningococcal (Serogroup C)<br>Polysaccharide 10 ug, Meningococcal (Serogroup Y)<br>Polysaccharide 10 ug, Meningococcal (Serogroup W135)<br>Polysaccharide 10 ug |                    | ug, Meningococcal (Serogroup C)<br>Polysaccharide 10 ug, Meningococcal (Serogroup Y)<br>Polysaccharide 10 ug, Meningococcal (Serogroup W135)<br>Polysaccharide 10 ug | disease caused by Neisseria meningitidis serogroups A, C, W, and Y.                                                                                                                                                                                                                                             |            |
| New Registration | New Drug     | Erleada   | Apalutamide                                                                                                                                                          | Film Coated Tablet | 240 mg                                                                                                                                                               | Indicated in adult men for:<br><br>- The treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease .<br><br>The treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT). | 21/10/2024 |
| New Registration | New Drug     | Mictonorm | Propiverine hydrochloride                                                                                                                                            | Film Coated Tablet | 5 mg                                                                                                                                                                 | Indicated for symptomatic treatment of urinary incontinence and/or increased urinary frequency and urgency in patients with overactive bladder or neurogenic detrusor overactivity.                                                                                                                             | 21/10/2024 |
| New Registration | Generic Drug | Cimuquit  | Varenicline                                                                                                                                                          | Film Coated Tablet | 0.5 mg                                                                                                                                                               | Indicated for smoking cessation in adults.                                                                                                                                                                                                                                                                      | 07/10/2024 |
| New Registration | Generic Drug | Flamex    | Celecoxib                                                                                                                                                            | Capsule            | 200 mg                                                                                                                                                               | Indicated in adults for the symptomatic relief in the treatment of Osteoarthritis, Rheumatoid Arthritis and Ankylosing Spondylitis.                                                                                                                                                                             | 07/10/2024 |
| New Registration | Generic Drug | Flamex    | Celecoxib                                                                                                                                                            | Capsule            | 400 mg                                                                                                                                                               | Indicated in adults for the symptomatic relief in the treatment of Osteoarthritis, Rheumatoid Arthritis and Ankylosing Spondylitis.                                                                                                                                                                             | 07/10/2024 |
| New Registration | Generic Drug | Arthfree  | Leflunomide                                                                                                                                                          | Film Coated Tablet | 20 mg                                                                                                                                                                | Indicated for the treatment of adult patients with:<br><br>- Active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD)<br>- Active psoriatic arthritis.                                                                                                                                   | 07/10/2024 |

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| New Registration | Generic Drug | Tonall                 | Nalbuphine            | Solution for injection | 20 mg/ml                        | Indicated for the relief of moderate to severe pain. Nalbuphine can also be used as a supplement to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery.                                                                                                                                                                                                                                                                                                                                                                                 | 07/10/2024 |
| New Registration | Generic Drug | Paricalcitol Spectro   | Paricalcitol          | Solution for injection | 5 mcg/ml                        | Indicated in adults for the prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure who are undergoing haemodialysis.                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 07/10/2024 |
| New Registration | Generic Drug | Lignox                 | Lidocaine, Prilocaine | Topical Cream          | 2.5%, 2.5% (5%W/W)<br><br>(30g) | Indicated for: <ul style="list-style-type: none"><li>- Topical anaesthesia of the skin in connection with:<ul style="list-style-type: none"><li>• needle insertion, e.g., intravenous catheters or blood sampling;</li><li>• superficial surgical procedures; in adults and in the paediatric population.</li></ul></li><li>- Topical anaesthesia of the genital mucosa, e.g., prior to superficial surgical procedures or infiltration anaesthesia; in adults and adolescents ≥ 12 years.</li><li>- Topical anaesthesia of leg ulcers to facilitate mechanical cleansing/debridement in adults only.</li></ul> | 21/10/2024 |
| New Registration | Generic Drug | Lignox                 | Lidocaine, Prilocaine | Topical Cream          | 2.5%, 2.5% (5%W/W)<br><br>(5g)  | Indicated for: <ul style="list-style-type: none"><li>- Topical anaesthesia of the skin in connection with:<ul style="list-style-type: none"><li>• needle insertion, e.g., intravenous catheters or blood sampling;</li><li>• superficial surgical procedures; in adults and in the paediatric population.</li></ul></li><li>- Topical anaesthesia of the genital mucosa, e.g., prior to superficial surgical procedures or infiltration anaesthesia; in adults and adolescents ≥ 12 years.</li><li>- Topical anaesthesia of leg ulcers to facilitate mechanical cleansing/debridement in adults only.</li></ul> | 21/10/2024 |
| New Registration | Generic Drug | Anastrozole Pharmacare | Anastrozole           | Film Coated Tablet     | 1 mg                            | Indicated for <ul style="list-style-type: none"><li>- Treatment of hormone receptor-positive advanced breast cancer in postmenopausal women.</li><li>- Adjuvant treatment of hormone receptor-positive early invasive breast cancer in postmenopausal women.</li></ul>                                                                                                                                                                                                                                                                                                                                          | 21/10/2024 |

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|                  |              |          |              |                          |       | <div>- Adjuvant treatment of hormone receptor-positive early invasive breast cancer in postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen.</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |            |
| New Registration | Generic Drug | Ticaglob | Ticagrelor   | Film Coated Tablet       | 90 mg | <div>Indicated for:</div> <div>Ticagrelor, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with</div> <div><div>- Acute coronary syndromes (ACS) or</div><div>- A history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event.</div></div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 21/10/2024 |
| New Registration | Generic Drug | Restomap | Esomeprazole | Gastro resistant tablets | 20 mg | <div>Indicated for:</div> <div><u>Adults:</u></div> <div><div>- Gastroesophageal Reflux Disease (GERD)<div><div>• Treatment of erosive reflux oesophagitis</div><div>• Long-term management of patients with healed oesophagitis to prevent relapse</div><div>• Symptomatic treatment of gastroesophageal reflux disease (GORD)</div></div></div><div>- In combination with appropriate antibacterial therapeutic regimens for the eradication of Helicobacter pylori<div><div>• Healing of Helicobacter pylori associated duodenal ulcer and</div><div>• Prevention of relapse of peptic ulcers in patients with Helicobacter pylori associated ulcers</div></div></div><div>- Patients requiring continued NSAID therapy<div><div>• Healing of gastric ulcers associated with NSAID therapy.</div><div>• Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk. Prolonged treatment after IV induced prevention of rebleeding of peptic ulcers.</div></div></div><div>- Treatment of Zollinger Ellison Syndrome</div></div> <div><u>Adolescents from the age of 12 years:</u></div> <div><div>- Gastroesophageal Reflux Disease (GERD)</div></div> | 21/10/2024 |



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|                  |              |                               |                                      |                                       |          | <ul style="list-style-type: none"><li>• Treatment of erosive reflux oesophagitis</li><li>• Long-term management of patients with healed oesophagitis to prevent relapse</li><li>• Symptomatic treatment of gastro-oesophageal reflux disease (GORD)</li></ul> <p>- In combination with antibiotics in treatment of duodenal ulcer caused by Helicobacter pylori</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |            |
| New Registration | Generic Drug | Gemcitabine Neapolis          | Gemcitabine hydrochloride            | Powder for solution for infusion      | 1000 mg  | <p>Indicated for:</p> <ul style="list-style-type: none"><li>- Treatment of locally advanced or metastatic bladder cancer in combination with cisplatin.</li><li>- Treatment of patients with locally advanced or metastatic adenocarcinoma of the pancreas.</li><li>- In combination with cisplatin, as first line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). Gemcitabine monotherapy can be considered in elderly patients or those with performance status 2.</li><li>- Treatment of patients with locally advanced or metastatic epithelial ovarian carcinoma, in combination with carboplatin, in patients with relapsed disease following a recurrence-free interval of at least 6 months after platinum-based, first-line therapy.</li><li>- In combination with paclitaxel, for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.</li></ul> | 21/10/2024 |
| New Registration | Generic Drug | Pemetrexed EVER Pharma 500 mg | Pemetrexed Disodium Hemipentahydrate | Concentrate for solution for infusion | 25 mg/ml | <p>Indicated for:</p> <p>Malignant pleural mesothelioma</p> <ul style="list-style-type: none"><li>- In combination with cisplatin, for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.</li></ul> <p>Non-small cell lung cancer</p> <ul style="list-style-type: none"><li>- In combination with cisplatin, for the first line treatment of patients with locally advanced or</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 21/10/2024 |

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|                  |              |                                      |                                            |                                                     |          | metastatic non-small cell lung cancer other than predominantly squamous cell histology. <ul style="list-style-type: none"><li>- 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 not progressed immediately following platinum-based chemotherapy.</li><li>- 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</li></ul>                                                                                                                                                                                                                                                                                                                                                                                   |            |
| New Registration | Generic Drug | Pemetrexed<br>EVER Pharma<br>1000 mg | Pemetrexed<br>Disodium<br>Hemipentahydrate | Concentrate for solution<br>for infusion            | 25 mg/ml | Indicated for:<br><br>Malignant pleural mesothelioma <ul style="list-style-type: none"><li>- In combination with cisplatin, for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.</li></ul><br>Non-small cell lung cancer <ul style="list-style-type: none"><li>- In combination with cisplatin, for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.</li><li>- 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 not progressed immediately following platinum-based chemotherapy.</li><li>- 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</li></ul> | 21/10/2024 |
| New Registration | Generic Drug | Bindolent                            | Bendamustine                               | Powder for concentrate<br>for solution for infusion | 25 mg    | Indicated for: <ul style="list-style-type: none"><li>- First-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate.</li><li>- Indolent non-Hodgkin’s lymphomas as monotherapy in patients who have progressed during or within 6</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 21/10/2024 |



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|                  |              |                       |              |                                                  |        | months following treatment with rituximab or a rituximab containing regimen. <ul style="list-style-type: none"><li>- 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.</li></ul>                                                                                                                                                                                                                                                                                                |            |
| New Registration | Generic Drug | Bindolent             | Bendamustine | Powder for concentrate for solution for infusion | 100 mg | Indicated for: <ul style="list-style-type: none"><li>- First-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate.</li><li>- Indolent non-Hodgkin’s lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen.</li><li>- 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.</li></ul> | 21/10/2024 |
| New Registration | Generic Drug | Treprostinil Tillomed | Treprostinil | Solution for infusion                            | 200 mg | Indicated for the treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of the disease in patients classified as New York Heart Association (NYHA) functional class III.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 21/10/2024 |
| New Registration | Generic Drug | Treprostinil Tillomed | Treprostinil | Solution for infusion                            | 100 mg | Indicated for the treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of the disease in patients classified as New York Heart Association (NYHA) functional class III.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 21/10/2024 |
| New Registration | Generic Drug | Treprostinil Tillomed | Treprostinil | Solution for infusion                            | 50 mg  | Indicated for the treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of the disease in patients                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 21/10/2024 |

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|                  |              |           |                                  |                        |                                  | classified as New York Heart Association (NYHA) functional class III.                                                                                                                                                                                                                                                                                                                                                                                              |            |
| New Registration | Generic Drug | Sondelbay | Teriparatide                     | Solution for injection | 250 mcg/ml                       | Indicated for: <ul style="list-style-type: none"><li>- Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture .In postmenopausal women, a significant reduction in the incidence of vertebral and nonvertebral fractures but not hip fractures has been demonstrated.</li><li>- Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.</li></ul> | 28/10/2024 |
| New Registration | Generic Drug | Relavers  | Sugammadex Sodium                | Solution for injection | 100mg/ml                         | Indicated for Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults .<br><br>For the pediatric population:<br><br>Sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years.                                                                                                                                                                                    | 28/10/2024 |
| New Registration | Generic Drug | Duvalsa   | Sacubitril 97mg, Valsartan 103mg | Film Coated Tablet     | Sacubitril 97mg, Valsartan 103mg | Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal .LVEF is a variable measure, so use clinical judgment in deciding whom to treat.                                                                                                                                | 28/10/2024 |
| New Registration | Generic Drug | Duvalsa   | Sacubitril 97mg, Valsartan 103mg | Film Coated Tablet     | Sacubitril 49mg, Valsartan 51mg  | Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal .LVEF is a variable measure, so use clinical judgment in deciding whom to treat.                                                                                                                                | 28/10/2024 |
| New Registration | Generic Drug | Duvalsa   | Sacubitril 97mg, Valsartan 103mg | Film Coated Tablet     | Sacubitril 24mg, Valsartan 26mg  | Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF)                                                                                                                                                                                                                              | 28/10/2024 |

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|                     |              |          |                                         |                    |       | below normal .LVEF is a variable measure, so use clinical judgment in deciding whom to treat.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |            |
| New<br>Registration | Generic Drug | Restomap | Esomeprazole<br>Magnesium<br>Trihydrate | Film Coated Tablet | 40 mg | <p>Indicated for:</p> <p><u>Adults:</u></p> <ul style="list-style-type: none"><li>- Gastroesophageal Reflux Disease (GERD)<ul style="list-style-type: none"><li>• Treatment of erosive reflux oesophagitis</li><li>• Long-term management of patients with healed oesophagitis to prevent relapse</li><li>• Symptomatic treatment of gastroesophageal reflux disease (GORD)</li></ul></li><li>- In combination with appropriate antibacterial therapeutic regimens for the eradication of Helicobacter pylori<ul style="list-style-type: none"><li>• Healing of Helicobacter pylori associated duodenal ulcer and</li><li>• Prevention of relapse of peptic ulcers in patients with Helicobacter pylori associated ulcers</li></ul></li><li>- Patients requiring continued NSAID therapy<ul style="list-style-type: none"><li>• Healing of gastric ulcers associated with NSAID therapy.</li><li>• Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk. Prolonged treatment after IV induced prevention of rebleeding of peptic ulcers.</li></ul></li><li>- Treatment of Zollinger Ellison Syndrome</li></ul> <p><u>Adolescents from the age of 12 years:</u></p> <ul style="list-style-type: none"><li>- Gastroesophageal Reflux Disease (GERD)<ul style="list-style-type: none"><li>• Treatment of erosive reflux oesophagitis</li><li>• Long-term management of patients with healed oesophagitis to prevent relapse</li><li>• Symptomatic treatment of gastro-oesophageal reflux disease (GORD)</li></ul></li></ul> <p>In combination with antibiotics in treatment of duodenal ulcer caused by Helicobacter pylori</p> | 28/10/2024 |

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| New Registration | Generic Drug | Promazi  | Chlorpromazine Hydrochloride | Film Coated Tablet | 25 mg      | Indicated for:<br><br>- Schizophrenia and other psychoses (especially paranoia), mania and hypomania. In anxiety, psychomotor agitation, excitement, violent or dangerously impulsive behavior. Is used as an adjunct in the short-term management of these conditions .<br>- Intractable hiccup .<br>- Nausea and vomiting in terminal illness (where other drugs have failed or are not available) .<br>- Induction of hypothermia is facilitated by Chlorpromazine Tablets which prevents shivering and causes vasodilatation.<br>- Childhood schizophrenia and autism | 28/10/2024 |
| New Registration | Generic Drug | Promazi  | Chlorpromazine Hydrochloride | Film Coated Tablet | 100 mg     | Indicated for:<br><br>- Schizophrenia and other psychoses (especially paranoia), mania and hypomania. In anxiety, psychomotor agitation, excitement, violent or dangerously impulsive behavior. Is used as an adjunct in the short-term management of these conditions .<br>- Intractable hiccup .<br>- Nausea and vomiting in terminal illness (where other drugs have failed or are not available) .<br>- Induction of hypothermia is facilitated by Chlorpromazine Tablets which prevents shivering and causes vasodilatation.<br>- Childhood schizophrenia and autism | 28/10/2024 |
| New Registration | Generic Drug | Prokitav | Tolvaptan                    | Tablet             | 30mg ,90mg | Indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 4 at initiation of treatment with evidence of rapidly progressing disease.                                                                                                                                                                                                                                                                                                   | 28/10/2024 |
| New Registration | Generic Drug | Prokitav | Tolvaptan                    | Tablet             | 30mg ,60mg | Indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 4 at initiation of treatment with evidence of rapidly progressing disease.                                                                                                                                                                                                                                                                                                   | 28/10/2024 |

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| New<br>Registration | Generic Drug | Prokitav        | Tolvaptan  | Tablet                 | 15mg ,45mg               | Indicated to slow the progression of cyst development and renal insufficiency of autosomal dominant polycystic kidney disease (ADPKD) in adults with chronic kidney disease (CKD) stage 1 to 4 at initiation of treatment with evidence of rapidly progressing disease.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 28/10/2024 |
| New<br>Registration | Generic Drug | Paclitaxel Kabi | Paclitaxel | Solution for Injection | 6 mg/ml<br><br>(50 ml)   | Indicated for: <ul style="list-style-type: none"><li>- First-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel is indicated in combination with cisplatin.</li><li>- The adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.</li><li>- Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.</li><li>- In combination with cisplatin, i for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.</li><li>- The second-line treatment of AIDS- related Kaposi’s sarcoma.</li></ul> | 28/10/2024 |
| New<br>Registration | Generic Drug | Paclitaxel Kabi | Paclitaxel | Solution for Injection | 6 mg/ml<br><br>(34.4 ml) | Indicated for: <ul style="list-style-type: none"><li>- First-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel is indicated in combination with cisplatin.</li><li>- The adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.</li><li>- Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.</li><li>- In combination with cisplatin, i for the first-line treatment of non-small cell lung cancer in patients who</li></ul>                                                                                                                                                      | 28/10/2024 |

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|                  |              |                 |            |                        |                          | <p>are not candidates for potentially curative surgery and/or radiation therapy.</p> <ul style="list-style-type: none"><li>- The second-line treatment of AIDS- related Kaposi's sarcoma.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |            |
| New Registration | Generic Drug | Paclitaxel Kabi | Paclitaxel | Solution for Injection | 6 mg/ml<br><br>(25 ml)   | <p>Indicated for:</p> <ul style="list-style-type: none"><li>- First-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel is indicated in combination with cisplatin.</li><li>- The adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.</li><li>- Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.</li><li>- In combination with cisplatin, i for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.</li><li>- The second-line treatment of AIDS- related Kaposi's sarcoma.</li></ul> | 28/10/2024 |
| New Registration | Generic Drug | Paclitaxel Kabi | Paclitaxel | Solution for Injection | 6 mg/ml<br><br>(16.7 ml) | <p>Indicated for:</p> <ul style="list-style-type: none"><li>- First-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel is indicated in combination with cisplatin.</li><li>- The adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.</li><li>- Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.</li><li>- In combination with cisplatin, i for the first-line treatment of non-small cell lung cancer in patients who</li></ul>                                                                                                                                                      | 28/10/2024 |



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|                  |              |                 |             |                        |                      | <p>are not candidates for potentially curative surgery and/or radiation therapy.</p> <ul style="list-style-type: none"><li>- The second-line treatment of AIDS- related Kaposi's sarcoma.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |            |
| New Registration | Generic Drug | Paclitaxel Kabi | Paclitaxel  | Solution for Injection | 6 mg/ml<br><br>(5ml) | <p>Indicated for:</p> <ul style="list-style-type: none"><li>- First-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel is indicated in combination with cisplatin.</li><li>- The adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.</li><li>- Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.</li><li>- In combination with cisplatin, i for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.</li><li>- The second-line treatment of AIDS- related Kaposi's sarcoma.</li></ul> | 28/10/2024 |
| New Registration | Generic Drug | Oseltamivir PPI | Oseltamivir | Capsule                | 30 mg                | <p>Indicated for:</p> <p>Treatment of influenza</p> <ul style="list-style-type: none"><li>- Indicated in adults and children including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.</li></ul> <p>Prevention of influenza</p> <ul style="list-style-type: none"><li>- Post-exposure prevention in individuals 1 year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.</li></ul>                                                                                                                                                                                                                                                                               | 28/10/2024 |

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|                  |              |                 |             |         |       | <ul style="list-style-type: none"> <li>- The appropriate use of oseltamivir phosphate capsules for prevention of influenza should be determined on a case by case basis by the circumstances and the population requiring protection. In exceptional situations (e.g. in case of a mismatch between the circulating and vaccine virus strains, and a pandemic situation) seasonal prevention could be considered in individuals one year of age or older.</li> </ul> <p>Oseltamivir phosphate capsules are not a substitute for influenza vaccination.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |            |
| New Registration | Generic Drug | Oseltamivir PPI | Oseltamivir | Capsule | 45 mg | <p>Indicated for:</p> <p>Treatment of influenza</p> <ul style="list-style-type: none"> <li>- Indicated in adults and children including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.</li> </ul> <p>Prevention of influenza</p> <ul style="list-style-type: none"> <li>- Post-exposure prevention in individuals 1 year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.</li> <li>- The appropriate use of oseltamivir phosphate capsules for prevention of influenza should be determined on a case by case basis by the circumstances and the population requiring protection. In exceptional situations (e.g. in case of a mismatch between the circulating and vaccine virus strains, and a pandemic situation) seasonal prevention could be considered in individuals one year of age or older.</li> </ul> <p>Oseltamivir phosphate capsules are not a substitute for influenza vaccination.</p> | 28/10/2024 |
| New Registration | Generic Drug | Oseltamivir PPI | Oseltamivir | Capsule | 75 mg | <p>Indicated for:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 28/10/2024 |

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|                  |              |       |              |         |       | <p>Treatment of influenza</p> <ul style="list-style-type: none"><li>- Indicated in adults and children including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.</li></ul> <p>Prevention of influenza</p> <ul style="list-style-type: none"><li>- Post-exposure prevention in individuals 1 year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.</li><li>- The appropriate use of oseltamivir phosphate capsules for prevention of influenza should be determined on a case by case basis by the circumstances and the population requiring protection. In exceptional situations (e.g. in case of a mismatch between the circulating and vaccine virus strains, and a pandemic situation) seasonal prevention could be considered in individuals one year of age or older.</li></ul> <p>Oseltamivir phosphate capsules are not a substitute for influenza vaccination.</p> |            |
| New Registration | Generic Drug | Aipro | Aripiprazole | Capsule | 15 mg | <p>Indicated for:</p> <ul style="list-style-type: none"><li>- The treatment of schizophrenia in adults and in adolescents aged 15 years and older.</li><li>- The treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment.</li><li>- The treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 28/10/2024 |

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| New Registration | Generic Drug | Salitav  | Tolvaptan       | Tablet                                 | 30 mg    | Indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 28/10/2024 |
| New Registration | Generic Drug | Salitav  | Tolvaptan       | Tablet                                 | 5 mg     | Indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 28/10/2024 |
| New Registration | Generic Drug | Brevie   | Brivaracetam    | Solution for injection/infusion        | 10 mg/ml | Indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 28/10/2024 |
| New Registration | Generic Drug | Famodine | Famotidine      | Concentrate for solution for injection | 10 mg/ml | <p>Indicated in some hospitalized patients with pathological hypersecretory conditions or intractable ulcers, or as an alternative to the oral dosage forms for short term use in patients who are unable to take oral medication for the following conditions:</p> <ul style="list-style-type: none"><li>- Short term treatment of active duodenal ulcer</li><li>- Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of an active ulcer.</li><li>- Short term treatment of active benign gastric ulcer</li><li>- Short term treatment of patients with symptoms of gastroesophageal reflux disease (GERD).</li><li>- Short term treatment of esophagitis due to GERD including erosive or ulcerative disease diagnosed by endoscopy.</li><li>- Treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison Syndrome, multiple endocrine adenomas)</li></ul> <p>Famodine, supplied as a concentrated solution for intravenous injection, is intended for intravenous use only</p> | 28/10/2024 |
| New Registration | Generic Drug | Sola D3  | Cholecalciferol | Film Coated Tablet                     | 50000 IU | Indicated for the treatment and prevention of vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency. Sola D3® tablets are indicated for use in adults, the elderly and adolescents.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 28/10/2024 |

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| New<br>Registration | Generic Drug | Sola D3                | Cholecalciferol              | Film Coated Tablet | 10000 IU | Indicated for the treatment and prevention of vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency. Sola D3® tablets are indicated for use in adults, the elderly and adolescents. | 28/10/2024 |
| New<br>Registration | Generic Drug | Sola D3                | Cholecalciferol              | Film Coated Tablet | 5000 IU  | Indicated for the treatment and prevention of vitamin D deficiency. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency. Sola D3® tablets are indicated for use in adults, the elderly and adolescents. | 28/10/2024 |
| New<br>Registration | Generic Drug | Hydralazine<br>Sciegen | Hydralazine<br>Hydrochloride | Tablet             | 25 mg    | Indicated for:<br><br>- Moderate to severe hypertension as an adjunct to other antihypertensive agents .<br><br>- Moderate to severe chronic congestive heart failure along with long acting nitrates in patients whose optimal doses        | 28/10/2024 |