



Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Saudi Drug Updates (SDU)

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SFDA Drug Approvals

Application Type	Drug Type	Trade Name	Active Ingredient(s)	Dosage form	Strength	SFDA Approved Indication(s)	Approval Date
New Registration	Biological Drug	Fibryga	Human Fibrinogen	Powder for solution for injection or infusion	1 g	Treatment of bleeding episodes and peri-operative prophylaxis in patients with congenital hypo- or afibrinogenaemia with bleeding tendency.	09/12/2024
New Registration	Biological Drug	Altuvoc	Efanesoctocog alfa	Powder and solvent for solution for injection	250 IU	Altuvoc is intended for the following indications: treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).	16/12/2024
New Registration	Biological Drug	Altuvoc	Efanesoctocog alfa	Powder and solvent for solution for injection	500 IU	Altuvoc is intended for the following indications: treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).	16/12/2024
New Registration	Biological Drug	Altuvoc	Efanesoctocog alfa	Powder and solvent for solution for injection	1000 IU	Altuvoc is intended for the following indications: treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).	16/12/2024

New Registration	Biological Drug	Altuvoct	Efanesoctocog alfa	Powder and solvent for solution for injection	2000 IU	Altuvoct is intended for the following indications: treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).	16/12/2024
New Registration	Biological Drug	Altuvoct	Efanesoctocog alfa	Powder and solvent for solution for injection	3000 IU	Altuvoct is intended for the following indications: treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).	16/12/2024
New Registration	Biological Drug	Altuvoct	Efanesoctocog alfa	Powder and solvent for solution for injection	4000 IU	Altuvoct is intended for the following indications: treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).	16/12/2024
New Registration	Biological Drug	Tecartus	Brexucabtagene autoleucel $1 \times 10^6 + 1 \times 10^8$ cells	Cell suspension for infusion	Brexucabtagene autoleucel $1 \times 10^6 + 1 \times 10^8$ cells	<p>Tecartus is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:</p> <ul style="list-style-type: none"> •Mantle Cell Lymphoma <p>Adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.</p> <ul style="list-style-type: none"> •Acute Lymphoblastic Leukemia <p>Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).</p>	30/12/2024
New Registration	New Drug	VYZULTA	Latanoprostene bunod	Ophthalmic solution	0.024%	VYZULTA™ is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.	02/12/2024
New Registration	New Drug	Oxlumo	lumasiran	Solution for injection	94.5 mg /0.5ml	Oxlumo is indicated for the treatment of primary hyperoxaluria type 1 (PH1).	02/12/2024
New Registration	New Drug	Filsuvez gel	Triterpene extract	Gel	100 mg/g (10%)	Treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older.	02/12/2024
New Registration	New Drug	Rezzayo	Rezafungin	Powder for concentrate for	200 mg	Rezzayo is indicated for the treatment of invasive candidiasis in adults.	09/12/2024

				solution for infusion			
New Registration	Generic Drug	Zylinamet	Linagliptin, Metformin HCL	Film-coated tablet	2.5 mg, 500 mg	<p>Zylinamet is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:</p> <ul style="list-style-type: none"> ·In patients inadequately controlled on their maximally tolerated dose of metformin alone ·In combination with other medicinal products for the treatment of diabetes, including insulin, in patients inadequately controlled with metformin and these medicinal products ·In patients already being treated with the combination of linagliptin and metformin as separate tablets. 	02/12/2024
New Registration	Generic Drug	Zylinamet	Linagliptin, Metformin HCL	Film-coated tablet	2.5 mg, 850 mg	<p>Zylinamet is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:</p> <ul style="list-style-type: none"> ·In patients inadequately controlled on their maximally tolerated dose of metformin alone ·In combination with other medicinal products for the treatment of diabetes, including insulin, in patients inadequately controlled with metformin and these medicinal products ·In patients already being treated with the combination of linagliptin and metformin as separate tablets. 	02/12/2024
New Registration	Generic Drug	Zylinamet	Linagliptin, Metformin HCL	Film-coated tablet	2.5 mg, 1000 mg	<p>Zylinamet is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:</p> <ul style="list-style-type: none"> ·In patients inadequately controlled on their maximally tolerated dose of metformin alone ·In combination with other medicinal products for the treatment of diabetes, including insulin, in patients inadequately controlled with metformin and these medicinal products 	02/12/2024

						·In patients already being treated with the combination of linagliptin and metformin as separate tablets.	
New Registration	Generic Drug	LAXIRA	Rocuronium Bromide	Solution for injection	10 mg/ml	Rocuronium bromide is indicated in adult and pediatric patients (from term neonates to adolescents [0 to <18 years]) as an adjunct to general anesthesia to facilitate tracheal intubation during routine induction and to provide skeletal muscle relaxation during surgery. In adults, Rocuronium bromide is also indicated to facilitate tracheal intubation during rapid sequence induction and as an adjunct in the intensive care unit (ICU) (to facilitate intubation), for short term use.	02/12/2024
New Registration	Generic Drug	Aubomide	Teriflunomide	Film-Coated Tablet	14 mg	Indicated for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS)	02/12/2024
New Registration	Generic Drug	Ambracy	Ambrisentan	Film-Coated Tablet	10 mg	<p>Ambrisentan is indicated for treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment.</p> <p>Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease.</p> <p>Ambrisentan is indicated for treatment of PAH in adolescents and children (aged 8 to less than 18 years) of WHO Functional Class (FC) II to III including use in combination treatment. Efficacy has been shown in IPAH, familial, corrected congenital and in PAH associated with connective tissue disease.</p>	02/12/2024
New Registration	Generic Drug	Ambracy	Ambrisentan	Film-Coated Tablet	5 mg	<p>Ambrisentan is indicated for treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment.</p> <p>Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease.</p> <p>Ambrisentan is indicated for treatment of PAH in adolescents and children (aged 8 to less than 18 years) of WHO Functional Class (FC) II to III including use in</p>	02/12/2024

						combination treatment. Efficacy has been shown in IPAH, familial, corrected congenital and in PAH associated with connective tissue disease.	
New Registration	Generic Drug	Disclero	Dimethyl Fumarate	Gastro-resistant capsule	240 mg	Disclero is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).	02/12/2024
New Registration	Generic Drug	Renulib	Sunitinib	Hard Capsule	12.5 mg	<p>Gastrointestinal stromal tumour (GIST)</p> <p>Renulib is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.</p> <p>Metastatic renal cell carcinoma (MRCC)</p> <p>Renulib is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.</p> <p>Pancreatic neuroendocrine tumours (pNET)</p> <p>Renulib is indicated for the treatment of unresectable or metastatic, well- differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.</p>	02/12/2024
New Registration	Generic Drug	Renulib	Sunitinib	Hard Capsule	25 mg	<p>Gastrointestinal stromal tumour (GIST)</p> <p>Renulib is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.</p> <p>Metastatic renal cell carcinoma (MRCC)</p> <p>Renulib is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.</p> <p>Pancreatic neuroendocrine tumours (pNET)</p> <p>Renulib is indicated for the treatment of unresectable or metastatic, well- differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.</p>	02/12/2024

New Registration	Generic Drug	Renulib	Sunitinib	Hard Capsule	50 mg	<p>Gastrointestinal stromal tumour (GIST)</p> <p>Renulib is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.</p> <p>Metastatic renal cell carcinoma (MRCC)</p> <p>Renulib is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.</p> <p>Pancreatic neuroendocrine tumours (pNET)</p> <p>Renulib is indicated for the treatment of unresectable or metastatic, well- differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.</p>	02/12/2024
New Registration	Generic Drug	Ondex	Ondansetron	Oral solution	0.8 mg/ml	<p>Adults:</p> <p>Ondex is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.</p> <p>Ondex is indicated for the prevention of post-operative nausea and vomiting (PONV).</p> <p>For treatment of established PONV, administration by injection is recommended.</p> <p>Paediatric Population:</p> <p>Ondex is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥ 6 months.</p>	09/12/2024
New Registration	Generic Drug	Briglor	Ticagrelor	Film-coated Tablet	60 mg	<p>co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with</p> <p>acute coronary syndromes (ACS) or</p> <p>- a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event</p>	09/12/2024

New Registration	Generic Drug	Briglor	Ticagrelor	Film-coated Tablet	90 mg	co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (ACS) or - a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event	09/12/2024
New Registration	Generic Drug	Evox	Levofloxacin hemihydrate	Film-coated tablet	500 mg	<p>Evox is indicated in adults for the treatment of the following infections:</p> <ul style="list-style-type: none"> •Acute pyelonephritis and complicated urinary tract infections •Chronic bacterial prostatitis •Inhalation Anthrax: postexposure prophylaxis and curative treatment <p>In following indication Evox tablets should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.</p> <ul style="list-style-type: none"> •Acute bacterial sinusitis •Acute exacerbations of chronic bronchitis obstructive pulmonary disease including bronchitis •Community-acquired pneumonia •Complicated skin and soft tissue infections •Uncomplicated cystitis <p>Evox may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous levofloxacin.</p> <p>Consideration should be given to official guidance on the appropriate use of antibacterial agents</p>	09/12/2024
New Registration	Generic Drug	Avocin	Clindamycin Hydrochloride	Capsule	150 mg	Treatment of infections:	09/12/2024

						<p>Clindamycin is indicated for the treatment of severe infections by susceptible micro-organisms causing namely:</p> <ul style="list-style-type: none">·ears, nose and throat infections,·bronchopulmonary infections,·stomatological infections,·skin infections,·genital infections,·osteoarticular infections,·post-surgical abdominal infections,·septicaemia. <p>Except for meningeal infections even if caused by susceptible micro-organisms, because the antibiotic does not diffuse into CSF in therapeutically effective quantities.</p> <p>Prophylaxis:</p> <p>Prophylaxis of infective endocarditis during dental care and upper respiratory tract procedures performed on an outpatient basis in patients allergic to beta lactams.</p>	
New Registration	Generic Drug	Avocin	Clindamycin Hydrochloride	Capsule	300 mg	<p>Treatment of infections:</p> <p>Clindamycin is indicated for the treatment of severe infections by susceptible micro-organisms causing namely:</p> <ul style="list-style-type: none">·ears, nose and throat infections,·bronchopulmonary infections,·stomatological infections,·skin infections,·genital infections,·osteoarticular infections,·post-surgical abdominal infections,·septicaemia.	09/12/202 4

						<p>Except for meningeal infections even if caused by susceptible micro-organisms, because the antibiotic does not diffuse into CSF in therapeutically effective quantities.</p> <p>Prophylaxis:</p> <p>Prophylaxis of infective endocarditis during dental care and upper respiratory tract procedures performed on an outpatient basis in patients allergic to beta lactams.</p>	
New Registration	Generic Drug	Clodreb	Cladribine	Tablet	10 mg	Clodreb is indicated for the treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging features	09/12/2024
New Registration	Generic Drug	Dandaxa	Tadalafil	Film-coated tablet	5 mg	<p>Treatment of erectile dysfunction in adult males.</p> <p>In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.</p> <p>Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males</p> <p>Tadalafil is not indicated for use by women.</p>	09/12/2024
New Registration	Generic Drug	Prenewel	Perindopril erbumine, Indapamide 1.25 MG	Tablet	4 mg, 1.25 mg	Substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril and indapamide given concurrently at the same dose level.	09/12/2024
New Registration	Generic Drug	Prenewel	Perindopril erbumine, Indapamide 1.25 MG	Tablet	8 mg, 2.5 mg	Substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril and indapamide given concurrently at the same dose level.	09/12/2024
New Registration	Generic Drug	Dapsone Tillomed	Dapsone	Tablet	100 mg	<p>The treatment of the following infections:</p> <ul style="list-style-type: none"> As part of a multidrug regimen in the treatment of all forms of leprosy. Treatment of blistering dermatoses such as dermatitis herpetiformis. Prophylaxis of Pneumocystis jirovecii pneumonia in immunodeficient subjects, especially AIDS patients. 	09/12/2024

New Registration	Generic Drug	Byraza Plus	Omeprazole, Sodium Bicarbonate	Capsule	40 mg, 1100 mg	<p>Indicated in adults for the:</p> <ul style="list-style-type: none"> •Short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy. •Short-term treatment (4 to 8 weeks) of active benign gastric ulcer. •Treatment of heartburn and other symptoms associated with GERD for up to 4 weeks. •Short-term treatment (4 to 8 weeks) of EE due to acid-mediated GERD which has been diagnosed by endoscopy in adults. –The efficacy of omeprazole/sodium bicarbonate used for longer than 8 weeks in patients with EE has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of EE or GERD symptoms (e.g., heartburn), additional 4 to 8-week courses of Locid Plus may be considered. • Maintenance of healing of EE due to acid-mediated GERD. Controlled studies do not extend beyond 12 months. 	09/12/202 4
New Registration	Generic Drug	Promazi	Chlorpromazine Hydrochloride	Solution for injection	50 mg/2 ml	<p>Promazi is intended for the following indications:</p> <p>Treatment of schizophrenia; to control nausea and vomiting; for relief of restlessness and apprehension before surgery; to control the manifestations of the manic type of manic-depressive illness; for relief of intractable hiccups; for the treatment of severe behavioral problems in children (1 to 12 years of age) marked by combativeness and/or explosive hyperexcitable behavior (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability, and poor frustration tolerance.</p>	16/12/202 4

New Registration	Generic Drug	Sugammadex Kabi	Sugammadex	Solution for injection	100 mg/ml	<p>Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults.</p> <p>For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years.</p>	16/12/202 4
New Registration	Generic Drug	Sugmastad	Sugammadex Sodium	Solution for injection	100 mg/ml	<p>Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults.</p> <p>For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years.</p>	16/12/202 4
New Registration	Generic Drug	Vertella	Posaconazole	Gastro-resistant tablet	100 mg	<p>Vertella is indicated for use in the treatment of the following fungal infections in adults:</p> <ul style="list-style-type: none"> -Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or inpatients who are intolerant of these medicinal products; -Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B; -Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole; -Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products. <p>Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy. Vertella is also indicated for prophylaxis of invasive fungal infections in the following patients:</p> <ul style="list-style-type: none"> -Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged 	16/12/202 4

						neutropenia and who are at high risk of developing invasive fungal infections; -Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections.	
New Registration	Generic Drug	Omace	Lisinopril	Tablet	5 mg	Hypertension Treatment of hypertension. Heart failure Treatment of symptomatic heart failure. Acute myocardial infarction Short-term (6 weeks) treatment of haemodynamically stable patients within 24 hours of an acute myocardial infarction. Renal complications of diabetes mellitus Treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy	16/12/2024
New Registration	Generic Drug	Omace	Lisinopril	Tablet	10 mg	Hypertension Treatment of hypertension. Heart failure Treatment of symptomatic heart failure. Acute myocardial infarction Short-term (6 weeks) treatment of haemodynamically stable patients within 24 hours of an acute myocardial infarction. Renal complications of diabetes mellitus Treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy	16/12/2024

New Registration	Generic Drug	Omacel	Lisinopril	Tablet	20 mg	<p>Hypertension</p> <p>Treatment of hypertension.</p> <p>Heart failure</p> <p>Treatment of symptomatic heart failure.</p> <p>Acute myocardial infarction</p> <p>Short-term (6 weeks) treatment of haemodynamically stable patients within 24 hours of an acute myocardial infarction.</p> <p>Renal complications of diabetes mellitus</p> <p>Treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy</p>	16/12/2024
New Registration	Generic Drug	Remox	Amoxicillin	Capsule	500 mg	<p>Remox is indicated for the treatment of the following infections in adults and children:</p> <p>Acute bacterial sinusitis</p> <p>Acute otitis media</p> <p>Acute streptococcal tonsillitis and pharyngitis</p> <p>Acute exacerbations of chronic bronchitis (AECB)/acute exacerbation of chronic obstructive pulmonary disease (AECOPD)</p> <p>Community acquired pneumonia</p> <p>Acute cystitis</p> <p>Asymptomatic bacteriuria in pregnancy</p> <p>Acute pyelonephritis</p> <p>Typhoid and paratyphoid fever</p> <p>Dental abscess with spreading cellulitis</p> <p>Prosthetic joint infections</p> <p>Helicobacter pylori eradication</p> <p>Lyme disease</p>	16/12/2024

						Remox is also indicated for the prophylaxis of endocarditis.	
New Registration	Generic Drug	Verdye	Indocyanine Green	Powder for solution for injection	5 mg/ml	<p>Diagnostic indications</p> <p>Cardiac, circulatory and micro-circulatory diagnostics:</p> <ul style="list-style-type: none"> ·measurement of cardiac output and stroke volume ·measurement of circulating blood volumes ·measurement of cerebral perfusion <p>Liver function diagnostics:</p> <ul style="list-style-type: none"> ·measurement of liver blood flow ·measurement of excretory function of the liver <p>Ophthalmic angiography diagnostics:</p> <ul style="list-style-type: none"> ·measurement of perfusion of the choroid 	16/12/202 4
New Registration	Generic Drug	Wamlox	Amlodipine besilate, Valsartan	Film-coated tablet	10 mg, 160 mg	<p>Treatment of essential hypertension.</p> <p>Wamlox is indicated in adults whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy</p>	30/12/202 4
New Registration	Generic Drug	Wamlox	Amlodipine besilate, Valsartan	Film-coated tablet	5 mg, 160 mg	<p>Treatment of essential hypertension.</p> <p>Wamlox is indicated in adults whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy</p>	30/12/202 4
New Registration	Generic Drug	Tadalo	Tadalafil	Film-coated tablet	20 mg	Treatment of erectile dysfunction in adult males	30/12/202 4
New Registration	Generic Drug	Irinotecan BOS	Irinotecan Hydrochloride	Solution for infusion	20mg/ml	<p>Irinotecan BOS is indicated for the treatment of patients with advanced colorectal cancer:</p> <ul style="list-style-type: none"> •in combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for advanced disease, •as a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen. <p>Irinotecan BOS in combination with cetuximab is indicated for the treatment of patients with epidermal growth factor</p>	30/12/202 4

						<p>receptor (EGFR)-expressing RAS wild-type metastatic colorectal cancer, who had not received prior treatment for metastatic disease or after failure of irinotecan including cytotoxic therapy.</p> <p>Irinotecan BOS in combination with 5-fluorouracil, folinic acid and bevacizumab is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum.</p> <p>Irinotecan BOS in combination with capecitabine with or without bevacizumab is indicated for first-line treatment of patients with metastatic colorectal carcinoma.</p>	
New Registration	Generic Drug	Domassel	Ticagrelor	Film-coated tablet	60 mg	<p>Ticagrelor, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with</p> <ul style="list-style-type: none"> -acute coronary syndromes (ACS) or - a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event 	30/12/2024
New Registration	Generic Drug	Sitfort	Sitagliptin Phosphate, Metformin Hydrochloride	Film-coated tablet	50 mg, 1000 mg	<p>For adult patients with type 2 diabetes mellitus:</p> <p>SITFORT is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin.</p> <p>SITFORT is indicated in combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.</p> <p>SITFORT is indicated as triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist.</p>	30/12/2024

						SITFORT is also indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycaemic control	
New Registration	Generic Drug	Sitfort	Sitagliptin Phosphate, Metformin Hydrochloride	Film-coated tablet	50 mg, 850 mg	<p>For adult patients with type 2 diabetes mellitus:</p> <p>SITFORT is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin.</p> <p>SITFORT is indicated in combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.</p> <p>SITFORT is indicated as triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist.</p> <p>SITFORT is also indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycaemic control</p>	30/12/2024
New Registration	Generic Drug	Avotrene Emulgel	Diclofenac Diethylamine 1%	Gel	1 %	<p>For external use in the treatment of pain, inflammation and swelling associated with:</p> <ul style="list-style-type: none"> •injuries to tendons, ligaments, muscles and joints, e.g. sprains, contusions, muscle strains and back pain following sporting activity or an accident. •localised rheumatism, (tennis elbow), shoulder-hand, syndrome, bursitis, periarthropathies; 	30/12/2024

						<ul style="list-style-type: none">• and for the symptomatic treatment of osteoarthritis of the small and medium-sized superficial e.g., or joints, finger knee joints.	
New Registration	Generic Drug	Arnaben	Nelarabine 5mg/ml	Solution for injection	5mg/ml	<p>Nelarabine is indicated for the treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens .</p> <p>Due to the small patient populations in these disease settings, the information to support these indications is based on limited data.</p>	30/12/2024