

Saudi Drug Updates (SDU)

Oct 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	SFDA Approved Indication(s)	Approval Date
New indication	New Drug	ZEVTERA	Ceftobiprole medocaril sodium	Powder for concentrate for solution for infusion	500 mg	<p>New Age Group:</p> <p>Indicated for the treatment of the following infections in term neonates, infants, children and adolescents:</p> <ul style="list-style-type: none">Hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP)Community-acquired pneumonia (CAP)	25/09/2024
New indication	New Drug	Precedex	Dexmedetomidine	Solution for Injection/ Infusion	100 µg/ml	<p>New Age Group:</p> <p>Indicated for Sedation of non-intubated pediatric patients aged 1 month to less than 18 years prior to and during non-invasive procedures.</p>	25/09/2024
New registration	Biological Drug	Ebglyss	Lebrikizumab,	Solution for injection	250 mg/2 mL	Indicated for the treatment of adult and adolescent patients 12 years of age and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It can be used with or without topical corticosteroids.	9/9/2024
New registration	Biological Drug	Haemocompletan P	Human Fibrinogen	Powder for solution for injection / infusion	20mg/ml	Indicated for the treatment and prophylaxis of haemorrhagic diatheses in congenital hypo- or afibrinogenaemia with bleeding tendency	9/9/2024
New registration	Biological Drug	Erelzi	Etanercept	Solution for injection	25 mg	<p>Indicated for:</p> <p>Rheumatoid arthritis</p> <ul style="list-style-type: none">In combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate.As monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. <p>Etanercept, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.</p>	9/9/2024

						<p>Juvenile idiopathic arthritis</p> <ul style="list-style-type: none">- Treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.- Treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.- Treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy. <p>Etanercept has not been studied in children aged less than 2 years.</p> <p>Psoriatic arthritis</p> <ul style="list-style-type: none">- Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate.Etanercept has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease. <p>Axial spondyloarthritis</p> <p>Ankylosing spondylitis (AS)</p> <ul style="list-style-type: none">- Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy. <p>Non-radiographic axial spondyloarthritis</p> <ul style="list-style-type: none">- Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs). <p>Plaque psoriasis</p> <ul style="list-style-type: none">- Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy, including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). <p>Pediatric plaque psoriasis</p> <ul style="list-style-type: none">- Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	
New registration	Biological Drug	Erelzi	Etanercept	Solution for injection	50 mg	<p>Indicated for:</p> <p>Rheumatoid arthritis</p> <ul style="list-style-type: none">- In combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate.- As monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.- Treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.	9/9/2024

						<p>Etanercept, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.</p> <p>Juvenile idiopathic arthritis</p> <ul style="list-style-type: none">- Treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.- Treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.- Treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy. <p>Etanercept has not been studied in children aged less than 2 years.</p> <p>Psoriatic arthritis</p> <ul style="list-style-type: none">- Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate.Etanercept has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease. <p>Axial spondyloarthritis</p> <p>Ankylosing spondylitis (AS)</p> <ul style="list-style-type: none">- Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy. <p>Non-radiographic axial spondyloarthritis</p> <ul style="list-style-type: none">- Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs). <p>Plaque psoriasis</p> <ul style="list-style-type: none">- Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy, including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). <p>Pediatric plaque psoriasis</p> <p>Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.</p>	
New registration	New Drug	MONUROL	fosfomycin	Granules for oral solution	3.0 g	<p>Indicated for:</p> <ul style="list-style-type: none">- The treatment of acute, uncomplicated cystitis in women and female adolescents- Perioperative antibiotic prophylaxis for transrectal prostate biopsy in adult man <p>Consideration should be given to official guidance on the appropriate use of antibacterial agents</p>	02/09/2024
New registration	New Drug	Truqap	Capivasertib	Film-coated tablet	200 mg	<p>Indicated in combination with Fulvestrant for the treatment of adult patients with oestrogen receptor (ER)-positive, HER2-negative locally advanced or metastatic breast</p>	16/09/2024

						<p>cancer with or more PIK3CA/AKT1/PTEN-alterations following recurrence or progression on or after an endocrine-based regimen.</p> <p>In pre- or perimenopausal women, Capivasertib plus Fulvestrant should be combined with a luteinising hormone releasing hormone (LHRH) agonist.</p> <p>For men, administration of LHRH agonist according to current clinical practice standards should be considered.</p>	
New registration	New Drug	Truqap	Capivasertib	Film-coated tablet	160 mg	<p>Indicated in combination with Fulvestrant for the treatment of adult patients with oestrogen receptor (ER)-positive, HER2-negative locally advanced or metastatic breast cancer with or more PIK3CA/AKT1/PTEN-alterations following recurrence or progression on or after an endocrine-based regimen.</p> <p>In pre- or perimenopausal women, Capivasertib plus Fulvestrant should be combined with a luteinising hormone releasing hormone (LHRH) agonist.</p> <p>For men, administration of LHRH agonist according to current clinical practice standards should be considered.</p>	16/09/2024
New registration	New Drug	Litfulo	Ritlecitinib	Capsule, hard	50 mg	Indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.	16/09/2024
New registration	Generic Drug	Siromune	Sirolimus	Oral solution	1 mg /ml	Indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a renal transplant. It is recommended that Siromune be used initially in combination with ciclosporin microemulsion and corticosteroids for 2 to 3 months. Siromune may be continued as maintenance therapy with corticosteroids only if ciclosporin microemulsion can be progressively discontinued	02/09/2024
New registration	Generic Drug	Cytomag	Ganciclovir sodium	Powder for concentrate for solution for infusion	500 mg	<p>Indicated in adults and adolescents ≥ 12 years of age for the:</p> <ul style="list-style-type: none"> - Treatment of cytomegalovirus (CMV) disease in immunocompromised patients; - Prevention of CMV disease using pre-emptive therapy in patients with drug-induced immunosuppression (for example following organ transplantation or cancer chemotherapy). <p>Consideration should be given to official guidance on the appropriate use of antiviral agents</p>	02/09/2024
New registration	Generic Drug	Pinolanz	Olanzapine	Powder for injection	10 mg	Indicated for the treatment of acute agitation associated with schizophrenia and bipolar I mania.	02/09/2024
New registration	Generic Drug	Provecta	Brivaracetam	Film-coated tablet	50 mg	Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.	02/09/2024
New registration	Generic Drug	Provecta	Brivaracetam	Film-coated tablet	100 mg	Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.	02/09/2024
New registration	Generic Drug	Provecta	Brivaracetam	Film-coated tablet	10 mg	Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.	02/09/2024
New registration	Generic Drug	Provecta	Brivaracetam	Film-coated tablet	25 mg	Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.	02/09/2024
New registration	Generic Drug	Provecta	Brivaracetam	Film-coated tablet	75 mg	Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.	02/09/2024
New registration	Generic Drug	Sarolm	Olmesartan Medoxomil	Film-coated tablet	10 mg	<p>Indicated for:</p> <ul style="list-style-type: none"> - Treatment of essential hypertension in adults. 	02/09/2024

						<div>- Treatment of hypertension in children and adolescents from 6 to less than 18 years of age.</div>	
New registration	Generic Drug	Sarolm	Olmesartan Medoxomil	Film-coated tablet	20 mg	<div>Indicated for:</div> <div>- Treatment of essential hypertension in adults.</div> <div>- Treatment of hypertension in children and adolescents from 6 to less than 18 years of age.</div>	02/09/2024
New registration	Generic Drug	Sarolm	Olmesartan Medoxomil	Film-coated tablet	40 mg	<div>Indicated for:</div> <div>- Treatment of essential hypertension in adults.</div> <div>- Treatment of hypertension in children and adolescents from 6 to less than 18 years of age.</div>	02/09/2024
New registration	Generic Drug	Docetaxel BOS	Docetaxel	Concentrate for solution for infusion	10 mg /ml	<div>Indicated for:</div> <div>Breast Cancer</div> <div>- In combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with<ul style="list-style-type: none">Operable node-positive breast cancerOperable node-negative breast cancer</div> <div>- For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer.</div> <div>- In combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition.</div> <div>- As monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent.</div> <div>- In combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumours overexpress HER2 and who previously have not received chemotherapy for metastatic disease.</div> <div>- In combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.</div> <div>Non-small Cell Lung Cancer</div> <div>- Treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy.</div> <div>- In combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition.</div> <div>Prostate Cancer</div> <div>- In combination with prednisone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer.</div> <div>Gastric Adenocarcinoma</div> <div>- In combination with cisplatin and fluorouracil is indicated for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.</div> <div>Head and Neck Cancer</div>	02/09/2024

						<ul style="list-style-type: none"> - In combination with cisplatin and fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN) 	
New registration	Generic Drug	Avores	Moxifloxacin Hydrochloride	Film-coated tablet	400 mg	<p>Indicated for the treatment of the following bacterial infections in patients of 18 years and older caused by bacteria susceptible to Moxifloxacin. Moxifloxacin should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections or when these have failed:</p> <ul style="list-style-type: none"> - Acute bacterial sinusitis (adequately diagnosed) - Acute exacerbations of chronic bronchitis (adequately diagnosed) - Community acquired pneumonia, except severe cases - Mild to moderate pelvic inflammatory disease (i.e. infections of female upper genital tract, including salpingitis and endometritis), without an associated tubo-ovarian or pelvic abscess. <p>AVORES is not recommended for use as monotherapy of mild to moderate pelvic inflammatory disease but should be given in combination with another appropriate antibacterial agent (e.g. a cephalosporin) due to increasing Moxifloxacin resistance of Neisseria gonorrhoeae unless Moxifloxacin-resistant Neisseria gonorrhoeae can be excluded.</p> <p>AVORES may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous Moxifloxacin for the following indications:</p> <ul style="list-style-type: none"> - Community-acquired pneumonia - Complicated skin and skin structure infections <p>AVORES should not be used to initiate therapy for any type of skin and skin structure infection or in severe community-acquired pneumonia.</p> <p>Consideration should be given to official guidance on the appropriate use of antibacterial agents.</p>	02/09/2024
New registration	Generic Drug	Paraxone	PARACETAMOL, CHLORZOXAZONE	Capsules	300mg, 250 mg	Indicated as an adjunct to rest, physical therapy and other measures for the relief of discomfort associated with acute musculoskeletal conditions. Such conditions may include skeletal muscle spasm and pain associated with sprains, strains and other traumatic muscle injuries; myalgias; arthritides; low back pain; tension headache; torticollis; fibrositis; spondylitis; and cervical root and disc syndromes	02/09/2024
New registration	Generic Drug	Emedius	Palonosetron Hydrochloride	Solution for injection	0.05 mg/ml	Indicated in adults for the prevention of nausea and vomiting associated with cancer chemotherapy in adults, adolescents and children over one month of age.	02/09/2024
New registration	Generic Drug	MEGAMOX	AMOXICILLIN CLAVULANIC ACID	Film-Coated Tablet	500 mg, 125 mg	<p>Indicated for the treatment of the following infections in adults and children:</p> <ul style="list-style-type: none"> - Acute bacterial sinusitis (adequately diagnosed) - Acute otitis media - Acute exacerbations of chronic bronchitis (adequately diagnosed) - Community acquired pneumonia - Cystitis - Pyelonephritis - Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis - Bone and joint infections, in particular osteomyelitis. 	02/09/2024
New registration	Generic Drug	Vastovas	Amlodipine, Atorvastatin	Film-Coated Tablet	10mg, 20mg	Indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate.	02/09/2024

New registration	Generic Drug	Vastovas	Amlodipine, Atorvastatin	Film-Coated Tablet	10mg, 10mg	Indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate.	02/09/2024
New registration	Generic Drug	Vastovas	Amlodipine, Atorvastatin	Film-Coated Tablet	5 mg, 20mg	Indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate.	02/09/2024
New registration	Generic Drug	Vastovas	Amlodipine, Atorvastatin	Film-Coated Tablet	5 mg, 10mg	Indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate.	02/09/2024
New registration	Generic Drug	Cigapix	Varenicline Tartrate	Film-coated tablet	1 mg	Indicated for smoking cessation in adults.	02/09/2024
New registration	Generic Drug	Cigapix	Varenicline Tartrate	Film-coated tablet	0.5 mg	Indicated for smoking cessation in adults.	02/09/2024
New registration	Generic Drug	Redex	Tadalafil	Film-coated tablet	10 mg	Indicated for treatment of erectile dysfunction in adult males. In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required. 5 mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. Tadalafil is not indicated for use by women.	02/09/2024
New registration	Generic Drug	Taycan	Vancomycin	Powder for concentrate for solution for infusion	1000 mg	Indicated in all age groups for the treatment of the following infections: <ul style="list-style-type: none">- Complicated skin and soft tissue infections (cssti)- Bone and joint infections- Community acquired pneumonia (CAP)- Hospital acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)- Infective endocarditis Vancomycin is also indicated in all age groups for the perioperative antibacterial prophylaxis in patients that are at high risk of developing bacterial endocarditis when undergoing major surgical procedures	02/09/2024
New registration	Generic Drug	Taycan	Vancomycin	Powder for concentrate for solution for infusion	500mg	Indicated in all age groups for the treatment of the following infections: <ul style="list-style-type: none">- Complicated skin and soft tissue infections (cssti)- Bone and joint infections- Community acquired pneumonia (CAP)- Hospital acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP)- Infective endocarditis Vancomycin is also indicated in all age groups for the perioperative antibacterial prophylaxis in patients that are at high risk of developing bacterial endocarditis when undergoing major surgical procedures	02/09/2024
New registration		VECANZOL	Voriconazole	Powder for solution for infusion	200 mg	Indicated in adults and children aged 2 years and above as follows: <ul style="list-style-type: none">- Treatment of invasive aspergillosis.- Treatment of candidaemia in non-neutropenic patients.- Treatment of fluconazole-resistant serious invasive Candida infections (including C. krusei).- Treatment of serious fungal infections caused by Scedosporium spp. and Fusarium spp. Voriconazole should be administered primarily to patients with progressive, possibly life-threatening infections.	02/09/2024

	Generic Drug					Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients	
New registration	Generic Drug	MEGAMOX	AMOXICILLIN, CLAVULANIC ACID	Tablet	875 mg, 125 mg	<p>Indicated for the treatment of the following infections in adults and children:</p> <ul style="list-style-type: none">- Acute bacterial sinusitis (adequately diagnosed)- Acute otitis media- Acute exacerbations of chronic bronchitis (adequately diagnosed)- Community acquired pneumonia- Cystitis- Pyelonephritis- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.- Bone and joint infections, in particular osteomyelitis. <p>Consideration should be given to official guidance on the appropriate use of antibacterial agents.</p>	9/9/2024
New registration	Generic Drug	Conestal	Prucalopride	Film-coated tablet	2 mg	Indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.	9/9/2024
New registration	Generic Drug	Conestal	Prucalopride	Film-coated tablet	1 mg	Indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.	9/9/2024
New registration	Generic Drug	Abiraterone Acetate Neapolis	Abiraterone acetate	Tablet	250 mg	<p>Indicated with prednisone or prednisolone for:</p> <ul style="list-style-type: none">- The treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).- The treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.- The treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.	9/9/2024
New registration	Generic Drug	Gliptus	Vildagliptin	Tablet	50 mg	<p>Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus:</p> <ul style="list-style-type: none">- As monotherapy in patients in whom metformin is inappropriate due to contraindications or intolerance.- In combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycemic control	9/9/2024
New registration	Generic Drug	Marvi	Varenicline Tartrate	Film-coated tablet	1 mg	Indicated for smoking cessation in adults.	9/9/2024
New registration	Generic Drug	Marvi	Varenicline Tartrate	Film-coated tablet	0.5 mg	Indicated for smoking cessation in adults.	9/9/2024
New registration	Generic Drug	ZINOPRIL	LISINOPRIL	Tablet	20 mg	<p>Indicated for:</p> <ul style="list-style-type: none">- Treatment of hypertension.- Treatment of symptomatic heart failure.- Short-term (6 weeks) treatment of hemodynamically stable patients within 24 hours of an acute myocardial infarction.- Treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy	16/09/2024
New registration	Generic Drug	ZINOPRIL	LISINOPRIL	Tablet	10 mg	<p>Indicated for:</p> <ul style="list-style-type: none">- Treatment of hypertension.- Treatment of symptomatic heart failure.	16/09/2024

						<ul style="list-style-type: none">- Short-term (6 weeks) treatment of hemodynamically stable patients within 24 hours of an acute myocardial infarction.- Treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy	
New registration	Generic Drug	ZINOPRIL	LISINOPRIL	Tablet	5 mg	Indicated for: <ul style="list-style-type: none">- Treatment of hypertension.- Treatment of symptomatic heart failure.- Short-term (6 weeks) treatment of hemodynamically stable patients within 24 hours of an acute myocardial infarction.- Treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy	16/09/2024
New registration	Generic Drug	Ondavell	Ondansetron Hydrochloride dehydrate	Solution for injection	2 mg/ml	Adults <ul style="list-style-type: none">- Indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondansetron is indicated for the post-operative nausea and vomiting (PONV). Pediatric Population <ul style="list-style-type: none">- Indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥ 6 months, and for the prevention and treatment of PONV in children aged ≥ 1 month.	16/09/2024
New registration	Generic Drug	Bilvardi	Bivalirudin	Powder for concentrate for solution for injection/infusion	250 mg	Indicated for: <ul style="list-style-type: none">- Anticoagulation in adult patients undergoing percutaneous coronary intervention (PCI), including patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI.- The treatment of adult patients with unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) planned for urgent or early intervention. Bivalirudin should be administered with acetylsalicylic acid and clopidogrel.	16/09/2024
New registration	Generic Drug	Atomibe	Atorvastatin Ezetimibe	Film-coated tablet	10mg, 10mg	Indicated for the following: <ul style="list-style-type: none">- To reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not.- As adjunctive therapy to diet for use in adults with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia where use of a combination product is appropriate.<ul style="list-style-type: none">• Patients not appropriately controlled with a statin alone• Patients already treated with a statin and ezetimibe- As adjunctive therapy to diet for use in adults with Homozygous Familial Hypercholesterolemia (HoFH). Patients may also receive adjunctive treatments (e.g. low-density lipoprotein [LDL] apheresis).	16/09/2024
New registration	Generic Drug	Atomibe	Atorvastatin Ezetimibe	Film-coated tablet	20mg, 10mg	Indicated for the following: <ul style="list-style-type: none">- To reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not.- As adjunctive therapy to diet for use in adults with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia where use of a combination product is appropriate.<ul style="list-style-type: none">• Patients not appropriately controlled with a statin alone• Patients already treated with a statin and ezetimibe	16/09/2024

						<div><div></div><div>- As adjunctive therapy to diet for use in adults with Homozygous Familial Hypercholesterolemia (HoFH). Patients may also receive adjunctive treatments (e.g. low-density lipoprotein [LDL] apheresis).</div></div>	
New registration	Generic Drug	Atomibe	Atorvastatin Ezetimibe	Film-coated tablet	40mg, 10mg	<div>Indicated for the following:</div> <div><div></div><div>- To reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not.</div><div>- As adjunctive therapy to diet for use in adults with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia where use of a combination product is appropriate.<div><div></div><div>Patients not appropriately controlled with a statin alone</div><div>Patients already treated with a statin and ezetimibe</div></div></div><div>- As adjunctive therapy to diet for use in adults with Homozygous Familial Hypercholesterolemia (HoFH). Patients may also receive adjunctive treatments (e.g. low-density lipoprotein [LDL] apheresis).</div></div>	16/09/2024
New registration	Generic Drug	Pemetrexed	Pemetrexed Disodium	Powder for concentrate for solution for infusion	500 mg	<div>Indicated for:</div> <div>Malignant pleural mesothelioma</div> <div><div></div><div>- In combination with cisplatin for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.</div></div> <div>Non-small cell lung cancer</div> <div><div></div><div>- 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.</div><div>- 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.</div><div>- 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.</div></div>	16/09/2024
New registration	Generic Drug	Pemetrexed	Pemetrexed Disodium	Powder for concentrate for solution for infusion	100 mg	<div>Indicated for:</div> <div>Malignant pleural mesothelioma</div> <div><div></div><div>- In combination with cisplatin for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.</div></div> <div>Non-small cell lung cancer</div> <div><div></div><div>- 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.</div><div>- 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.</div><div>- 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.</div></div>	16/09/2024