

# 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	Acura	Bevacizumab	Concentrate for solution for infusion	400 mg/16ml (25mg/ml)	<p>Indicated for:</p> <p>Metastatic Colorectal Cancer (mCRC)</p> <p>First-or second-line treatment in combination with intravenous fluorouracil-based chemotherapy for patients with metastatic colorectal cancer (mCRC)</p> <p>Second-line treatment in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for patients with mCRC who have progressed on a first-line bevacizumab product-containing regimen</p> <p>Limitations of Use: not indicated for adjuvant treatment of colon cancer.</p> <p>First-Line Non-Squamous Non–Small Cell Lung Cancer (NSCLC)</p> <p>First-line treatment in combination with carboplatin and paclitaxel for patients with unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer (NSCLC).</p>	04/11/2024

						<p>Recurrent Glioblastoma (GBM)</p> <p>Treatment of recurrent glioblastoma (GBM) in adults.</p> <p>Metastatic Renal Cell Carcinoma (mRCC)</p> <p>Treatment of metastatic renal cell carcinoma (mRCC) in combination with interferon alfa.</p> <p>Persistent, Recurrent, or Metastatic Cervical Cancer</p> <p>Treatment of patients with persistent, recurrent, or metastatic cervical cancer in combination with paclitaxel and cisplatin or paclitaxel and topotecan</p> <p>Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer</p> <p>Treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection in combination with carboplatin and paclitaxel, followed by Bevacizumab as a single agent.</p> <p>In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.</p> <p>Treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Bevacizumab as a single agent</p> <p>Hepatocellular Carcinoma (HCC)</p> <p>in combination with atezolizumab for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.</p>	
New Registration	Biological Drug	Acura	Bevacizumab	Concentrate for solution for infusion	400 mg/4ml (25mg/ml)	<p>Indicated for:</p> <p>Metastatic Colorectal Cancer (mCRC)</p> <p>First-or second-line treatment in combination with intravenous fluorouracil-based chemotherapy for patients with metastatic colorectal cancer (mCRC)</p>	04/11/2024

					<p>Second-line treatment in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for patients with mCRC who have progressed on a first-line bevacizumab product-containing regimen</p> <p>Limitations of Use: not indicated for adjuvant treatment of colon cancer.</p> <p>First-Line Non-Squamous Non–Small Cell Lung Cancer (NSCLC)</p> <p>First-line treatment in combination with carboplatin and paclitaxel for patients with unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer (NSCLC).</p> <p>Recurrent Glioblastoma (GBM)</p> <p>Treatment of recurrent glioblastoma (GBM) in adults.</p> <p>Metastatic Renal Cell Carcinoma (mRCC)</p> <p>Treatment of metastatic renal cell carcinoma (mRCC) in combination with interferon alfa.</p> <p>Persistent, Recurrent, or Metastatic Cervical Cancer</p> <p>Treatment of patients with persistent, recurrent, or metastatic cervical cancer in combination with paclitaxel and cisplatin or paclitaxel and topotecan</p> <p>Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer</p> <p>Treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection in combination with carboplatin and paclitaxel, followed by Bevacizumab as a single agent.</p> <p>In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.</p> <p>Treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Bevacizumab as a single agent</p>	
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						Hepatocellular Carcinoma (HCC)  in combination with atezolizumab for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.	
New Registration	Biological Drug	Adacel	Pertussis (acellular) 2.5 ug, Diphtheria 2 LfU, Tetanus 5 LfU	Suspension for injection	2.5 ug, 2 LfU, 5 LfU	Indicated for:  Active immunization against tetanus, diphtheria and pertussis in persons 11 to 64 years of age as a booster following primary immunization.  Passive immunization against pertussis in early infancy following maternal immunization during pregnancy.	04/11/2024
New Registration	Biological Drug	Imjudo	Tremelimumab	Intravenous Infusion	300 mg/15ml	Indicated in combination with durvalumab for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC) who have not received prior treatment with a PD-1/PD-L1 inhibitor. This indication is approved with commitment to provide verification and deion of clinical benefit in a confirmatory trial.	11/25/2024
New Registration	Biological Drug	Imjudo	Tremelimumab	Intravenous Infusion	25 mg/1.25ml	Indicated in combination with durvalumab for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC) who have not received prior treatment with a PD-1/PD-L1 inhibitor. This indication is approved with commitment to provide verification and deion of clinical benefit in a confirmatory trial.	11/25/2024
New Registration	Biological Drug	OMVOH	Mirikizumab	Solution for injection	100 mg/ml	Indicated for the treatment of moderately to severely active ulcerative colitis in adults.	11/25/2024
New Registration	Biological Drug	OMVOH	Mirikizumab	Solution for injection	300 mg/15ml	Indicated for the treatment of moderately to severely active ulcerative colitis in adults.	11/25/2024
New Registration	Biological Drug	Boostrix Polio	Diphtheria 2 IU, tetanus 20 IU, acellular pertussis 18.5 µg (adsorbed) and inactivated poliomyelitis 80 D-antigen unit	Suspension for injection	Diphtheria 2 IU, tetanus 20 IU, acellular pertussis 18.5 µg (adsorbed) and inactivated poliomyeliti	Indicated for:  - Booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis of individuals from the age of three years.  Passive protection against pertussis in early infancy following maternal immunisation during pregnancy.	11/25/2024

					s 80 D- antigen unit		
New Registration	Biological Drug	Ultomiris	Ravulizumab	Concentrate for solution for infusion	1100 mg/11 mL	Indicated for:  - The treatment of adult and pediatric patients with a body weight of 10 kg or above with paroxysmal nocturnal hemoglobinuria (PNH). - The treatment of adults and pediatric patients with a body weight of 10 kg or above with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).	11/25/2024
New Registration	Biological Drug	Ultomiris	Ravulizumab	Concentrate for solution for infusion	300 mg/3 mL	Indicated for :  - The treatment of adult and pediatric patients with a body weight of 10 kg or above with paroxysmal nocturnal hemoglobinuria (PNH) . - The treatment of adults and pediatric patients with a body weight of 10 kg or above with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA) . - The treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive .  The treatment of adult patients with anti-aquaporin 4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD).	11/25/2024
New Registration	New Drug	XADAGO	Safinamide	Film-coated tablet	100 mg	Indicated for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.	04/11/2024
New Registration	New Drug	XADAGO	Safinamide	Film-coated tablet	50 mg	Indicated for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.	04/11/2024
New Registration	New Drug	Voydeya	Danicopan	Film-coated tablet	100mg	Indicated as an add-on to ravulizumab or eculizumab for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have residual haemolytic anaemia.	11/11/2024



New Registration	New Drug	Voydeya	Danicopan	Film-coated tablet	50 mg, 100mg	Indicated as an add-on to ravulizumab or eculizumab for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have residual haemolytic anaemia.	11/11/2024
New Registration	New Drug	OLIMEL N12E	Glucose with calcium solution, Amino acid with electrolytes solution and Lipid emulsion. Concentration: 27.5 g Glucose with calcium solution, 14.2 g Amino acid with electrolytes solution and 17.5 g Lipid emulsion/100ml.	Emulsion for infusion	27.5 g Glucose with calcium solution, 14.2 g Amino acid with electrolytes solution and 17.5 g Lipid emulsion/100ml	Indicated for parenteral nutrition for adults and children greater than 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.	11/11/2024
New Registration	New Drug	Telfast - D	fexofenadine hydrochloride, pseudoephedrine hydrochloride	Film-coated tablet	60 mg, 120 mg	Indicated for the relief of the symptoms of allergic rhinitis with nasal congestion when both the antiallergic properties of fexofenadine hydrochloride and the decongestant activity of pseudoephedrine hydrochloride are required.	11/11/2024
New Registration	New Drug	Pemazyre	Pemigatinib	Tablet	4.5mg	Indicated for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least prior line of systemic therapy.  This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and deion of clinical benefit in a confirmatory trial(s).	11/25/2024
New Registration	Generic Drug	Hydroxyurea medac	Hydroxycarbamide	Capsules	500mg	Treatment of chronic myeloid leukaemia.  Treatment of cancer of the cervix in conjunction with radiotherapy.	04/11/2024
New Registration	Generic Drug	Olmexa	Olmesartan Medoxomil 20mg, Amlodipine Besylate 10mg	Film-coated tablet	20mg, 10mg	Treatment of essential hypertension. In adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy.	04/11/2024

New Registration	Generic Drug	Olmexa	Olmesartan Medoxomil 40mg, Amlodipine Besylate 5mg	Film-coated tablet	40mg, 5mg	Treatment of essential hypertension. In adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy.	04/11/2024
New Registration	Generic Drug	Olmexa	Olmesartan Medoxomil 40mg, Amlodipine Besylate 10mg	Film-coated tablet	40mg, 10mg	Treatment of essential hypertension. In adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy.	04/11/2024
New Registration	Generic Drug	Olmexa	Olmesartan Medoxomil 20mg, Amlodipine Besylate 5mg	Film-coated tablet	20mg, 5mg	Treatment of essential hypertension. In adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy.	04/11/2024
New Registration	Generic Drug	Enzular	Enzalutamide	Capsule	40mg	Indicated for:  <ul style="list-style-type: none"> <li>- The treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy.</li> <li>- The treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC)</li> <li>- The treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.</li> <li>- The treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.</li> </ul>	04/11/2024
New Registration	Generic Drug	Experta	Apixaban	Film-coated tablet	5mg	Indicated for:  Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II).  Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	04/11/2024
New Registration	Generic Drug	Experta	Apixaban	Film-coated tablet	2.5mg	Indicated for:  Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥ 75	04/11/2024

						years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II).  Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.	
New Registration	Generic Drug	Deslor	Desloratadine	Syrup	0.5mg/ml	Indicated for adults, adolescents and children over the age of 1 year for the relief of symptoms associated with:  -allergic rhinitis  - urticaria	04/11/2024
New Registration	Generic Drug	Olmexa Plus	Olmesartan Medoxomil 40mg, Amlodipine Besylate 10mg, Hydrochlorothiazide 25mg	Film-coated tablet	40mg, 10mg, 25mg	Indicated for the treatment of essential hypertension.  Add-on therapy  In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.  Substitution therapy  In adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide, taken as a dual-component (Olmesartan medoxomil and amlodipine or Olmesartan medoxomil and hydrochlorothiazide) and a single-component formulation (hydrochlorothiazide or amlodipine)	04/11/2024
New Registration	Generic Drug	Olmexa Plus	Olmesartan Medoxomil 40mg, Amlodipine Besylate 5mg, Hydrochlorothiazide 25mg	Film-coated tablet	40mg, 5mg, 25mg	Indicated for the treatment of essential hypertension.  Add-on therapy  In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.  Substitution therapy  In adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide, taken as a dual-component (Olmesartan medoxomil and amlodipine or Olmesartan medoxomil and	04/11/2024



						hydrochlorothiazide) and a single-component formulation (hydrochlorothiazide or amlodipine)	
New Registration	Generic Drug	Olmexa Plus	Olmesartan Medoxomil 20mg, Amlodipine Besylate 5mg, Hydrochlorothiazide 12.5mg	Film-coated tablet	20mg, 5mg, 12.5mg	Indicated for the treatment of essential hypertension.  Add-on therapy  In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.  Substitution therapy  In adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide, taken as a dual-component (Olmesartan medoxomil and amlodipine or Olmesartan medoxomil and hydrochlorothiazide) and a single-component formulation (hydrochlorothiazide or amlodipine)	04/11/2024
New Registration	Generic Drug	Olmexa Plus	Olmesartan Medoxomil 40mg, Amlodipine Besylate 10mg, Hydrochlorothiazide 12.5mg	Film-coated tablet	40mg, 10mg, 12.5mg	Indicated for the treatment of essential hypertension.  Add-on therapy  In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.  Substitution therapy  In adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide, taken as a dual-component (Olmesartan medoxomil and amlodipine or Olmesartan medoxomil and hydrochlorothiazide) and a single-component formulation (hydrochlorothiazide or amlodipine)	04/11/2024
New Registration	Generic Drug	Olmexa Plus	Olmesartan Medoxomil 40mg, Amlodipine Besylate 5mg, Hydrochlorothiazide 12.5mg	Film-coated tablet	40mg, 5mg, 12.5mg	Indicated for the treatment of essential hypertension.  Add-on therapy  In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.	04/11/2024

						<p>Substitution therapy</p> <p>In adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide, taken as a dual-component (Olmesartan medoxomil and amlodipine or Olmesartan medoxomil and hydrochlorothiazide) and a single-component formulation (hydrochlorothiazide or amlodipine)</p>	
New Registration	Generic Drug	Pentix	Gabapentin	Capsule	300mg	<p>Indicated for:</p> <p>Epilepsy</p> <ul style="list-style-type: none"><li>- Adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.</li><li>- Monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.</li></ul> <p>Treatment of peripheral neuropathic pain</p> <ul style="list-style-type: none"><li>- Treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.</li></ul>	04/11/2024
New Registration	Generic Drug	Pentix	Gabapentin	Capsule	400mg	<p>Indicated for:</p> <p>Epilepsy</p> <ul style="list-style-type: none"><li>- Adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.</li><li>- Monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.</li></ul> <p>Treatment of peripheral neuropathic pain</p> <p>Treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.</p>	04/11/2024
New Registration	Generic Drug	Speranta	Neratinib Maleate	Film-coated tablet	40mg	<p>Indicated for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-</p>	04/11/2024

						overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.	
New Registration	Generic Drug	CRONOXAM PLUS	Sitagliptin 50mg, Metformin 850mg	Tablet	50mg, 850mg	<p>Indicated for adult patients with type 2 diabetes mellitus:</p> <p>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>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>As triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPAR<math>\gamma</math>) 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 PPAR<math>\gamma</math> agonist.</p> <p>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>	04/11/2024
New Registration	Generic Drug	CRONOXAM PLUS	Sitagliptin 50mg, Metformin 1000mg	Tablet	50mg, 1000mg	<p>Indicated for adult patients with type 2 diabetes mellitus:</p> <p>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>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>As triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPAR<math>\gamma</math>) 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 PPAR<math>\gamma</math> agonist.</p>	04/11/2024

							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	VIRLAIO	Tenofovir Fumarate	Disoproxil	Film-coated tablet	245mg	<p>Indicated for:</p> <p>HIV-1 infection</p> <p>In combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults.</p> <p>In adults, the demonstration of the benefit of Tenofovir/Disoproxil Fumarate in HIV-1 infection is based on results of one study in treatment-naïve patients, including patients with a high viral load (&gt; 100,000 copies/ml) and studies in which Tenofovir/Disoproxil Fumarate was added to stable background therapy (mainly tritherapy) in antiretroviral pre-treated patients experiencing early virological failure (&lt; 10,000 copies/ml, with the majority of patients having &lt; 5,000 copies/ml.(</p> <p>Treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents, aged 12 to &lt; 18 years.</p> <p>The choice of Tenofovir/Disoproxil Fumarate to treat antiretroviral-experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients.</p> <p>Hepatitis B infection</p> <p>Treatment of chronic hepatitis B in adults with:</p> <ul style="list-style-type: none"><li>- Compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.</li><li>- Evidence of lamivudine-resistant hepatitis B virus.</li><li>- Decompensated liver disease.</li><li>- Treatment of chronic hepatitis B in adolescents 12 to &lt; 18 years of age with:</li><li>- Compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated</li></ul>	04/11/2024

						serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in paediatric patients.	
New Registration	Generic Drug	BAGENTA	Gentamicin	Solution for injection	40 mg/ml	<p>Indicated to treat severe infections caused by bacteria susceptible to Gentamicin such as, but not limited to:</p> <ul style="list-style-type: none"><li>- Urinary tract infections</li><li>- Respiratory tract infections</li><li>- Intra-abdominal infections</li><li>- CNS infections</li><li>- Severe neonatal infections</li></ul> <p>It is usually active against most strains of the following organisms: Escherichia coli, Klebsiella spp.,</p> <p>Proteus spp. (indole positive and indole negative), Pseudomonas aeruginosa, Staphylococci, Enterobacter spp., Citrobacter spp. and Providencia spp. Consideration should be given to official local guidance on the appropriate use of antibacterial agents.</p>	11/11/2024
New Registration	Generic Drug	Dexorolin	Cabergoline	Tablet	0.5mg	<p>Indicated for:</p> <p>Inhibition/suppression of physiological lactation</p> <p>Cabergoline is indicated for the inhibition of physiological lactation soon after delivery and for suppression of already established lactation:</p> <p>1 .After parturition, when the mother elects not to breast feed the infant or when breast feeding is contraindicated due to medical reasons related to the mother or the new-born.</p> <p>2 .After stillbirth or abortion.</p> <p>Cabergoline prevents/suppresses physiological lactation by inhibiting prolactin secretion.</p> <p>In controlled clinical trials, cabergoline given as a single 1 mg administration during the first day post-partum, was effective in inhibiting milk secretion, as well as breast engorgement and pain in 70 - 90% of the women. Less than 5% of women experienced rebound breast symptomatology during the third post-partum week (which was usually mild in severity).</p>	11/11/2024



						<p>Suppression of milk secretion and relief of breast engorgement and pain are obtained in approximately 85% of nursing women treated with a total dose of 1 mg cabergoline given in four divided doses over two days. Rebound breast symptomatology after day 10 is uncommon (approximately 2% of cases).</p> <p>Treatment of hyperprolactinaemic disorders</p> <p>Cabergoline is indicated for the treatment of dysfunctions associated with hyperprolactinaemia, including amenorrhoea, oligomenorrhoea, anovulation and galactorrhoea. Cabergoline is indicated in patients with prolactin-secreting pituitary adenomas (micro- and macroprolactinomas), idiopathic hyperprolactinaemia, or empty sella syndrome with associated hyperprolactinaemia, which represent the basic underlying pathologies contributing to the above clinical manifestations.</p> <p>On chronic therapy, cabergoline at doses ranging between 1 and 2 mg per week, was effective in normalising serum prolactin levels in approximately 84% of hyperprolactinaemic patients. Regular cycles were resumed in 83% of previously amenorrhoeic women. Restoration of ovulation was documented in 89% of women with progesterone levels monitored during the luteal phase. Galactorrhoea disappeared in 90% of cases showing this symptom before therapy. Reduction in tumour size was obtained in 50 - 90% of female and male patients with micro- or macroprolactinoma.</p>	
New Registration	Generic Drug	Warfarin ZYD	Warfarin Sodium	Tablet	10mg	<p>Indicated for:</p> <ul style="list-style-type: none"> <li>- Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE).</li> <li>- Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement</li> <li>- Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.</li> </ul>	11/11/2024
New Registration	Generic Drug	Warfarin ZYD	Warfarin Sodium	Tablet	5mg	<p>Indicated for:</p> <ul style="list-style-type: none"> <li>- Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE).</li> </ul>	11/11/2024

						<ul style="list-style-type: none"><li>- Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement</li><li>- Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.</li></ul>	
New Registration	Generic Drug	Warfarin ZYD	Warfarin Sodium	Tablet	3mg	Indicated for: <ul style="list-style-type: none"><li>- Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE).</li><li>- Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement</li><li>- Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.</li></ul>	11/11/2024
New Registration	Generic Drug	Warfarin ZYD	Warfarin Sodium	Tablet	2.5mg	Indicated for: <ul style="list-style-type: none"><li>- Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE).</li><li>- Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement</li><li>- Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.</li></ul>	11/11/2024
New Registration	Generic Drug	Warfarin ZYD	Warfarin Sodium	Tablet	2 mg	Indicated for: <ul style="list-style-type: none"><li>- Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE).</li><li>- Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement</li><li>- Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.</li></ul>	11/11/2024
New Registration	Generic Drug	Warfarin ZYD	Warfarin Sodium	Tablet	1 mg	Indicated for:	11/11/2024

						<ul style="list-style-type: none"> <li>- Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE).</li> <li>- Prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement</li> <li>- Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.</li> </ul>	
New Registration	Generic Drug	Diclopid	Diclofenac potassium	Film-coated tablet	50mg	<p>Indicated for Short-term treatment of all grades of pain and inflammation in the following acute conditions:</p> <ul style="list-style-type: none"> <li>- Post-traumatic pain, inflammation and swelling, e.g. due to sprains.</li> <li>- acute musculo-skeletal disorders such as periarthritits (for example frozen shoulder), tendonitis, tenosynovitis, bursitis</li> <li>- Post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery.</li> <li>- Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis and associated menorrhagia.</li> <li>- Migraine attacks.</li> <li>- Acute gout</li> <li>- Painful syndromes of the vertebral column.</li> <li>- Non-articular rheumatism.</li> <li>- As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.</li> </ul>	11/11/2024
New Registration	Generic Drug	Amilian	Amisulpride	Tablet	100mg	<p>Indicated for the treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.</p> <p>Amisulpride also regulates secondary negative symptoms in productive state, as well as affective disorders such as depressive mood.</p>	11/11/2024

New Registration	Generic Drug	Amilian	Amisulpride	Tablet	200mg	<p>Indicated for the treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.</p> <p>Amisulpride also regulates secondary negative symptoms in productive state, as well as affective disorders such as depressive mood.</p>	11/11/2024
New Registration	Generic Drug	Amilian	Amisulpride	Tablet	400mg	<p>Indicated for the treatment of acute and chronic schizophrenic disorders, in which positive symptoms (such as delusions, hallucinations, thought disorders) and/or negative symptoms (such as blunted affect, emotional and social withdrawal) are prominent, including patients characterised by predominant negative symptoms.</p> <p>Amisulpride also regulates secondary negative symptoms in productive state, as well as affective disorders such as depressive mood.</p>	11/11/2024
New Registration	Generic Drug	Apixaban JPI	Apixaban	Film-coated tablet	2.5mg	<p>Indicated for:</p> <ul style="list-style-type: none"> <li>- Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.</li> <li>- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II).</li> <li>- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.</li> </ul>	11/11/2024
New Registration	Generic Drug	Apixaban JPI	Apixaban	Film-coated tablet	5mg	<p>Indicated for:</p> <ul style="list-style-type: none"> <li>- Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.</li> <li>- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAf), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA);</li> </ul>	11/11/2024

						<p>age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II).</p> <ul style="list-style-type: none"> <li>- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.</li> </ul>	
New Registration	Generic Drug	DuoZet	Ezetimibe 10mg, Simvastatin 20mg	Tablet	10mg, 20mg	Indicated 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.	11/11/2024
New Registration	Generic Drug	DuoZet	Ezetimibe 10mg, Simvastatin 40mg	Tablet	10mg, 40mg	Indicated 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.	11/11/2024
New Registration	Generic Drug	Capitan	Isotretinoin	Capsule	10mg	Indicated for severe forms of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy.	11/11/2024
New Registration	Generic Drug	Capitan	Isotretinoin	Capsule	20mg	Indicated for severe forms of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy.	11/11/2024
New Registration	Generic Drug	Lorinex	Desloratadine	Film-coated tablet	5mg	<p>Indicated in adults and adolescents aged 12 years and older for the relief of symptoms associated with:</p> <ul style="list-style-type: none"> <li>• Allergic rhinitis</li> <li>• Urticaria</li> </ul>	11/11/2024
New Registration	Generic Drug	Funzol	Fluconazole	Capsule	150mg	<p>Indicated in adults for the treatment of:</p> <ul style="list-style-type: none"> <li>- Cryptococcal meningitis.</li> <li>- Coccidioidomycosis.</li> <li>- Invasive candidiasis.</li> <li>- Mucosal candidiasis including oropharyngeal, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis.</li> <li>- Chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient.</li> <li>- Vaginal candidiasis, acute or recurrent; when local therapy is not appropriate.</li> <li>- Candidal balanitis when local therapy is not appropriate.</li> </ul>	11/11/2024



						<ul style="list-style-type: none"> <li>- Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infections when systemic therapy is indicated.</li> <li>- Tinea unguinum (onychomycosis) when other agents are not considered appropriate.</li> </ul> <p>Indicated in adults for the prophylaxis of:</p> <ul style="list-style-type: none"> <li>- Relapse of cryptococcal meningitis in patients with high risk of recurrence.</li> <li>- Relapse of oropharyngeal or oesophageal candidiasis in patients infected with HIV who are at high risk of experiencing relapse.</li> <li>- To reduce the incidence of recurrent vaginal candidiasis (4 or more episodes a year).</li> <li>- Prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematological malignancies receiving chemotherapy or patients receiving Hematopoietic Stem Cell Transplantation).</li> </ul> <p>Fluconazole is indicated in term newborn infants, infants, toddlers, children, and adolescents aged from 0 to 17 years old:</p> <p>Fluconazole is used for the treatment of mucosal candidiasis (oropharyngeal, oesophageal), invasive candidiasis, cryptococcal meningitis and the prophylaxis of candidal infections in immunocompromised patients. FUNZOL can be used as maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of reoccurrence.</p> <p>Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly.</p> <p>Consideration should be given to official guidance on the appropriate use of antifungals.</p>	
New Registration	Generic Drug	Dapsone Tillomed	Dapsone	Tablet	50 mg	<p>The treatment of the following infections:</p> <ul style="list-style-type: none"> <li>- As part of a multidrug regimen in the treatment of all forms of leprosy.</li> <li>- Treatment of blistering dermatoses such as dermatitis herpetiformis.</li> </ul>	11/11/2024

						<ul style="list-style-type: none"> <li>- Prophylaxis of <i>Pneumocystis jirovecii</i> pneumonia in immunodeficient subjects, especially AIDS patients.</li> </ul> <p>Consideration should be given to official guidance on the appropriate use of antibacterial agents.</p>	
New Registration	Generic Drug	Disclero	Dimethyl Fumarate	Gastro-resistant capsule, hard	120 mg	Indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).	11/11/2024
New Registration	Generic Drug	Racad	Racecadotril	Granules for oral suspension	10mg	Indicated for complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months) and in children together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition, and when causal treatment is not possible.	11/11/2024
New Registration	Generic Drug	Racad	Racecadotril	Granules for oral suspension	30mg	Indicated for complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months) and in children together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition, and when causal treatment is not possible.	11/11/2024
New Registration	Generic Drug	Cefuroxime-Kotra	Cefuroxime Sodium	Powder for injection	750mg	<p>Cefuroxime is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms.</p> <p>It is indicated for the treatment of infections before the infecting organism has been identified or when caused by sensitive bacteria. Susceptibility to Cefuroxime will vary with geography and time and local susceptibility data should be consulted where available (see Pharmacodynamics).</p> <p>Indications include:</p> <ul style="list-style-type: none"> <li>- Respiratory tract infections for example, acute exacerbation of chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections.</li> <li>- Ear, nose and throat infections for example, sinusitis, tonsillitis, pharyngitis and otitis media.</li> <li>- Urinary tract infections for example, acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria.</li> <li>- Soft-tissue infections for example, cellulitis, erysipelas and wound infections.</li> </ul>	11/11/2024

						<ul style="list-style-type: none"> <li>- Bone and joint infections for example, osteomyelitis and septic arthritis.</li> <li>- Obstetric and gynaecological infections, pelvic inflammatory diseases.</li> <li>- Gonorrhoea particularly when penicillin is unsuitable.</li> <li>- Other infections including septicaemia, meningitis and peritonitis.</li> <li>- Prophylaxis against infection in abdominal, pelvic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection.</li> </ul> <p>Usually Cefuroxime will be effective alone, but when appropriate it may be used in combination with an aminoglycoside antibiotic, or in conjunction with metronidazole (orally or by suppository or injection), especially for prophylaxis in colonic or gynaecological surgery.</p> <p>Where appropriate Cefuroxime is effective when used prior to oral therapy with Cefuroxime (cefuroxime axetil) in the treatment of pneumonia and acute exacerbations of chronic bronchitis.</p>	
New Registration	Generic Drug	Bicalutamide Pharmacare	Bicalutamide	Film-coated tablet	50 mg	Indicated for the treatment of advanced prostate cancer in combination with luteinizing-hormone releasing hormone (LHRH) analogue therapy or surgical castration.	11/11/2024
New Registration	Generic Drug	Rufzel	Rufinamide	Film coated tablet	200mg	Indicated as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 1 year of age and older.	11/25/2024
New Registration	Generic Drug	Rufzel	Rufinamide	Film coated tablet	400mg	Indicated as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 1 year of age and older.	11/25/2024
New Registration	Generic Drug	0.9% w/v Sodium Chloride	Sodium Chloride	Solution for infusion	0.9%	<p>Indicated for:</p> <ul style="list-style-type: none"> <li>- Treatment of isotonic extracellular dehydration</li> <li>- Treatment of sodium depletion</li> <li>- Vehicle or diluent of compatible drugs for parenteral administration.</li> </ul>	11/25/2024
New Registration	Generic Drug	ADOL	Paracetamol	Caplet	500mg	Indicated for the treatment of most painful and febrile conditions, for example, headache including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea,	11/25/2024

						sore throat, and for relieving the fever, aches and pains of colds and flu. Also recommended for the symptomatic relief of pain due to non-serious arthritis.	
New Registration	Generic Drug	Octreotide BOS	Octreotide Acetate	Solution for injection/infusion	100 mcg/ml	<p>Indicated for:</p> <p>Symptomatic control and reduction of growth hormone (GH) and IGF-1 plasma levels in patients with acromegaly who are inadequately controlled by surgery or radiotherapy.</p> <p>Acromegalic patients unfit or unwilling to undergo surgery, or in the interim period until radiotherapy becomes fully effective.</p> <p>Relief of symptoms associated with functional gastro-entero-pancreatic (GEP) endocrine tumours, e.g. carcinoid tumours with features of the carcinoid syndrome.</p> <p>Octreotide is not an anti-tumour therapy and is not curative in these patients.</p> <p>Prevention of complications following pancreatic surgery.</p> <p>Emergency management to stop bleeding and to protect from re-bleeding owing to gastrooesophageal varices in patients with cirrhosis. Octreotide is to be used in association with specific treatment such as endoscopic sclerotherapy.</p> <p>Treatment of TSH-secreting pituitary adenomas:</p> <ul style="list-style-type: none"> <li>- Ehen secretion has not normalised after surgery and/or radiotherapy.</li> <li>- In patients in whom surgery is inappropriate.</li> <li>- In irradiated patients, until radiotherapy is effective.</li> </ul>	11/25/2024
New Registration	Generic Drug	Razapena	Mirtazapine	Film-coated tablet	30mg	Indicated for the treatment of episodes of major depression.	11/25/2024
New Registration	Generic Drug	Razapena	Mirtazapine	Film-coated tablet	15mg	Indicated for the treatment of episodes of major depression.	11/25/2024
New Registration	Generic Drug	Diclomax	Diclofenac Sodium	Enteric coated tablet	50mg	<p>Indicated for the relief of all grades of pain and inflammation in a wide range of conditions, including:</p> <p>1 .Arthritic conditions: rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout,</p>	11/25/2024

						<p>2 .Acute musculo-skeletal disorders such as periarthrititis (for example frozen shoulder), tendinitis, tenosynovitis, bursitis,</p> <p>3. Other painful conditions resulting from trauma, including fracture, low back pain, sprains, strains, dislocations, orthopaedic, dental and other minor surgery.</p>	
New Registration	Generic Drug	Nilo	Nilotinib	Capsule	200 mg	<p>Indicated for the treatment of:</p> <ul style="list-style-type: none"> <li>- Adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase</li> <li>- Adult patients with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available</li> <li>- Paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib.</li> </ul>	11/25/2024
New Registration	Generic Drug	Nilo	Nilotinib	Capsule	150 mg	<p>Indicated for the treatment of:</p> <ul style="list-style-type: none"> <li>- Adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase</li> <li>- Adult patients with chronic phase and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available</li> <li>- Paediatric patients with chronic phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including imatinib.</li> </ul>	11/25/2024
New Registration	Generic Drug	Sodium Nitroprusside	Sodium Nitroprusside	Solution for injection	25 g/ml	<p>Indicated for:</p> <ul style="list-style-type: none"> <li>- The treatment of hypertensive crises in adults</li> <li>- Controlled intraoperative hypotension in adults.</li> </ul> <p>Sodium nitroprusside is not suitable for permanent therapy.</p>	11/25/2024