

Saudi Drug Updates (SDU)

Feb-Mar 2025 A monthly electronic bulletin published by the drug

SFDA Drug Approvals

Application Type	Drug Type	Trade Name	Active Ingredient(S)	Dosage form	Strength	SFDA Approved Indication(s)	Approval Date
New Registration	Biological	Ravac	Rabies Vaccine Inactivated	Lyophilisate for solution for injection	2.5 IU	<p>RAVAC is indicated for the prevention of rabies in children and adults. It can be used before or after exposure, as a primary immunization or as a booster dose.</p> <p>a) Pre-Exposure prophylaxis</p> <p>Pre-exposure vaccination should be offered to subjects at high risk of contamination by the rabies virus. This vaccination is particularly recommended for veterinarians, veterinary medicine students, animal keepers, hunters, forestry workers, animal handlers, butchers, personnel in rabies research laboratories etc., children at high risk of exposure or prior to visits to areas in which rabies is endemic.</p> <p>b) Post-Exposure prophylaxis</p> <p>RAVAC is indicated in post-exposure prophylaxis of rabies infection, when given to individuals with suspected rabies exposure. RAVAC must always be used as per recommendations of the World Health</p>	01/2025

New Registration	Biological	Wegovy	Semaglutide	Solution for injection in pre-filled pen	2.4 mg	<p>Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of</p> <ul style="list-style-type: none"> • 30≤kg/m2 (obesity), or • ≥27 kg/m2 to <30 kg/m2 (overweight) <p>in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.</p>	01/2025
New Registration	Biological	Wegovy	Semaglutide	Solution for injection in pre-filled pen	1.7 mg	<p>Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of</p> <ul style="list-style-type: none"> • 30kg/m2 (obesity), or • ≥27 kg/m2 to <30 kg/m2 (overweight) <p>in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.</p>	01/2025
New Registration	Biological	Wegovy	Semaglutide	Solution for injection in pre-filled pen	1 mg	<p>Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of</p> <ul style="list-style-type: none"> • 30kg/m2 (obesity), or • ≥27 kg/m2 to <30 kg/m2 (overweight) <p>in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.</p>	01/2025
New Registration	Biological	Wegovy	Semaglutide	Solution for injection in pre-filled pen	0.5 mg	<p>Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of</p>	01/2025

						<ul style="list-style-type: none">• 30kg/m2 (obesity), or• ≥27 kg/m2 to <30 kg/m2 (overweight) <p>in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.</p>	
New Registration	Biological	Wegovy	Semaglutide	Solution for injection in pre-filled pen	0.25 mg	<p>Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of</p> <ul style="list-style-type: none">• 30kg/m2 (obesity), or• ≥27 kg/m2 to <30 kg/m2 (overweight) <p>in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.</p>	01/2025
New Registration	Biological	Ryzodeg Flexpen	Insulin Aspart, Insulin Degludec	Solution for injection in pre-filled pen	100 U/ml	Treatment of diabetes mellitus in adults, adolescents and children from the age of 2 years.	01/2025
New Registration	Biological	Norditropin Flexpro	Somatropin	Solution for injection in pre-filled pen	3.3 mg/ml	<p>Children:</p> <ul style="list-style-type: none">• Growth failure due to growth hormone deficiency (GHD)• Growth failure in girls due to gonadal dysgenesis (Turner syndrome)• Growth retardation in prepubertal children due to chronic renal disease• Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS < 0 during the last year) by 4 years of age or later.• Growth failure due to Noonan syndrome. <p>Adults:</p> <p>Childhood growth hormone deficiency:</p>	01/2025

						<p>Patients with childhood GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is < -2 SDS after at least four weeks off growth hormone treatment.</p> <p>In all other patients an IGF-1 measurement and growth hormone stimulation test is required.</p> <p>Adult growth hormone deficiency:</p> <p>Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with other deficient axis, other than prolactin. GHD should be demonstrated by provocative test after institution of adequate replacement therapy for any other deficient axis.</p> <p>In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended. An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test.</p>	
New Registration	Biological	Norditropin Flexpro	Somatropin	Solution for injection in pre-filled pen	6.7 mg/ml	<p>Children:</p> <ul style="list-style-type: none">•Growth failure due to growth hormone deficiency (GHD)•Growth failure in girls due to gonadal dysgenesis (Turner syndrome)•Growth retardation in prepubertal children due to chronic renal disease•Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -	01/2025

						<p>2 SD, who failed to show catch-up growth (HV SDS < 0 during the last year) by 4 years of age or later.</p> <p>·Growth failure due to Noonan syndrome.</p> <p>Adults:</p> <p>Childhood growth hormone deficiency:</p> <p>Patients with childhood GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is < -2 SDS after at least four weeks off growth hormone treatment.</p> <p>In all other patients an IGF-1 measurement and growth hormone stimulation test is required.</p> <p>Adult growth hormone deficiency:</p> <p>Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with other deficient axis, other than prolactin. GHD should be demonstrated by provocative test after institution of adequate replacement therapy for any other deficient axis.</p> <p>In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended. An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test</p>	
New Registration	Biological	Norditropin Flexpro	Somatropin	Solution for injection in pre-filled pen	10 mg/ml	<p>Children:</p> <p>·Growth failure due to growth hormone deficiency (GHD)</p>	01/2025

					<ul style="list-style-type: none">•Growth failure in girls due to gonadal dysgenesis (Turner syndrome)•Growth retardation in prepubertal children due to chronic renal disease•Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below - 2 SD, who failed to show catch-up growth (HV SDS < 0 during the last year) by 4 years of age or later.•Growth failure due to Noonan syndrome. <p>Adults:</p> <p>Childhood growth hormone deficiency:</p> <p>Patients with childhood GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is < -2 SDS after at least four weeks off growth hormone treatment.</p> <p>In all other patients an IGF-1 measurement and growth hormone stimulation test is required.</p> <p>Adult growth hormone deficiency:</p> <p>Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with other deficient axis, other than prolactin. GHD should be demonstrated by provocative test after institution of adequate replacement therapy for any other deficient axis.</p> <p>In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended.</p>	
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						An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test.	
New Registration	Biological	Tresiba Flexpen	Insulin Degludec	Solution for injection in pre-filled pen	100 U/ml	Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year.	01/2025
New Registration	Biological	Comirnaty Omicron Xbb 1.5	BNT162b2 Omicron XBB.1.5 Mrna	Concentrate for dispersion for injection	30 mcg	Active immunisation to prevent COVID19 caused by SARSCoV2 in individuals 12 years of age and older who have previously received at least a primary vaccination course against COVID19	01/2025
New Registration	Biological	Comirnaty Omicron Xbb 1.5	BNT162b2 Omicron XBB.1.5 Mrna	Concentrate for dispersion for injection	10 mcg	Active immunisation to prevent COVID19 caused by SARSCoV2 in children aged 5 to 11 years who have previously received at least a primary vaccination course against COVID19	01/2025
New Registration	NCE	Dayvigo	Lemborexant	Film-coated tablet	5 mg	Lemborexant is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	01/2025
New Registration	NCE	Dayvigo	Lemborexant	Film-coated tablet	10 mg	Lemborexant is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	01/2025
New Registration	NCE	Meteospasmyl	Alverine Citrate,Simeticone	Capsule	60 mg, 300 mg	Symptomatic treatment of functional bowel disorders, especially those with bloating, including relief of abdominal pain in irritable bowel syndrome.	02/2025
New Registration	NCE	Trelegy Ellipta	Fluticasone Furoate,Umeclidinium Bromide,Vilanterol	Inhalation powder, pre-dispensed	200 mcg, 74.2mcg, 40 mcg	Trelegy Ellipta is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Maintenance Treatment of Asthma Trelegy Ellipta is indicated for the maintenance treatment of asthma in patients aged 18 years and older. Limitations of Use Trelegy Ellipta is NOT indicated for the relief of acute asthma exacerbation	02/2025
New Registration	NCE	Movapo	Apomorphine	Solution for injection	10 mg/ml	The treatment of motor fluctuations ('on-off' phenomena) in patients with Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medication.	02/2025

New Registration	NCE	Xifaxan	Rifaximin	Film-coated tablet	550 mg	Rifaximin is indicated for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years of age	01/2025
New Registration	Generic	Avotrene Emulgel	Diclofenac Diethylamine	Gel	1 %	local symptomatic relief of pain and inflammation in: - trauma of the tendons, ligaments, muscles and joints, eg due to sprains, strains and bruises - localised forms of soft tissue rheumatism. It is recommended that the treatment be reviewed after 14 days in these indications. For the treatment of osteoarthritis of superficial joints such as the knee. In the treatment of osteoarthritis, therapy should be reviewed after 4 weeks.	01/2025
New Registration	Generic	Remox	Amoxicillin	Capsule	500MG	Amoxicillin is indicated for the treatment of the following infections in adults and children: Acute bacterial sinusitis Acute otitis media Acute streptococcal tonsillitis and pharyngitis Acute exacerbations of chronic bronchitis (AECB)/acute exacerbation of chronic obstructive pulmonary disease (AECOPD) Community acquired pneumonia Acute cystitis Asymptomatic bacteriuria in pregnancy Acute pyelonephritis Typhoid and paratyphoid fever Dental abscess with spreading cellulitis Prosthetic joint infections Helicobacter pylori eradication Lyme disease	01/2025

						Amoxicillin is also indicated for the prophylaxis of endocarditis. Consideration should be given to official guidance on the appropriate use of antibacterial agents.	
New Registration	Generic	Sugmastad	Sugammadex	Solution for injection	100 mg/ml	Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults. For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years.	01/2025
New Registration	Generic	Domassel	Ticagrelor	Film-coated tablet	60 mg	Ticagrelor, 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	01/2025
New Registration	Generic	Tadalo	Tadalafil	Film-coated tablet	20 mg	Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.	01/2025
New Registration	Generic	Irinotecan BOS	Irinotecan	Concentrate for solution for infusion	20 mg/ml	Irinotecan is indicated for the treatment of patients with advanced colorectal cancer: •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. Irinotecan in combination with cetuximab is indicated for the treatment of patients with epidermal growth factor 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. Irinotecan 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.	01/2025

						Irinotecan in combination with capecitabine with or without bevacizumab is indicated for first-line treatment of patients with metastatic colorectal carcinoma.	
New Registration	Generic	Fenobat	Ketotifen	Syrup	0.2 mg/ml	Ketotifen is indicated for symptomatic treatment of allergic conditions including rhinitis and conjunctivitis.	01/2025
New Registration	Generic	Etoposide-Venus	Etoposide	Solution for injection	20 mg/ml	<p>-Testicular cancer</p> <p>Etoposide injection is indicated in combination with other approved chemotherapeutic agents for the treatment of first line, recurrent or refractory testicular cancer in adults.</p> <p>-Small cell lung cancer</p> <p>Etoposide injection is indicated in combination with other approved chemotherapeutic agents for the treatment of small-cell lung cancer in adults.</p> <p>-Hodgkin"s lymphoma</p> <p>Etoposide injection is indicated in combination with other approved chemotherapeutic agents for the treatment of Hodgkin"s lymphoma in adult and Paediatric patients.</p> <p>-Non-Hodgkin"s lymphoma</p> <p>Etoposide injection is indicated in combination with other approved chemotherapeutic agents for the treatment of non-Hodgkin"s lymphoma in adult and Paediatric patients.</p> <p>-Acute myeloid leukemia</p> <p>Etoposide injection is indicated in combination with other approved chemotherapeutic agents for the treatment of acute myeloid leukaemia in adult and paediatric patients.</p> <p>-Gestational trophoblastic neoplasia</p> <p>Etoposide injection is indicated for first line and second line therapy in combination with other approved chemotherapeutic agents for the treatment of high-risk gestational trophoblastic neoplasia in adults.</p> <p>-Ovarian cancer</p>	01/2025

						Etoposide injection is indicated in combination with other approved chemotherapeutic agents for the treatment of non-epithelial ovarian cancer in adults. Etoposide injection is indicated for the treatment of platinum-resistant/refractory epithelial ovarian cancer in adults.	
New Registration	Generic	Sacvaly	Sacubitril,Valsartan	Film-coated tablet	97,103 mg	Indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.	01/2025
New Registration	Generic	Sacvaly	Sacubitril,Valsartan	Film-coated tablet	49,51 mg	Indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction.	01/2025
New Registration	Generic	Sacvaly	Sacubitril,Valsartan	Film-coated tablet	24,26 mg	Indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction	01/2025
New Registration	Generic	Flamotal 600 Mg	Ibuprofen	Film-coated tablet	600 mg	<p>Ibuprofen is indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies .</p> <p>In the treatment of non-articular rheumatic conditions, Ibuprofen is indicated in periarticular conditions such as frozen shoulder (capsulitis), bursitis, tendinitis, tenosynovitis and low back pain; Ibuprofen can also be used in soft tissue injuries such as sprains and strains .</p> <p>Ibuprofen is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache, including migraine headache.</p>	01/2025
New Registration	Generic	Broncast	Montelukast Sodium	Film-coated tablet	10 mg	<p>Montelukast is indicated in the treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom “as needed” short acting β-agonists provide inadequate clinical control of asthma.</p> <p>Montelukast is indicated for the relief of symptoms of seasonal allergic rhinitis and perennial allergic rhinitis. Because the benefits of Montelukast may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis,</p>	01/2025

						<p>reserve use for patients who have an inadequate response or intolerance to alternative therapies</p> <p>Montelukast is also indicated in the prophylaxis of asthma in which the predominant component is exercise induced bronchoconstriction.</p>	
New Registration	Generic	Byraza Plus	Omeprazole,Sodium Bicarbonate	Capsule	20 mf, 1100 mg	<p>Byraza Plus Hard Capsules are 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. <p>– 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 Byraza Plus may be considered.</p> <ul style="list-style-type: none">•Maintenance of healing of EE due to acid-mediated GERD. Controlled studies do not extend beyond 12 months. <p>Pediatric use</p> <p>Safety and effectiveness of omeprazole/sodium bicarbonate have not been established in pediatric patients.</p>	02/2025
New Registration	Generic	Lyrgaba	Pregabalin	Capsule	75 mg	<p>Neuropathic pain</p> <p>Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.</p> <p>Epilepsy</p>	02/2025

						<p>Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.</p> <p>Generalised anxiety disorder</p> <p>Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.</p>	
New Registration	Generic	Acetazolamide	Acetazolamide	Tablet	250 mg	<p>Acetazolamide is indicated in the treatment of:</p> <p>Glaucoma: Acetazolamide is useful in glaucoma (chronic simple (open angle) glaucoma, secondary glaucoma, and perioperatively in acute angle closure glaucoma where delay of surgery is desired in order to lower intraocular pressure) because it acts on inflow, decreasing the amount of aqueous secretion.</p> <p>Abnormal retention of fluids: Acetazolamide is a diuretic whose effect is due to the effect on the reversible hydration of carbon dioxide and dehydration of carbonic acid reaction in the kidney. The result is renal loss of HCO₃⁻ ion which carries out sodium, water and potassium. Acetazolamide can be used in conjunction with other diuretics when effects on several segments of the nephron are desirable in the treatment of fluid retaining states.</p> <p>Epilepsy: In conjunction with other anticonvulsants best results with Acetazolamide have been seen in petit mal in children. Good results, however, have been seen in patients, both children and adults, with other types of seizures such as grand mal, mixed seizure patterns, myoclonic jerk patterns etc.</p>	02/2025