Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Saudi Drug Updates (SDU)

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SFDA Drug Approvals

Application Type	Drug Type	Trade Name	Active Ingredient(s)	Dosage form	Strength	SFDA Approved Indication(s)	Approval Date
New Registration	Biological	Elrexfio	Elranatamab	Solution for injection	44 mg 76 mg	Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody .	02/2025
New Registration	Biological	Hemgenix	Etranacogene dezaparvovec	Concentrate for solution for infusion	1*10^13 GC	Indicated for the treatment of severe and moderately severe Haemophilia B (congenital Factor IX deficiency) in adult patients without a history of Factor IX inhibitors.	02/2025
New Registration	Biological	Imjudo	Tremelimumab	Concentrate for solution for infusion	20 mg/ml	Imjudo in combination with durvalumab is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC) who have not received prior treatment with a PD-1/PD-L1 inhibitor.	03/2025
New Registration	NCE	Vumerity	Diroximel fumarate	Modified-release capsule, hard	231 mg	Indicated for the treatment of adult patients with relapsing remitting multiple sclerosis.	02/2025
New Registration	NCE	Abilify Asimtufii	Aripiprazole	Prolonged-release suspension for injection	960 mg	Indicated for the treatment of schizophrenia. Maintenance monotherapy treatment of bipolar I disorder in adults.	02/2025
New Registration	NCE	Rezzayo	Rezafungin	Powder for concentrate for solution for infusion	200 mg	Indicated for the treatment of invasive candidiasis in adults.	02/2025

New Registration	NCE	Salofalk	Mesalazine	Prolonged-release granules	500 mg 1000 mg 1500 mg 3000 mg	For the treatment of acute episodes and the maintenance of remission of ulcerative colitis	03/2025
New Registration	NCE	Soluvit N	Biotin,Cyanocobalamin, Folic Acid,Nicotinamide,Pyridoxine (Vitamin B6),Riboflavin,Sodium Ascorbate,Sodium Pantothenate,Thiamine	Powder for solution for infusion	60 µg ,5 µg,0.4 mg,40 mg,4.9 mg,4.9 mg,113 mg,16.5, mg 3.1 mg	Soluvit N is indicated in adult patients and children as a supplement in intravenous nutrition to meet the daily requirements of water-soluble vitamins	03/2025
New Registration	NCE	MOVAPO	Apomorphine	Solution for infusion in cartridge	5 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.	03/2025
New Registration	NCE	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.	03/2025
New Registration	Biological	Yuflyma	Adalimumab	Solution for injection in pre-filled pen	40 mg	Rheumatoid arthritis Yuflyma in combination with methotrexate, is indicated for: •The treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate. •The treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Yuflyma can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate. Juvenile idiopathic arthritis Polyarticular juvenile idiopathic arthritis Yuflyma in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Yuflyma can be given as monotherapy in case of intolerance to methotrexate or when continued	03/2025

						treatment with methotrexate is inappropriate. Adalimumab has not been studied in patients aged less than 2 years. **Enthesitis-related arthritis** **Yuflyma is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.** **Axial spondyloarthritis** **Ankylosing spondylitis (AS)** **Yuflyma is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.** **Axial spondyloarthritis without radiographic evidence of AS** **Yuflyma is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).** **Psoriatic arthritis** **Yuflyma is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate.** **Adalimumab has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease (see section 5.1) and to improve physical function.** **Psoriasis** **Yuflyma is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.** **Paediatric plaque psoriasis** **Yuflyma is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.** **Hidradenitis suppurativa (HS)** **Yuflyma is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults and**	

						adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy. **Crohn’s disease** **Yuflyma is indicated for treatment of moderately to severely active Crohn’s disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.** **Paediatric Crohn's disease** **Yuflyma is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and a corticosteroid and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies.** **Ulcerative colitis** **Yuflyma is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.** **Paediatric ulcerative colitis** **Yuflyma is indicated for the treatment of moderately to severely active ulcerative colitis in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.** **Uveitis** **Yuflyma is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroidsparing, or in whom corticosteroid treatment is inappropriate.** **Paediatric uveitis** **Yuflyma is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.**	

New Registration	Generic	Alatript	Amitriptyline Hydrochloride	Film-coated tablet	25 mg 50 mg	Amitriptyline is indicated for : 1. The treatment of major depressive disorder in adults 2. The treatment of neuropathic pain in adults 3. The prophylactic treatment of chronic tension type headache (CTTH) in adults 4. The prophylactic treatment of migraine in adults 5. The treatment of nocturnal enuresis in children aged 6 years and above when organic pathology, including spina bifida and related disorders, have been excluded and no response has been achieved to all other non-drug and drug treatments, including antispasmodics and vasopressin-related products.	02/2025
New Registration	Generic	Lexipia	Selexipag	Film-coated tablet	800 µg	Indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II–III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies.	02/2025
New Registration	Generic	Brevie	Brivaracetam	Film-coated tablet	25 mg 50 mg	Indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.	02/2025
New Registration	Generic	Speranta	Neratinib	Film-coated tablet	40 mg	Indicated for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.	02/2025
New Registration	Generic	Acumig	Lasmiditan	Film-coated tablet	50 mg 100 mg	Indicated for the acute treatment of migraine with or without aura in adults.	02/2025
New Registration	Generic	Bloka	Esomeprazole Sodium	Powder and solvent for solution for infusion	40 mg	Indicated in adults, as an alternative to oral therapy in: •Treatment of duodenal ulcers •Prevention of relapse of duodenal ulcers •Treatment of gastric ulcers •Prevention of relapse of gastric ulcers •In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease •Treatment of NSAID-associated gastric and duodenal ulcers • Prevention of NSAID-associated gastric and duodenal ulcers in patients	02/2025

New Registration	Generic	Dimex	Dimetindene Maleate	Gel	0.1 %	Local treatment of itching in skin diseases, insect bites, minor burns, and sunburn.	02/2025
New Registration	Generic	Paricalcitol Spectro	Paricalcitol	Solution for injection	5 µg/ml	Indicated in adults for the prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure who are undergoing haemodialysis.	02/2025
New Registration	Generic	Filozad	Carfilzomib	Powder for solution for injection	60 mg	Carfilzomib indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with: Lenalidomide and dexamethasone; or Dexamethasone; or Daratumumab and dexamethasone. Carfilzomib indicated as a single agent for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	02/2025
New Registration	Generic	Broncast Pediatric	Montelukast Sodium	Chewable tablet	5 mg	Broncast pediatric 5mg 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. Broncast pediatric 5mg may also be an alternative treatment option to low-dose inhaled corticosteroids for patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids Broncast pediatric 5mg is also indicated in the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction. Broncast pediatric 5mg is indicated for the relief of symptoms of seasonal allergic rhinitis and perennial allergic rhinitis in patients 6 years of age and older.	03/2025
New Registration	Generic	Lyrgaba	Pregabalin	Capsule, hard	150 mg	Indicated for - Treatment of Peripheral and central neuropathic pain in adults. - As adjunctive therapy in adults with partial seizures with or without secondary generalisation. - Treatment of Generalised Anxiety Disorder (GAD) in adults.	03/2025
New Registration	Generic	Diclopid	Diclofenac Potassium	Tablet	50 mg	Short-term treatment of all grades of pain and inflammation in the following acute conditions: •Post-traumatic pain, inflammation and swelling, e.g. due to sprains.	03/2025

						•acute musculo-skeletal disorders such as periarthritis (for example frozen shoulder), tendonitis, tenosynovitis, bursitis •Post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery. •Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis and associated menorrhagia. •Migraine attacks. •Acute gout •Painful syndromes of the vertebral column. •Non-articular rheumatism. •As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis.	
New Registration	Generic	Omace	Lisinopril	Tablet	5 mg 10 mg 20 mg	Indicated for - Treatment of hypertension. - Treatment of symptomatic heart failure. - Acute myocardial infarction Short-term (6 weeks) treatment of haemodynamically stable patients within 24 hours of an acute myocardial infarction. - Renal complications of diabetes mellitus Treatment of renal disease in hypertensive patients with Type 2 diabetes mellitus and incipient nephropathy	03/2025
New Registration	Generic	Mycophenolate Mofetil Marcan	Mycophenolate Mofetil	Powder for oral suspension	200 mg /ml	Indicated in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants.	03/2025
New Registration	Generic	Motilone	Domperidone	Coated Tablet	10 mg	Indicated for the relief of the symptoms of nausea and vomiting.	03/2025
New Registration	Generic	Paclitaxel Kabi	Paclitaxel	Solution for injection	6 mg/ml	PACLITAXEL KABI is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, PACLITAXEL KABI is indicated in combination with cisplatin. PACLITAXEL KABI is indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy. PACLITAXEL KABI is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.	03/2025

						PACLITAXEL KABI in combination with cisplatin, is indicated for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy. PACLITAXEL KABI is indicated for the second-line treatment of AIDS- related Kaposi's sarcoma.	
New Registration	Generic	Taycan	Vancomycin	Powder for concentrate for solution for infusion	1000 mg	Vancomycin is indicated in all age groups for the treatment of the following infections: •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	03/2025
New Registration	Generic	Plasma-Lyte 148 (pH 7.4) and Glucose 5% w/v	Sodium Chloride,Potassium Chloride,Magnesium Chloride Hexahydrate,Sodium Acetate Trihydrate,Sodium Gluconate,Glucose Monohydrate	Solution for infusion	5.26,0.37,0.30, 3.68,5.02,55 (g/l)	Plasma-Lyte 148 (pH 7.4) is indicated: -for fluid replacement (e.g. after burns, head injury, fracture, infection, and peritoneal irritation -as intraoperative fluid replacement, -in haemorrhagic shock and clinical conditions requiring rapid blood transfusions - in mild to moderate metabolic acidosis, also in case of lactate metabolism impairment.	03/2025
New Registration	Generic	Dexrofex	Deferasirox	Film-coated tablet	90 mg 180 mg 360 mg	Indicated for the treatment of chronic iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older. Dexrofex is also indicated for the treatment of chronic iron overload due to blood transfusions when Feroxamine therapy is contraindicated or inadequate in the following patient groups: - in paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) aged 2 to 5 years, - in adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7 ml/kg/month of packed red blood cells) aged 2 years and older, - in adult and paediatric patients with other anaemias aged 2 years and older. Ferox is also indicated for the treatment of	03/2025

						chronic iron overload requiring chelation therapy when Feroxamine therapy is contraindicated or inadequate in patients with non-transfusion- dependent thalassaemia syndromes aged 10 years and older.	
New Registration	Generic	Clodreb	CLADRIBINE	Tablet	10 mg	Clodreb is indicated for the treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging features	03/2025
New Registration	Generic	Olaparib BOS	OLAPARIB	Film-coated tablet	100 mg	Ovarian cancer Olaparib BOS is indicated as monotherapy for the: •maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2- mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first line platinum-based chemotherapy. •maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Olaparib BOS in combination with bevacizumab is indicated for the: •maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a BRCA1/2 mutation and/or genomic instability. Breast cancer Olaparib BOS is indicated as: •monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germlineBRCA1/2-mutations who have HER2-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy. •monotherapy for the treatment of adult patients with germline BRCA1/2-mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxanein the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or	03/2025

						after prior endocrine therapy, or be considered unsuitable for endocrine therapy. Adenocarcinoma of the pancreas Olaparib BOS is indicated as monotherapy for the maintenance treatment of adult patients with germline BRCA1/2-mutationswho have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen. Prostate cancer Olaparib BOS is indicated as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and BRCA1/2-mutations (germline and/or somatic) who have progressed following prior therapy that included anew hormonal agent.	
New Registration	Generic	Sitfort	Sitagliptin Phosphate,Metformin Hydrochloride	Film-coated tablet	50 mg,1000 mg 50 mg, 850 mg	SITFORT is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin. SITFORT is indicated in combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. SITFORT is indicated as triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist. SITFORT is also indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycaemic control	03/2025
New Registration	Generic	Fluxetyl	Fluoxetine	Oral solution	4 mg/ml	Indicated for treatment Adults with ·Major depressive episodes ·Obsessive-compulsive disorder ·Bulimia nervosa: Fluxetyl is indicated as a complement of psychotherapy for the reduction of binge-eating and purging activity . Indicated for Children and adolescents aged 8 years and above	03/2025

						Moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4-6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression in combination with a concurrent psychological therapy.	
New Registration	Generic	Provecta	Brivaracetam	70 mg 100 mg	Film-coated tablet	Provecta is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.	03/2025
New Registration	Generic	Omacillin	Amoxicillin	250 mg	Capsule	Omacillin capsules 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 •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 Omacillin capsule is also indicated for the prophylaxis of endocarditis.	03/2025
New Registration	Generic	Dunarez	Darunavir	Film-coated tablet	400 mg 600 mg	Darunavir, co-administered with low dose ritonavir is indicated in combination with other antiretroviral medicinal products for the treatment of patients with human immunodeficiency virus (HIV-1) infection. Darunavir, co-administered with cobicistat is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adults and adolescents (aged 12 years and older, weighing at least 40 kg) Darunavir 400 mg and 800 mg tablets may be used to provide suitable dose regimens for the treatment of HIV-1 infection in adult and paediatric patients from the age of 3 years and at least 40 kg body weight who are:	03/2025

						Antiretroviral therapy (ART)-naïve • ART-experienced with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and CD4+ cell count ≥ 100 cells x 106/L. In deciding to initiate treatment with darunavir in such ART-experienced patients, genotypic testing should guide the use of darunavir	
New Registration	Generic	Sugammadex Kabi	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.	03/2025
New Registration	Generic	Gupisone	Prednisolone	Tablet	20 mg	Indicated for the treatment and/or suppression of inflammatory and allergic disorders.	03/2025
New Registration	Generic	Oxytocin EVER Pharma	Oxytocin	Solution for injection	10 IU/ml	Induction of labour for medical reasons; stimulation of labour in hypotonic uterine inertia; during caesarean section, following delivery of the child; prevention and treatment of postpartum uterine atony and haemorrhage. Early stages of pregnancy as a adjunctive therapy for the management of incomplete, inevitable, or missed abortion	03/2025
New Registration	Generic	Donfer	Pirfenidone	Film–Coated Tablet	801 mg 267 mg	Indicated in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF)	03/2025
New Registration	Generic	Sitaglu	Sitagliptin Hydrochloride	Film-coated tablet	25 mg 50 mg 100 mg	For adult patients with type 2 diabetes mellitus, Sitagliptin beta is indicated to improve glycaemic control: as monotherapy: in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. as dual oral therapy in combination with: metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control. a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance. a peroxisome proliferator-activated receptor gamma (PPARg) agonist (i.e. a thiazolidinedione) when use of a PPARg agonist is appropriate and when diet and exercise plus the PPARg agonist alone do not provide adequate glycaemic control. as triple oral therapy in combination with:	03/2025

						a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. a PPARg agonist and metformin when use of a PPARg agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Sitagliptin beta is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.	
New Registration	Generic	Quillivant XR	Methylphenidate	Film-coated tablet	20 mg 30 mg 40 mg	Indicated as part of a comprehensive treatment program for Attention Deficit Hyperactivity Disorder (ADHD) in children aged 6 years of age and over and adults when remedial measures alone prove insufficient.	03/2025