Kingdom of Saudi Arabia
Saudi Food & Drug Authority

SAUDI DRUG UPDATES (SDU)

Dec 2025

About

Saudi Drug Updates

Saudi Drug Updates is a monthly release issued by the Saudi Food and Drug Authority (SFDA) to keep healthcare professionals informed about the latest developments in pharmaceuticals. It features updates on regulatory decisions, safety communications, drug registration changes, and other topics under the Authority's oversight. The goal is to support informed decision-making and promote safe and effective medical practices.

Product Registration Updates

SFDA Drug Approvals

Application Type | Drug Type	Trade Name (Scientific Name)	Strength | Dosage Form	SFDA Approved Use
Registration | New Drug	Ojjaara (Momelotinib)	100 mg, 150 mg, 200 mg Film-coated tablet	Momelotinib is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia, intermediate or high-risk myelofibrosis who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor nave or have been treated with ruxolitinib.
Registration | Biological Drug	Cytotect CP Biotest (Human Cytomegalovirus Immunoglobulin (CMVIG))	100 U/ml Solution for infusion	Prophylaxis of clinical manifestations of cytomegalovirus infection in patients subjected to immunosuppressive therapy, particularly in transplant recipients. The concomitant use of adequate virostatic agents should be considered for CMV-prophylaxis.
	OMVOH (Mirikizumab)	100 mg/ml, 300 mg/ 15ml Solution for injection in pre-filled syringe	Mirikizumab is indicated for the treatment of moderately to severely active ulcerative colitis in adults.
	Densibon (Denosumab)	60 mg/ mL Solution for injection in pre-filled syringe	**Denosumab is intended for the following indications:** ▪ Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women it significantly reduces the risk of vertebral, non-vertebral and hip fractures. ▪ Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. In men with prostate cancer receiving hormone ablation, it significantly reduces the risk of vertebral fractures. ▪ Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.
	Imuldosa (Ustekinumab)	130 mg Concentrate for solution for infusion	**Crohn's Disease:** Ustekinumab is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. **Ulcerative colitis:** Ustekinumab is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

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Approved
Clinical Trials on Drugs

Study Title	Investigational Medicinal Product	Sponsor / CRO	Study Sites
A Phase 3, Parallel-Group Treatment, Blinded, Randomized, Placebo-Controlled Study to Assess the Efficacy and Safety of Pegtibatinase Administered Subcutaneously in Addition to Standard of Care in Participants with Classical Homocystinuria Due to Cystathionine Beta Synthase Deficiency (Harmony)	Pegtibatinase	Travere Therapeutics, Inc./ CTI	1- King Faisal Specialist Hospital and Research Center (Riyadh) 2- King Abdulaziz Hospital NG (Riyadh)
A Phase 2/3 Randomized, Placebo-Controlled, Double-blind, Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Vericiguat in Pediatric Participants with Heart Failure due to Systemic Left Ventricular Systolic Dysfunction (VALOR)	Vericiguat	Merck Sharp & Dohme KSA GmbH	1- King Faisal Specialist Hospital and Research Center (Riyadh) 2- King Abdulaziz Hospital NG (Riyadh)
Immune Ablation Therapy Followed by Autologous Hematopoietic Stem Cell Transplantation for The Treatment of Multiple Sclerosis: A Single-Arm Study	Busulfan BOS / Cyclophosphamide/ Thymoglobulin	King Faisal Specialist Hospital and Research Center (Riyadh)	1- King Faisal Specialist Hospital and Research Center (Riyadh)
Randomized, Phase 3, double-blind, 52-week study to evaluate the efficacy and safety of rilzabrutinib (SAR444671) compared to placebo in adult participants with active IgG4- related disease	Rilzabrutinib (SAR444671)	Sanofi / Arab Med	1- King Faisal Specialist Hospital and Research Center (Riyadh)
A low-interventional study to evaluate long-term effectiveness of real-world prophylactic treatment with efanesoctocog alfa on joint health in people with haemophilia A (ALTITUDE)	Efanesoctocog alfa	Swedish Orphan Biovitrum AB / Balsam	1- King Faisal Specialist Hospital and Research Center (Riyadh)

Recalls,

Market Withdrawals & Safety Alerts

SFDA has issued a recall of the following Products:

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Drug Sector Guidelines

New Guidelines

General Guideline on Regulatory and Scientific Requirements for Development and Approval of Biosimilars

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Updated Guidelines

- Pricing Rules for Pharmaceutical Products

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- The Procedure of Implementing Prices on Pharmaceutical Product

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