



Kingdom of Saudi Arabia
Saudi Food & Drug Authority

SAUDI DRUG UPDATES (SDU)

Jan 2026

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 Biological Drug	EVKEEZA (EVINACUMAB)	150 mg/ml Concentrate for solution for infusion	EVINACUMAB is indicated as an adjunct to diet and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and paediatric patients aged 5 years and older with homozygous familial hypercholesterolaemia (HoFH).
Registration NEW Drug	CARTIMOV (DIACEREIN)	50 mg/ Hard Capsule	Symptomatic treatment of functional symptoms and signs of osteoarthritis. Note: action onset is deferred: a period of 30 to 45 days precedes analgesic effect onset. Treatment may therefore have to be initiated with standard immediate action onset analgesics/anti- inflammatories.
Registration Biological Drug	ORYLMYTE (DERMATOPHAGOIDE S FARINAE EXTRACT, DERMATOPHAGOIDE S PTERONYSSINUS EXTRACT)	300 IR/Sublingual tablet	ORYLMYTE is indicated in adolescents (12-17 years) and adults for treatment of moderate to severe house dust mite-induced allergic rhinitis or rhinoconjunctivitis, diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE).
Registration NEW Drug	Creon (Pancreatin)	150 mg/Capsule	Exocrine pancreatic insufficiency associated with maldigestion. To support pancreatic insufficiency in cystic fibrosis.
Registration Biological Drug	XIMLUCI (Ranibizumab)	10 mg/ml Solution for injection	Ranibizumab is intended for the following indications: <ol style="list-style-type: none"> 1.The treatment of neovascular (wet) age-related macular degeneration (AMD) 2.The treatment of visual impairment due to diabetic macular oedema (DME) 3.The treatment of proliferative diabetic retinopathy (PDR) 4.The treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) 5.The treatment of visual impairment due to choroidal neovascularisation (CNV)

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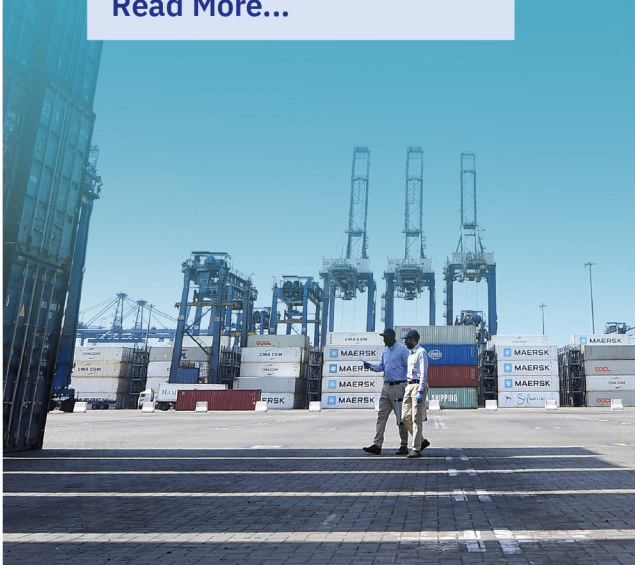
Approved Clinical Trials on Drugs

Study Title	Investigational Medicinal Product	Sponsor / CRO	Study Sites
Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Self-Administered Subcutaneous Selatogrel for Prevention of All-Cause Death and Treatment of Acute Myocardial Infarction in Subjects with A Recent History of Acute Myocardial Infarction	(ACT-246475) / Selatogrel	Viartis Innovation GmbH / IQVIA	1. King Faisal Specialist Hospital and Research Center (Riyadh).
A Phase 3, Multicenter, Randomized, Open Label Study to Compare the Efficacy and Safety of Golcadomide in Combination with Rituximab (Golca + R) Vs Investigator's Choice in Participants with Relapsed/Refractory Follicular Lymphoma	Golcadomide / Rituximab	Celgene Corporation / Balsam Clinical Research	1. King Faisal Specialist Hospital and Research Center (Riyadh).
Randomized Double-Blind Placebo-Controlled Phase 3 Study to Evaluate the Efficacy and Safety of Maralixibat in the Treatment of Participants with Cholestatic Pruritus	Maralixibat	Mirum Pharmaceuticals, Inc. / CTI	King Faisal Specialist Hospital and Research Center (Riyadh).
Randomized, Multicenter, Multinational, Double-Blind Study to Compare the Pharmacokinetics, Efficacy, Safety and Immunogenicity of MB12 (Proposed PembrolizumabBiosimilar) versus Keytruda® in Combination with Chemotherapy for the Treatment of Patients with Advanced Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (BENITO Study)	aMB12 /Pembrolizumab biosimilar	mAbxience Research SLU / Balsam	King Saud University Medical City (Riyadh).
A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effect of Dupilumab on Airway Inflammation Through Assessments of Mucus Plugging and Other Lung Imaging Parameters in Patients with Chronic Obstructive Pulmonary Disease	Dupilumab	Arabia trading limited / Arabmed	King Khalid University Hospital (Riyadh).

Recalls, Market Withdrawals & Safety Alerts

SFDA has issued a recall of the following Products:

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SFDA Approved Risk Management Measures (RMMs)

The summary view in the table includes reviewed and approved Risk minimization measures by SFDA:

Normosang® (Human Hemin)

[HCP Guide](#)



Yescarta® (Axicabtagene Ciloleuce)

[DHPC](#)



Ledaga® (Chlormethine)

[Patient Card - Arabic\English](#)



SDU Bulletin

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