

## Safety Signals Identified by the SFDA

October – December 2025



Signal Detection Section  
National Pharmacovigilance Center



*“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”*

## Introduction

This periodic report contains the detected potential signals by Saudi Food and Drug Authority National Pharmacovigilance Center. The objective of sharing this information is to increase the transparency and effective communication between SFDA and its stakeholders. This list intended to support Marketing Authorization Holders, healthcare professionals, and researchers in identifying and addressing newly detected potential signals, thereby contributing to improved public health and patient safety.

**Table 1. List of Quarterly Detected Signals**

Active Ingredient	Adverse Event	Status	Outcome
AMPICILLIN	Rash - Bradycardia - Hypertension Redness	Pending	SFDA is validating this potential risk
CERTOLIZUMAB	Arthralgia - Yellow skin	Pending	SFDA is validating this potential risk
CEFTRIAZONE	Hypotension - Allergic reaction	Pending	SFDA is validating this potential risk
COLISTIMETHATE SODIUM	Hypomagnesemia	Pending	SFDA is validating this potential risk
AMOXICILLIN	Gastroenteritis	Pending	SFDA is validating this potential risk
CEFOTAXIME	Skin cyst excision	Pending	SFDA is validating this potential risk
AZITHROMYCIN	Skin cyst excision	Pending	SFDA is validating this potential risk
LENVATINIB	Hand and foot syndrome	Pending	SFDA is validating this potential risk
CARBOPLATIN	Hypothyroidism	Pending	SFDA is validating this potential risk
PACLITAXEL	Hypothyroidism	Pending	SFDA is validating this potential risk
AMOXICILLIN	Acute upper respiratory tract infection	Pending	SFDA is validating this potential risk
MELATONIN	Cardiac failure	Pending	SFDA is validating this potential risk
NEMOLIZUMAB	Erythema multiforme	Pending	SFDA is validating this potential risk
RABEPRAZOLE	Sexual dysfunction	Pending	SFDA is validating this potential risk
PANTOPRAZOLE	Sexual dysfunction	Pending	SFDA is validating this potential risk
OMEPRazole	Sexual dysfunction	Pending	SFDA is validating this potential risk
METRONIDAZOLE	SOB	Pending	SFDA is validating this potential risk
NIFEDIPINE	Reflex tachycardia	Pending	SFDA is validating this potential risk
DEXTROMETHORPHAN	Pharyngitis	Pending	SFDA is validating this potential risk
DOCETAXEL	Stiff joint	Pending	SFDA is validating this potential risk
BLINATUMOMAB	Myoclonic jerks - Tonic seizure - Oxygen saturation decreased	Pending	SFDA is validating this potential risk
AFLIBERCEPT	Hypertension	Pending	SFDA is validating this potential risk
AFLIBERCEPT	Blood creatinine increased	Pending	SFDA is validating this potential risk
AFLIBERCEPT	Palmar-plantar erythrodysesthesia syndrome	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hyperglycaemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hypokalaemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hypoglycaemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hyperkalaemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hyponatraemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hypernatraemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hypophosphataemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hypocalcaemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hypoalbuminaemia	Pending	SFDA is validating this potential risk
VEMURAFENIB	Hyperglycaemia	Pending	SFDA is validating this potential risk
ATOMOXETINE	Dystonia	Pending	SFDA is validating this potential risk
TEMOZOLOMIDE	Oesophagitis	Pending	SFDA is validating this potential risk
FLUOXETINE	Deafness	Pending	SFDA is validating this potential risk
MIRTAZAPINE	Rhabdomyolysis	Pending	SFDA is validating this potential risk
ROFLUMILAST	Melaena	Pending	SFDA is validating this potential risk

BACLOFEN	Renal failure	Pending	SFDA is validating this potential risk
ABIRATERONE	Thrombocytopenia	Pending	SFDA is validating this potential risk
PAZOPANIB	Pericardial effusion	Pending	SFDA is validating this potential risk
GOLIMUMAB	Meningitis	Pending	SFDA is validating this potential risk
VEMURAFENIB	Granulocytopenia	Pending	SFDA is validating this potential risk
ROFLUMILAST	Pancreatitis	Pending	SFDA is validating this potential risk
FINASTERIDE	Seizure	Pending	SFDA is validating this potential risk
AGOMELATINE	Hypotension	Pending	SFDA is validating this potential risk
ROFLUMILAST	Pneumonia	Pending	SFDA is validating this potential risk
FEBUXOSTAT	Cardiac failure	Pending	SFDA is validating this potential risk
AGOMELATINE	Thrombocytopenia	Pending	SFDA is validating this potential risk
ATOMOXETINE	Neutropenia	Pending	SFDA is validating this potential risk
LINAGLIPTIN	Cardiac failure	Pending	SFDA is validating this potential risk
VEMURAFENIB	Sepsis	Pending	SFDA is validating this potential risk
GOLIMUMAB	Migraine	Pending	SFDA is validating this potential risk
PRUCALOPRIDE	Suicidal ideation	Pending	SFDA is validating this potential risk
LEVETIRACETAM	Acute kidney injury	Pending	SFDA is validating this potential risk
DIMENHYDRINATE	Toxic epidermal necrolysis	Pending	SFDA is validating this potential risk
DENOSUMAB	Psoriasis	Pending	SFDA is validating this potential risk
LAMIVUDINE	Deafness	Pending	SFDA is validating this potential risk
LEVOTHYROXINE	Panic attack	Pending	SFDA is validating this potential risk
RUXOLITINIB	Neuropathy peripheral	Pending	SFDA is validating this potential risk
VEMURAFENIB	Cardiac failure	Pending	SFDA is validating this potential risk
AFLIBERCEPT	Deep vein thrombosis	Pending	SFDA is validating this potential risk
VORTIOXETINE	Aggression	Pending	SFDA is validating this potential risk
COLECALCIFEROL	Insomnia	Pending	SFDA is validating this potential risk
ACICLOVIR	Acute generalised exanthematous pustulosis	Pending	SFDA is validating this potential risk
TRAMADOL	Hyponatraemia	Pending	SFDA is validating this potential risk
LEVETIRACETAM	Hypokalaemia	Pending	SFDA is validating this potential risk
METHOTREXATE	Muscle spasms	Pending	SFDA is validating this potential risk
ZOSTER VACCINE	Lymphadenopathy - Cellulitis - Injection site reaction - Injection site swelling - Injection site painrash	Pending	SFDA is validating this potential risk
SITAGLIPTIN HYDROCHLORIDE HYDRATE	Colon injury - Kidney stones	Pending	SFDA is validating this potential risk
FERROUS SULFATE	Dizziness	Pending	SFDA is validating this potential risk
FERROUS SULFATE	Pruritus	Pending	SFDA is validating this potential risk
ENTRECTINIB	Brugada syndrome	Pending	SFDA is validating this potential risk
SELUMETINIB	Gingival hypertrophy	Pending	SFDA is validating this potential risk
BINIMETINIB	Gingival hypertrophy	Pending	SFDA is validating this potential risk
TIRZEPATIDE	Intestinal obstruction	Pending	SFDA is validating this potential risk
OCRELIZUMAB	Central nervous system infection	Pending	SFDA is validating this potential risk
OFATUMUMAB	Central nervous system infection	Pending	SFDA is validating this potential risk
OFATUMUMAB	Hepatic failure	Pending	SFDA is validating this potential risk

VEMURAFENIB	Gingival hypertrophy	Pending	SFDA is validating this potential risk
DABRAFENIB	Gingival hypertrophy	Pending	SFDA is validating this potential risk
ENCORAFENIB	Gingival hypertrophy	Pending	SFDA is validating this potential risk
TALQUETAMAB	Progressive multifocal leukoencephalopathy	Pending	SFDA is validating this potential risk
GLOFITAMAB	Progressive multifocal leukoencephalopathy	Pending	SFDA is validating this potential risk
SULFASALAZINE	Idiopathic intracranial hypertension	Pending	SFDA is validating this potential risk
EPCORITAMAB	Hypogammaglobulinaemia	Pending	SFDA is validating this potential risk
BOSUTINIB	Cutaneous vasculitis	Pending	SFDA is validating this potential risk
ADALIMUMAB	Morphoea	Pending	SFDA is validating this potential risk
TIRZEPATIDE	Drug interaction	Pending	SFDA is validating this potential risk
RABEPRAZOLE	Erectile dysfunction	Pending	SFDA is validating this potential risk
DEXLANSOPRAZOLE	Erectile dysfunction	Pending	SFDA is validating this potential risk
PANTOPRAZOLE	Erectile dysfunction	Pending	SFDA is validating this potential risk
LANSOPRAZOLE	Erectile dysfunction	Pending	SFDA is validating this potential risk
OMEPRazole	Erectile dysfunction	Pending	SFDA is validating this potential risk
INSULIN GLARGINE	Tachycardia	Pending	SFDA is validating this potential risk
CLOPIDOGREL	Blood calcium increased	Pending	SFDA is validating this potential risk
REGORAFENIB	Disorientation	Pending	SFDA is validating this potential risk
SECUKINUMAB	Arthralgia	Pending	SFDA is validating this potential risk
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	Speech disorder	Pending	SFDA is validating this potential risk
TIGECYCLINE	Electrocardiogram QT prolonged	Pending	SFDA is validating this potential risk
TACROLIMUS	Areflexia	Pending	SFDA is validating this potential risk
LEVOCETIRIZINE	Cardiac failure acute	Pending	SFDA is validating this potential risk
TERBINAFINE	Leukocytosis	Pending	SFDA is validating this potential risk
PAROXETINE	Palpitations - Chills - Irritability - Nervousness - Feeling guilty - Panic attack - Negative thoughts - Crying - Chest discomfort - Chest pain	Pending	SFDA is validating this potential risk
AMOXICILLIN SODIUM;CLAVULANIC ACID	Hypotension - Redness facial - Bradycardia	Pending	SFDA is validating this potential risk
METRONIDAZOLE	Dizziness - Lip swelling - Blurred vision - Itching - Rash - Nausea - Low blood pressure	Pending	SFDA is validating this potential risk
PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE	ArthralgiaDepression - Hallucinations - Dry mouth - Joint pain	Pending	SFDA is validating this potential risk
QUETIAPINE	Intracranial hypertension - Nervousness	Pending	SFDA is validating this potential risk
TIRZEPATIDE	Sexual desire decreased - Erectile dysfunction	Pending	SFDA is validating this potential risk
LORATADINE	Drowsiness	Pending	SFDA is validating this potential risk



AMINOSALICYLATE SODIUM;AMINOSALICYLIC ACID	Face and mouth X-ray	Pending	SFDA is validating this potential risk
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**Table 2. List of Quarterly Validated Signals**

Active Ingredient	Adverse Event	Status	Outcome
ONASEMNOGENE	Pneumonia	Closed	Valid
LIXISENATIDE	Hepatocellular carcinoma	Closed	Refuted
DULAGLUTIDE	Hepatocellular carcinoma	Closed	Refuted
TIRZEPATIDE	Hepatocellular carcinoma	Closed	Refuted
SEMAGLUTIDE	Hepatocellular carcinoma	Closed	Refuted
ERTAPENEM SODIUM	Stevens Johnson syndrome	Closed	Valid
SEMAGLUTIDE	Sleep disorder	Closed	Valid
DULAGLUTIDE	Sleep disorder	Closed	Valid
YELLOW FEVER VACCINE	Oral herpes	Closed	Valid
YELLOW FEVER VACCINE	Tinnitus	Closed	Valid
BARICITINIB	Fracture	Closed	Valid
CYTARABINE	Palmar-plantar erythrodysaesthesia syndrome	Closed	Valid
DOXYCYCLINE	Fixed eruption	Closed	Refuted
SEMAGLUTIDE	Pancreatic carcinoma -	Closed	Valid
NIFEDIPINE	Aortic stenosis -	Closed	Refuted



Thank   
you