

# Safety Signals Identified by the SFDA

January – March 2026



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
AMLODIPINE BESILATE	Shortness of breath - Chest tightness	Closed	validation process ended
VANCOMYCIN	Cough - SOB (shortness of breath) - Itching	Closed	validation process ended
CHLORPROMAZINE	Short of breath	Pending	SFDA is validating this potential risk
METFORMIN HYDROCHLORIDE	Acidity - acid reflux	Closed	validation process ended
LIRAGLUTIDE	Diarrhea - Vomiting - red spot	Closed	validation process ended
LORNOXICAM	Severe and persistent stomach pain - Severe irritation in the stomach - Chest tightness - Belching / burping	Closed	validation process ended
AMLODIPINE	weakness or sluggishness in the heart muscle - Allergy - Proteinuria	Closed	validation process ended
LEVOTHYROXINE	Hypothyroidism	Closed	validation process ended
RIFAXIMIN	severe diarrhea - Generalized body spasms - syncope - Upper back pain between the shoulder blades	Closed	validation process ended
IBUPROFEN	Fibrous growth in my lower gum / mandibular gum	Pending	SFDA is validating this potential risk
IPRATROPIUM BROMIDE	Depression - Hallucination - Arthralgia - Dry mouth	Pending	SFDA is validating this potential risk
ALFUZOSIN;SOL IFENACIN	Dysuria	Closed	validation process ended
ALFUZOSIN;SOL IFENACIN	Urination frequency of	Closed	validation process ended
MULTIVITAMIN S, COMBINATIONS	Odour body	Closed	validation process ended
ACETYLSALICYLATE LYSINE	Head banging	Closed	validation process ended
Cysteamine Bitartrate	Syncope - Dizziness - Headache	Pending	SFDA is validating this potential risk
ACETYLSALICYLIC ACID	Heartburn	Pending	SFDA is validating this potential risk
LORATADINE	Palpitation - Shortness of breath - Insomnia - Dizziness	Closed	validation process ended
ACETYLSALICYLIC ACID	Hedinger syndrome	Pending	SFDA is validating this potential risk
ACETYLSALICYLIC ACID	Head deformity NOS	Pending	SFDA is validating this potential risk
CYCLOPENTOLATE HYDROCHLORIDE	Syncope - Faint	Pending	SFDA is validating this potential risk
ACETYLSALICYLIC ACID	Myalgia	Closed	validation process ended
Chikungunya Vaccine	Meningitis aseptic	Pending	SFDA is validating this potential risk



OMALIZUMAB	Acquired haemophilia	Pending	SFDA is validating this potential risk
SEMAGLUTIDE	Blindness	Pending	SFDA is validating this potential risk
CARBIDOPA;LEVODOPA	Vitamin B6 deficiency	Pending	SFDA is validating this potential risk
vosoritide	Epiphysiolysis	Pending	SFDA is validating this potential risk
ATEZOLIZUMAB	Paraesthesia	Pending	SFDA is validating this potential risk
ATEZOLIZUMAB	Mucosal inflammation	Pending	SFDA is validating this potential risk
METFORMIN	Insomnia	Pending	SFDA is validating this potential risk
METFORMIN	Cystitis	Pending	SFDA is validating this potential risk
Ursodeoxycholic acid	Oropharyngeal pain	Pending	SFDA is validating this potential risk
FINERENONE	Albuminuria	Pending	SFDA is validating this potential risk
PREDNISOLONE	Leukocytoclastic vasculitis	Pending	SFDA is validating this potential risk
RISANKIZUMAB	Pemphigoid	Pending	SFDA is validating this potential risk
DILTIAZEM	increased risk for serious bleeding in patients with AF receiving apixaban or rivaroxaban	Pending	SFDA is validating this potential risk
RELACORILANT	Insomnia	Pending	SFDA is validating this potential risk
RELACORILANT	Headache	Pending	SFDA is validating this potential risk
RELACORILANT	Bursitis	Pending	SFDA is validating this potential risk
RELACORILANT	Arthralgia	Pending	SFDA is validating this potential risk
RELACORILANT	Acne	Pending	SFDA is validating this potential risk
RELACORILANT	Back pain	Pending	SFDA is validating this potential risk
MORPHINE SULFATE	SOB (shortness of breath)	Pending	SFDA is validating this potential risk
ROSUVASTATIN	Headache - Heartburn - Fever - Dizziness	Pending	SFDA is validating this potential risk
SEMAGLUTIDE	Muscle weakness - throbbing knee pain	Pending	SFDA is validating this potential risk
SALBUTAMOL	Stomach pain - Feline oesophagus	Pending	SFDA is validating this potential risk
XYLOMETAZOLINE	Numbness in face - Blurred vision	Pending	SFDA is validating this potential risk
PARACETAMOL	SOB (shortness of breath) - Wheezing	Pending	SFDA is validating this potential risk
CETIRIZINE HYDROCHLORIDE	Generalized rash	Pending	SFDA is validating this potential risk
LEVOTHYROXINE	Hypothyroidism - Hyperlipidaemia	Pending	SFDA is validating this potential risk
MELOXICAM	Weight increased - Insulin resistance syndrome	Pending	SFDA is validating this potential risk
TADALAFIL	Headache - Heartburn - Vertigo - Pyrexia	Pending	SFDA is validating this potential risk
CEFTRIAXONE	Itching - generalised - Coughing	Pending	SFDA is validating this potential risk



**Table 2. List of Quarterly Validated Signals**

<b>Active Ingredient</b>	<b>Adverse Event</b>	<b>Status</b>	<b>Outcome</b>
ALBENDAZOLE	Hyperactivity syndrome aggravated - Lethargy - Social problem	Closed	Refuted
LORNOXICAM	Acute kidney injury	Closed	Refuted
Nogapendekin alfa inbakicept	Ureteral necrosis	Closed	Refuted
Nogapendekin alfa inbakicept	Malignant peritoneal neoplasm	Closed	Refuted
MORPHINE SULFATE	SOB (shortness of breath)	Closed	Valid
TOFACITINIB	Hair loss	Closed	Valid
CEFADROXIL	SOB (shortness of breath)	Closed	Valid
LINAGLIPTIN	Diarrhea	Closed	Valid
CHLORAMPHENICOL	Nightmare	Closed	Refuted
PALIPERIDONE	Induces dissociation - impaired mental function	Closed	Valid
SITAGLIPTIN	Hyperglycemia	Closed	Refuted
EMPAGLIFLOZIN	Vertigo - Vomiting - Movement disorder	Closed	Refuted
CAPSAICIN	Severe generalized erythematous rash - ulceration	Closed	Refuted
METFORMIN HYDROCHLORIDE	Dysphagia - Vomiting - Nausea - MEDICATION INTOLERANCE	Closed	Valid
MIDAZOLAM	Hyperventilation syndrome	Closed	Refuted
AMIVANTAMAB	SOB (shortness of breath)	Closed	Refuted
ACETYLSALICYLIC ACID	Visual disturbance	Closed	Valid
AMLODIPINE	Bleeding	Closed	Refuted
APIXABAN	Hyperacidity	Closed	Valid
PARACETAMOL	severe fever	Closed	Refuted
LENVATINIB	Hand and foot syndrome	Closed	Valid
CARBOPLATIN	Hypothyroidism	Closed	Valid
PACLITAXEL	Hypothyroidism	Closed	Valid
ROFLUMILAST	Pneumonia	Closed	Refuted
FEBUXOSTAT	Cardiac failure	Closed	Refuted
LAMIVUDINE	Deafness	Closed	Refuted
VORTIOXETINE	Aggression	Closed	Refuted
ENTRECTINIB	Brugada syndrome	Closed	Refuted
QUETIAPINE	Intracranial hypertension - Nervousness	Closed	Refuted
AXICABTAGENE CILOLEUCEL	Serum ferritin increased	Closed	Refuted
TECLISTAMAB	Haemophagocytic lymphohistiocytosis	Closed	Refuted
ERTAPENEM	Encephalopathy	Closed	Valid
AMANTADINE	Volvulus	Closed	Refuted
MOGAMULIZUMAB	Colitis	Closed	Valid
AFATINIB	Cardiac failure	Closed	Refuted
RIFAMPICIN	Blood uric acid increased	Closed	Valid



GLUCOSE	Hyperkalemia	Closed	Valid
TOZINAMERAN	Troponin I increased	Closed	Valid
TOZINAMERAN	Cardiac arrest	Closed	Valid



Thank   
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