

Safety Signals Identified by the SFDA

January – March 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
TEZEPELUMAB	Epistaxis	Pending	SFDA is validating this potential risk
LEFLUNOMIDE	Rheumatoid lung	Pending	SFDA is validating this potential risk
ERTAPENEM	Encephalopathy	Pending	SFDA is validating this potential risk
TIRZEPATIDE	Seizure	Pending	SFDA is validating this potential risk
TIRZEPATIDE	Septic shock	Pending	SFDA is validating this potential risk
CILTACABTAGENE AUTOLEUCEL	Progressive multifocal leukoencephalopathy	Pending	SFDA is validating this potential risk
SEMAGLUTIDE	Sleep disorder	Pending	SFDA is validating this potential risk
LIRAGLUTIDE	Sleep disorder	Pending	SFDA is validating this potential risk
EXENATIDE	Sleep disorder	Pending	SFDA is validating this potential risk
DULAGLUTIDE	Sleep disorder	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Anaemia	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Hypoglycaemia	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Myocardial infarction	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Cerebral haemorrhage	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Sepsis	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Oral herpes	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Tinnitus	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Conjunctivitis allergic	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Vulvovaginal candidiasis	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Cough	Pending	SFDA is validating this potential risk
HEPARIN	Hematemesis	Pending	SFDA is validating this potential risk
MEROPENEM	Acute kidney injury	Pending	SFDA is validating this potential risk
LACOSAMIDE	Hyponatremia	Pending	SFDA is validating this potential risk
IBUPROFEN	Facial swelling	Pending	SFDA is validating this potential risk
IBUPROFEN	Lips swelling non-specific	Pending	SFDA is validating this potential risk
VALSARTAN	Hyperacidity	Pending	SFDA is validating this potential risk
ACETYLSALICYLIC ACID	Tinnitus	Pending	SFDA is validating this potential risk
LINAGLIPTIN	Hypercholesterolemia	Pending	SFDA is validating this potential risk
BISOPROLOL	Hypercholesterolemia	Pending	SFDA is validating this potential risk
DAPTOMYCIN	Hyperkalaemia	Pending	SFDA is validating this potential risk
DICLOFENAC	Dementia	Pending	SFDA is validating this potential risk
CELECOXIB	Dementia	Pending	SFDA is validating this potential risk
IBUPROFEN	Dementia	Pending	SFDA is validating this potential risk
NAPROXEN	Dementia	Pending	SFDA is validating this potential risk
MELOXICAM	Dementia	Pending	SFDA is validating this potential risk
ESCITALOPRAM	Electric shock sensation in head	Pending	SFDA is validating this potential risk
REGORAFENIB	Hyperammonaemic encephalopathy	Pending	SFDA is validating this potential risk
YELLOW FEVER VACCINE	Malaria	Pending	SFDA is validating this potential risk
Cetylpyridinium chloride	Sleepiness	Pending	SFDA is validating this potential risk



Table 2. List of Quarterly Validated Signals

Active Ingredient	Adverse Event	Status	Outcome
DOXYCYCLINE	Fixed eruption	Closed	Refuted
TOZINAMERAN	Liver injury	Closed	Valid
ESCITALOPRAM	Cardiac arrest	Closed	Valid
ESCITALOPRAM	Haemorrhagic stroke	Closed	Refuted
SEMAGLUTIDE	Pancreatic carcinoma	Closed	Valid
DASABUVIR	Jaundice	Closed	Refuted
NIFEDIPINE	Aortic stenosis	Closed	Refuted
NIFEDIPINE	Shock	Closed	Valid



Thank 
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