

## Safety Signals Identified by the SFDA

April – June 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
TRIPTORELIN	Suicidal behaviour	Pending	SFDA is validating this potential risk
DULAGLUTIDE	Optic ischaemic neuropathy	Pending	SFDA is validating this potential risk
LIRAGLUTIDE	Optic ischaemic neuropathy	Pending	SFDA is validating this potential risk
SEMAGLUTIDE	Optic ischaemic neuropathy	Pending	SFDA is validating this potential risk
TIRZEPATIDE	Optic ischaemic neuropathy	Pending	SFDA is validating this potential risk
EXENATIDE	Optic ischaemic neuropathy	Pending	SFDA is validating this potential risk
LIXISENATIDE	Optic ischaemic neuropathy	Pending	SFDA is validating this potential risk
DUPILUMAB	Cutaneous T-cell lymphoma	Pending	SFDA is validating this potential risk
COLISTIMETHATE SODIUM	Pseudo-Bartter syndrome	Pending	SFDA is validating this potential risk
CITALOPRAM	Cutaneous vasculitis	Pending	SFDA is validating this potential risk
CABOZANTINIB	Cardiac failure	Pending	SFDA is validating this potential risk
ERDAFITINIB	Cataract	Pending	SFDA is validating this potential risk
CERITINIB	Optic neuropathy	Pending	SFDA is validating this potential risk
LORLATINIB	Optic neuropathy	Pending	SFDA is validating this potential risk
BRIGATINIB	Optic neuropathy	Pending	SFDA is validating this potential risk
ALECTINIB	Optic neuropathy	Pending	SFDA is validating this potential risk
INSULIN ASPART	Depression	Pending	SFDA is validating this potential risk
TAMSULOSIN;TOLTERODINE	Dreaming abnormal	Pending	SFDA is validating this potential risk
TAMSULOSIN HYDROCHLORIDE;TOLTERODINE L-TARTRATE	Redness of eyes - Epiphora - Otagia - Rash - Itching	Pending	SFDA is validating this potential risk
BENRALIZUMAB	Optic neuritis - Arthralgia	Pending	SFDA is validating this potential risk
PREDNISOLONE	Endophthalmitis	Pending	SFDA is validating this potential risk
OFLOXACIN HYDROCHLORIDE	Endophthalmitis	Pending	SFDA is validating this potential risk

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

Active Ingredient	Adverse Event	Status	Outcome
RISANKIZUMAB	Neutropenia	Closed	Valid
ERTAPENEM SODIUM	Stevens Johnson syndrome	Closed	Valid
PREDNISOLONE	Respiratory failure	Closed	Valid
ELRANATAMAB	Haemophagocytic lymphohistiocytosis	Closed	Refuted
TEZEPELUMAB	Epistaxis	Closed	Refuted
CILTACABTAGENE AUTOLEUCCEL	Progressive multifocal leukoencephalopathy	Closed	Refuted
ESOMEPRAZOLE	Dementia	Closed	Refuted
VITAMIN B COMPLEX	Bad taste	Closed	Valid
TOZINAMERAN	Cardiac failure	Closed	Refuted
DASABUVIR	Increased appetite	Closed	Valid



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