SFDA SAFETY SIGNAL

"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"

01-02-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Daratumumab and the Risk of Conjunctivitis

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Conjunctivitis** associated with the use of **Daratumumab**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Daratumumab injection is used alone or together with other medicines to treat multiple myeloma (a type of bone marrow cancer). It is used alone in patients who have received at least 3 prior treatments that did not work well, including a proteasome inhibitor and an immunomodulatory agent, or who did not respond to both agents. [1] Conjunctivitis, the inflammation or infection of the conjunctiva, represents the most prevalent cause of eye redness in both primary care and the emergency department. The etiology of this condition could be infectious or noninfectious; the most common is viral conjunctivitis, followed by bacterial conjunctivitis, and among noninfectious etiologies, the most common etiologies are allergic and toxin-induced conjunctivitis. [2] The aim of this review is to evaluate the risk of Conjunctivitis associated with the use of Daratumumab and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the potential link between Conjunctivitis and Daratumumab use. The search conducted on December 2025.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 9 global case reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied WHO causality assessment tool on all cases. [3] Among them, one case was probably linked to Daratumumab, one case resulted in possible association, and seven cases were unassessable due to insufficient information.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (-1.5) for this drug/ADR combination which reflects negative statistical association. [3]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Daratumumab. The search identified one published study suggesting a possible association between the drug and this potential risk. Furthermore, The ADR is listed in Canadian drug monograph. [4], [5].

Conclusion

The weighted cumulative evidence identified from assessed cases, and literature are suggestive for causal association between Daratumumab and Conjunctivitis. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References

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5. Approved Product Monograph 1.docx EDMS-RIM-1127087 v.5.0 Darzalex (daratumumab for injection) PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION Pr DARZALEX® daratumumab for injection 20 mg/mL Concentrate for Solution for Infusion Professed Standard Antineoplastic, monoclonal antibody ATC Code L01FC01 (no date). Available at: https://pdf.hres.ca/dpd_pm/00075445.PDF.