



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”

08-10-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Omalizumab and the Risk of Acquired haemophilia

*The Saudi Food and Drug Authority (SFDA) recommends that all healthcare professionals be aware of the safety signal of **Acquired haemophilia** associated with the use of **Omalizumab**. The signal originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Omalizumab is indicated for allergic asthma in adults, adolescents and children (6 to < 12 years of age). It's a recombinant DNA-derived humanised monoclonal antibody that selectively binds to human immunoglobulin E (IgE) and prevents binding of IgE to FcεRI (high-affinity IgE receptor) on basophils and mast cells, thereby reducing the amount of free IgE that is available to trigger the allergic cascade.^[1] Acquired hemophilia is an uncommon but severe bleeding disorder. It is caused by the development of autoantibodies directed against one of the antihemophilic factors, most frequently factor VIII (FVIII).^[2] This review aims to evaluate this potential risk and to suggest regulatory recommendations if required.

Methodology

The Signal Detection Team at SFDA performed a signal review using the National Pharmacovigilance Center (NPC) database and the World Health Organization (WHO) database, Vigibase, along with a literature review to retrieve all relevant information and assess the potential link between acquired haemophilia and omalizumab use.

Results

Cases Review: The Signal Detection Team at SFDA searched the Saudi national database and the WHO database to identify individual case safety reports (ICSRs). The WHO database yielded 14 global case reports. The authors used the signal detection tool (VigiLyze) to retrieve global cases.^[3] The authors applied the WHO causality assessment tool to all cases. Four cases were considered probably associated with omalizumab, four cases were assessed as possibly to be associated, and the remaining 6 cases were unassessable.

Datamining: The disproportionality between the observed and expected reporting rates for a drug/adverse drug reaction (ADR) pair is estimated using the Information Component (IC), a tool developed by WHO-UMC to measure the reporting ratio. A positive IC reflects a higher statistical association, while negative values indicate a lower statistical association. The IC result for this drug/ADR combination was 2.9, reflecting a positive statistical association.^[3]



Literature: The Signal Detection team reviewed regulatory sources and published literature to identify evidence linking omalizumab to the risk of acquired haemophilia. The result shows multiple relevant evidence supporting this signal ^[4-8]

Conclusion

The cumulative weight of evidence identified from global cases, literature, and disproportionality analysis suggests a potential causal association between omalizumab and acquired haemophilia. Healthcare professionals and health regulators should be aware of this potential risk in patients receiving omalizumab.

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@sfd.gov.sa

References

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