SFDA

Safety communication

[XX/04/2022]

Potential Risk of Acute Generalized Exanthematous Pustulosis (AGEP) Associated with the Use of Tocilizumab

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the potential risk of Acute Generalized Exanthematous Pustulosis (AGEP) associated with the use of Tocilizumab.

Tocilizumab is a recombinant humanized monoclonal antibody that is approved by the SFDA for treatment of rheumatoid arthritis, systematic juvenile idiopathic arthritis and polyarticular juvenile idiopathic arthritis. AGEP is a rare skin reaction marked by an acute onset of rash, non-follicular pustules on an erythematous base, fever and neutrophilia. AGEP is classified as a T cell-mediated type IV hypersensitivity reaction that in 90% of the cases it begins usually within 48 hours after drug exposure. The incidence rate of AGEP is 1-5 cases per million in the general population and it is more common in women.

We reviewed case reports published in the literature and cases retrieved from post marketing databases on the potential risk of AGEP associated with tocilizumab use. Our review found two published case reports suggesting a possible association between AGEP and tocilizumab use. In addition, we identified cumulative 4 spontaneous case reports in the World Health Organization (WHO) database, reported in adult women who were treated for rheumatoid arthritis; two cases in Japan and one each in Australia and Colombia. In three out of four cases, the event was assessed as treatment-related. Two out of the four cases were serious but majority (3 out of 4 cases) were recovering at the time the report was made. Age ranges in most cases were between 30 to 48 years old.

Therefore, the SFDA requests to update the product information of tocilizumab by adding AGEP as post-marketing adverse event.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):
Fax: +966-11-205-7662 SFDA
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.s