March 2025

Direct Healthcare Professional Communication

Tocilizumab [ACTEMRA®]: Associated Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Dear Healthcare professional,

Roche Products Saudi Arabia in agreement with The Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

SUMMARY

• Updated safety information of the product regarding drug reaction with eosinophilia and systemic symptoms (DRESS), identified from post marketing reports.

• SFDA has determined that this risk should be addressed in warnings and precautions section of the local Product Information.

BACKGROUND ON THE SAFETY CONCERN

ACTEMRA® is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

- **Rheumatoid Arthritis (RA)** Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
- **Giant Cell Arteritis (GCA)** Adult patients with giant cell arteritis.
- Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis associated interstitial lung disease.
- **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.
- **Systemic Juvenile Idiopathic Arthritis (SJIA)** Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.
- **Cytokine Release Syndrome (CRS)** Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or lifethreatening cytokine release syndrome.

The SFDA approved safety labeling changes to address the risk DRESS with ACTEMRA®, including an update to the Warnings and Precautions section of the local Product Information.

Prescriber Action

- Inform patients that some patients who have been treated with ACTEMRA® have developed serious allergic reactions, including anaphylaxis and DRESS.
- Advise patients to stop taking ACTEMRA® and seek immediate medical attention if they experience any symptom of serious allergic reactions (including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing).

CALL FOR REPORTING

Healthcare professionals should report any adverse events, which are suspected to be associated with the use of ACTEMRA®, in accordance with the requirements via the national spontaneous reporting systems to:

The National Pharmacovigilance Centre (NPC)
Land Line: 19999.
Web-page: http://ade.sfda.gov.sa
Email: npc.drug@sfda.gov.sa

Roche Products Saudi Arabia L.L.C.
Direct Tel. +966 11 439 1100
Mobile: +966 56 784 4692
Email: jeddah.drug_safety@roche.com

COMPANY CONTACT POINT

Should you have any questions regarding the use of ACTEMRA®, please feel free to contact us at *jeddah.medinfo@roche.com*

Yours sincerely,

Doha Samargandi, Patient Safety Lead
Roche Products Saudi Arabia LLC.

Signed by:
Doha Samargandi
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Farid Askar, Country Medical Director
Roche Products Saudi Arabia LLC.

Signed by:
Farid Askar
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