Genentech
A Member of the Roche Group

November 2024

Subject: Serious Risk with Use of ACTEMRA® (tocilizumab injection, for intravenous or subcutaneous use): Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Dear Health Care Provider:

The purpose of this letter is to inform you of updated safety information for ACTEMRA® regarding drug reaction with eosinophilia and systemic symptoms (DRESS) in the US Prescribing Information (USPI).

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 life-threatening cytokine release syndrome.
- **Coronavirus Disease 2019** (COVID-19) Adult hospitalized patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Serious Risk with Use of ACTEMRA®

Risk of drug reaction with eosinophilia and systemic symptoms (DRESS)

Safety information from post-marketing reports in the FDA Adverse Event Reporting System (FAERS) has shown evidence of the event of Drug reaction with eosinophilia

with systemic symptoms (DRESS), a severe adverse drug reaction characterized by an extensive skin rash in association with visceral organ involvement, lymphadenopathy, eosinophilia, and atypical lymphocytosis in patients treated with ACTEMRA®.

FDA has therefore determined that this risk should be addressed in WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS and PATIENT COUNSELING INFORMATION sections of the USPI, and in the Medication Guide.

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).

Reporting Adverse Events / Product Complaints and Company Contact

Health Care Providers should report any adverse events suspected to be associated with the use of ACTEMRA® to Genentech at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Please report any product complaint suspected to be associated with the use of ACTEMRA® to Genentech at (800) 334-0290.

Should you have any questions about the information in this letter or the safe and effective use of ACTEMRA®, please feel free to contact us at: Genentech Medical Information/Communications Department at (800) 821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of ACTEMRA®. Please refer to the enclosed full prescribing information.

Sincerely,

Toby Patterson, MBBS
Senior Vice President
Head of U.S. Medical Affairs