Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

April 2020

Subject: Actemra® (tocilizumab) 400 mg/20 mL vial for intravenous use

- Shipping short-dated vial with a dark blue cap, new vial, vial label and packaging configurations (NDC 50242-137-01)

Dear Health Care Provider:

The purpose of this letter is to inform you that Genentech will be shipping supply of Actemra® 400 mg/20 mL (NDC 50242-137-01) with dark blue colored vial caps. These lots are packaged with a different vial, vial label and carton configuration than the standard Actemra® 400 mg/20 mL with red cap. The two configurations have the same NDC, drug substance and formulation.

The introduction of this interim Actemra® 400 mg/20 mL configuration is due to an increase in prescriber demand from the COVID-19 outbreak. It is important to note that at present there are no studies demonstrating the safety or efficacy of Actemra® in clinical treatment of severe COVID-19 pneumonia, and U.S. Food & Drug Administration (FDA) has not approved Actemra® for use in this indication.

The interim Actemra 400mg/20mL vial configuration with the dark blue caps, will have **less than 6 months expiration dating**.

This table highlights differences between the Actemra® 400 mg/20 mL configurations:

Item	Standard Actemra® 400 mg/20 mL Vial with Red Cap	Interim Actemra® 400 mg/20 mL Vial with Dark Blue Cap
NDC	No Change to NDC (50242-137-01)	
Intended Use	• Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Systemic Juvenile Idiopathic Arthritis (SJIA) • Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (CRS)	
USPI	No change to the USPI (see attached)	
Vial and Cap	• Vial is taller and narrower • Vial cap is red, wider, with a flip cap overhang with a red seal	• Vial is shorter and wider • Vial cap is dark blue, narrower, with no flip cap overhang with a silver seal
Vial Label	• Vial label contains one peel-off label • Barcode located on the front of label	• Vial label does not contain a peel-off label • Barcode located on back of label (above lot and expiration date)
Tamper Evident Seal	• Hologram sticker applied to top of carton closure	• No sticker (carton glued closed)

Appearance *(Not actual size, for illustrative purposes only)*		

What's Not Changing

Genentech will continue to distribute Actemra® 400 mg/20 mL (NDC 50242-137-01) vials with red caps. Both vial types, cap colors, vial label and packaging configurations will be in the market at the same time.

There is no change to Actemra® 80 mg (NDC 50242-135-01), Actemra® 200 mg (NDC 50242-136-01), Actemra® 162 mg/0.9 mL prefilled syringe (NDC 50242-138-01) or Actemra® 162 mg/0.9 mL single-dose autoinjector (ACTPen™) (NDC 50242-143-01) configurations.

Prescriber and Pharmacist Actions

Please follow instructions for Preparation and Administration as per the current USPI Section 2.7. Generate and affix an appropriate label to the infusion bag upon preparation as needed.

Maintain, distribute, administer all short-dated inventory of this product through its expiration.

Reporting Adverse Events and Product Complaints

Health Care Providers should report any adverse events and product complaints suspected to be associated with the use of Actemra® to Genentech at 1-888-835-2555 and 1-800-334-0290 respectively.

Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Company Contact Point

Should you have any questions about the information in this letter or the safe and effective use of Actemra®, please feel free to contact the 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 full prescribing information and medication guide.

Sincerely,

Jamie Freedman

Jamie Freedman MD, PhD
Head of U.S. Medical Affairs