13.09.2021

Actemra® (tocilizumab) - Notification of Temporary Supply Shortage for solution for infusion (IV) & recommendations to manage potential risk of disease flare in patients

Dear Healthcare professional,

F. Hoffmann-La Roche Ltd in agreement with the European Medicines Agency and the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan would like to inform you of the following:

Summary

- Actemra®(tocilizumab) is expected to be temporarily in supply shortage in Armeniaas follows:
    - Actemra®20 mg/mL concentrate for solution for infusion (IV) is expected to be temporarily in supply shortage as of 20 August, 2021. Re-supply is expected by the end of December 2021. It will be informed additionally.
- During this supply interruption, please re-assess your patient's current overall disease condition, treatment regimen, and the potential risk of flare (if Actemra doses are missed for the duration of the shortage of 16 weeks.
- A risk of "flare-up" (increased disease activity/worsening symptoms) in the approved indications for IV (Rheumatoid Arthritis (RA) (adults), Polyarticular Juvenile Idiopathic Arthritis (pJIA) (2 years and older), Systemic Juvenile Idiopathic Arthritis (sJIA) (1 year and older)) cannot be excluded if patients miss one or more scheduled doses of Actemra due to this temporary shortage.
- Alternative treatment options are available for patients at risk of a flare-up (please also refer to appropriate treatment guidelines):
    - for Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis and Systemic Juvenile Idiopathic Arthritis
    - Where neither SC nor IV are available or at the HCP`s discretion: consider adding/increasing the dose of conventional/biological/targeted oral DMARDs and/or glucocorticoids

In some circumstances, patients may have to attend their hospital/clinic for administration of alternate treatment.

Background on the shortage

Actemra®(tocilizumab) is indicated for:

- Rheumatoid Arthritis (RA) in adult patients (IV)

- Polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older (IV)
- Systemic Juvenile Idiopathic Arthritis (sJIA) in patients 2 years of age and older (IV)

The purpose of this communication is to inform you about an upcoming temporary supply shortage for Actemra 20 mg/mL concentrate for solution for infusion, and to provide options to be considered to mitigate any potential risk of flare to the patients during this supply shortage.

This supply shortage has not arisen due to any safety concern. During the COVID-19 pandemic, the demand for Actemra has been increasing at an unprecedented rate globally.

Roche has carefully considered various options for how to best manage this gap between supply and demand. For Actemra IV, the situation is being proactively managed on a continual basis. It is aimed to minimize impact on any individual patient. However, different countries will be impacted at different times, dependent on the current inventories, and it cannot be ruled out that some countries may experience a shortage of Actemra IV at the same time. Different countries will be impacted at different times depending on the current inventory; the dates the supply shortage is expected to last in your country is communicated both below and in the Summary section above.

Roche is urgently working to increase manufacturing capacity and supply by extending the production network, and through active collaboration with external partners to maximise the production of Actemra, wherever possible with the goal of increasing the available supply globally.

Based on the current data, we expect to be in supply shortage for Armenia as follows:

- **A shortage of Actemra is expected as of 20 August, 2021. Re-supply is expected by the end of December, 2021.**

Call for reporting

Health care professionals should report any adverse events suspected to be associated with the use of Actemra (tocilizumab) to: SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELYAN CJSC via following contacts: address: 49/4 Komitas av., 0051 Yerevan, Armenia; tel.: (374 60 830073); HOT LINE: (+ 374 10) 20-05-05, (+374 10) 22-05-05 email: vigilance@pharm.am.

Also you may contact to Gayane Ghazaryan, Medical Manager / Local Safety Responsible for F.Hoffmann La Roche products in Armenia via following contacts: mob.: +374 91 796688, email: gayaneh.ghazaryan@gmail.com; or back up, Nune Karapetyan, via following contacts: mob: +374 91 721153 or email: nune.karapetyan.roche@gmail.com, or direct your reports to Roche Georgia LLC., via following contacts: tel.: Tel: 995 322 505284; 995 322 506284; Tel: 995 322 507284; Mob: 995 577 260552; E-mail: georgia.safety@roche.com.

Company contact point

Should you have any questions regarding the use of Actemra, please feel free to contact us at: Yerevan 0014, Azatutyan str.27, room N 707 to Gayane Ghazaryan, or via mob.phone: +374 91 796688, email: gayaneh.ghazaryan@gmail.com; or Nune Karapetyan, via mob.phone: +374 91 721153 or email: nune.karapetyan.roche@gmail.com., or Roche Georgia LLC., via following contacts: tel.: Tel: 995 322 505284; 995 322 506284; Tel: 995 322 507284; Mob: 995 577 260552; Email: elen.kharaishvili@roche.com.

Yours sincerely,
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