Direct Healthcare Professional Communication

28 September 2021

RoActemra (tocilizumab) - Temporary Supply Shortage RoActemra 20 mg/mL concentrate for solution for infusion (IV) & recommendations to manage potential risk of disease flare in patients

Dear Healthcare Professional,

Roche Registration GmbH in agreement with the European Medicines Agency and the Italian Medicines Agency would like to inform you of the following:

Summary

- RoActemra 20 mg/mL concentrate for solution for infusion (IV) is expected to be temporarily in supply shortage in Italy as of **16/09/2021**. Re-supply is expected by **21/12/2021.**

- Stopping treatment with RoActemra in case of shortage could lead to a flare-up (increased disease activity/worsening symptoms) in the following approved indications for IV formulations: Rheumatoid Arthritis (RA) (adults), Polyarticular Juvenile Idiopathic Arthritis (pJIA) (2 years and older), Systemic Juvenile Idiopathic Arthritis (sJIA) (2 years and older).

- You should therefore re-assess the patient's current overall disease condition, treatment regimen, and the potential risk of flare (if RoActemra doses are missed for the duration of the shortage of approximately 14 weeks).

- Alternative treatment options are available for patients at risk of a flare-up:

    - for RA, pJIA and sJIA

        - For RA, sarilumab SC is also authorized; consider whether transitioning the patient to this medicinal product may be appropriate.

        -If IV is out of supply, start tocilizumab SC at the next scheduled IV dose. Once the shortage is resolved, IV tocilizumab can be reintroduced ~ 2 weeks after the last SC injection.

        -If neither SC nor IV tocilizumab is available or at the healthcare professional`s discretion: consider adding/increasing the dose of conventional/biological/targeted oral DMARDs and/or glucocorticoids.

    - for CAR-T cell-induced cytokine-release syndrome (CRS): as only tocilizumab IV is approved for CRS, the MAH is committed to supplying ev

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

Background information and potential impact of stopping treatment

RoActemra (tocilizumab) is indicated for:

- Rheumatoid Arthritis (RA) in adult patients (SC and IV)
- Polyarticular Juvenile Idiopathic Arthritis (pJIA)
  - in patients 2 years of age and older
- Systemic Juvenile Idiopathic Arthritis (sJIA)
  - in patients 2 years of age and older (IV)
- CAR-T induced Cytokine Release Syndrome (CRS) in adult patients and paediatric patients 2 years of age and older (IV only).

In Italy, tocilizumab e.v. it is also used for the hospitalized adults with severe COVID-19 and/or with high levels of systemic inflammatory indices (Law 648/1996). The authorization of alternative treatments is being evaluated.
https://www.aifa.gov.it/documents/20142/1525693/Allegato-1_tocilizumab_18.06.2021.pdf

The purpose of this communication is to inform you about a temporary supply shortage for RoActemra 20 mg/mL concentrate for solution for infusion (RoActemra IV), 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, only e.v formulation is affected. The demand for RoActemra has been increasing at an unprecedented rate globally. Tocilizumab s.c formulation is not currently in supply shortage.

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

A risk of "flare-up" (increased disease activity/worsening symptoms) cannot be excluded if patients miss one or more scheduled doses of RoActemra due to this temporary shortage. Alternative treatment options are available for patients at risk of flare-up as described 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 RoActemra wherever possible with the goal of increasing the available supply globally.

Based on the current data, a shortage of RoActemra IV is expected as of 16/09/2021. Re-supply is expected by 21/12/2021.

Call for reporting

Health care professionals should report any adverse events suspected to be associated with the use of RoActemra (tocilizumab) to: <Insert local contact information>.

To be modified dependent on country: <Details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>