Direct Healthcare Professional Communication

08th September 2021

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

Dear Healthcare Professional,

Roche Products (Ireland) Limited in agreement with the European Medicines Agency and the Malta Medicines Authority (MMA) would like to inform you of the following:

Summary

- RoActemra (tocilizumab) is expected to be temporarily in supply shortage in **Malta** as follows:
    - RoActemra 20 mg/mL concentrate for solution for infusion (IV) is expected to be temporarily in supply shortage from mid-September until December 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 and/or SC formulations: Rheumatoid Arthritis (RA) (adults), Giant Cell Arteritis (GCA) (adults), Polyarticular Juvenile Idiopathic Arthritis (pJIA) (2 years and older), Systemic Juvenile Idiopathic Arthritis (sJIA) (1 year 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).
- Alternative treatment options are available for patients at risk of a flare-up (please also refer to appropriate treatment guidelines):
    - for RA, pJIA and sJIA

      -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 GCA: as tocilizumab IV is not approved for GCA, if SC is out of supply, alternative treatment options may include re-initiating or increasing the dose of other treatments (e.g. corticosteroids).

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- for CAR-T cell-induced cytokine-release syndrome (CRS): as only tocilizumab IV is approved for CRS, if IV is out of supply please refer to CRS treatment guidance for other potential alternatives.

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)
- Giant Cell Arteritis (GCA) in adult patients, SC only
- Polyarticular Juvenile Idiopathic Arthritis (pJIA)
  - in patients 2 years of age and older (pre-filled syringe and IV)
  - in patients 12 years of age and older (pre-filled pen)
- Systemic Juvenile Idiopathic Arthritis (sJIA)
  - in patients 1 years of age and older (pre-filled syringe)
  - in patients 2 years of age and older (IV)
  - in patients 12 years of age and older (pre-filled pen)
- CAR-T induced Cytokine Release Syndrome (CRS) in adult patients and paediatric patients 2 years of age and older (IV only)

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. The demand for RoActemra 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 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, we expect to be in supply shortage for Malta as follows:

- **A shortage of RoActemra IV is expected from mid-September until December 2021.**

Call for reporting

Health care professionals should report any adverse events suspected to be associated with the use of RoActemra (tocilizumab) to: the Drug Surveillance Centre in Roche Products (Ireland) Limited by telephone (01-4690700) or email (Ireland.drug_surveillance_centre@roche.com).

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form available online at http://www.medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt.

Company contact point

Should you have any questions regarding the use of RoActemra (tocilizumab), please feel free to contact us Medical Information at Roche Products (Ireland) Limited by telephone (01 4690700) or email (Ireland.druginfo@roche.com).

Yours sincerely,

DocuSigned by:

Signer Name: James Mawby
Signing Reason: I approve this document
Signing Time: 06-Sep-2021 | 10:07:32 AM CEST
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Dr. James Mawby

Medical Director