Allergic reactions

Serious allergic reactions including anaphylaxis have been reported in association with RoActemra. Such reactions may be more severe, and potentially fatal, in patients who have experienced allergic reactions during previous treatment with RoActemra.

IV infusion (in the clinic)
During the infusion, the doctor or nurse will be monitoring you/your child closely for any signs of an allergic reaction.

SC injections (in the clinic or at home)
The doctor will assess your/your child's suitability to use RoActemra SC injections at home.

If you/your child experience any symptoms suggestive of an allergic reaction such as chest tightness, wheezing, severe dizziness or lightheadedness, swelling of the lips, tongue, face or skin itching, hives or rash during or after the injection, tell the doctor immediately. You/your child should **not** take the next dose until you have informed the doctor AND the doctor has told you/your child to take the next dose.

The patient should seek immediate medical attention and RoActemra should be stopped immediately and permanently discontinued if a severe hypersensitivity reaction (also known as anaphylaxis) occurs. Symptoms include the following:

- Rash, itching or hives
- Shortness of breath or trouble breathing
- Swelling of the lips, tongue or face
- Chest pain or chest tightness
- Feeling dizzy or faint
- Severe stomach pain or vomiting
- Very low blood pressure

Hepatotoxicity

If you/your child has **liver disease**, tell your doctor. Before you/your child uses RoActemra, your doctor may do a blood test to measure your/your child's liver function. Increases in a specific set of blood laboratory tests called liver enzymes have been seen commonly in the blood of patients with RoActemra. You/your child will be monitored closely for changes in liver enzymes in the blood during treatment with RoActemra and appropriate action taken by your doctor.

Cases of liver failure resulting in liver transplantation have been reported. Patients should be advised to immediately seek medical help if they experience signs and symptoms of liver injury. Rare side effects may affect up to 1 in every 1,000 users and includes inflammation of the liver (hepatitis) and jaundice. Very rare side effects may affect up to 1 in every 10,000 users and can include liver failure.

Tell your doctor immediately if you notice a yellowing of the skin and eyes, have dark brown coloured urine, pain or swelling in the upper right side of the stomach area or you feel very tired and confused. You/your child might not have any symptoms in which case this increase in liver enzymes will be detected during blood tests.

Call for reporting

For full information on all possible side effects please see the RoActemra Package Leaflet, which can be found at the EMA website (www.ema.europa.eu) or www.medicines.ie.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:
Post: The Drug Surveillance Centre,
Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24.
Telephone: 00 353 (0)1 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:

http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

MT v25.1.0
Zinc Number: IE/RACTE/1119/0014c
Date of Preparation: November 2019
Date of Malta Medicines Authority Approval: December 2019

FOR USE IN MALTA

RoActemra® (tocilizumab) (SC and IV)
Patient Alert Card

Please read this card along with the Package Leaflet supplied with this medicine or also available on www.ema.europa.eu and www.medicines.ie before taking this medicine.

This Patient Alert Card contains important safety information that you need to be aware of before and during treatment with RoActemra.

This Patient Alert Card must be read together with the RoActemra Patient Brochure (provided by your doctor) and the RoActemra Package Leaflet that comes with your medication (and is also available on www.ema.europa.eu and www.medicines.ie) as it contains important information about RoActemra including Instructions for Use.

Note: this card is for use by RoActemra patients (or their parents/guardians if the patient is a child).

Keep this card with you for at least 3 months after your/your child's last RoActemra dose since side effects could occur 3 months or more after the last dose of RoActemra. If you/your child experience any untoward effects and have been treated with RoActemra in the past, contact the healthcare professional for advice.

Dates of RoActemra treatment:*

Start: _____

Most recent: _____

Route of administration:

Under the skin (subcutaneous, SC) injection

Into the vein (intravenous, IV) infusion

Next scheduled administration:_____

** Please make sure you also have a list of all your other medicines with you at any visit to a healthcare professional.*

Contact Information

Patient's Name:_____

Doctor's Name:_____

Doctor's Phone: _____

RoActemra Patient Alert Card

This Patient Alert Card contains important safety information that you need to be aware of before and during treatment with RoActemra.

- Show this card to ANY healthcare professional involved in your/your child's care

This Patient Alert Card must be read together with the RoActemra Package Leaflet that comes with your/your child's medication (and also available on www.medicines.ie) and RoActemra Patient Brochure (provided by your doctor) as they contain important information about RoActemra including Instructions for Use.

Infections

RoActemra can reduce your body's ability to respond to infections and may make an existing infection worse or increase the chance of getting a new infection. You/your child should not receive RoActemra if you have an active serious infection. In addition, some previous infections may reappear with use of RoActemra.

- Infections can become serious if not treated so tell your/your child's doctor immediately if signs/symptoms of infection develop such as:
  - Fever and chills
  - Persistent cough
  - Weight loss
  - Throat pain or soreness
  - Wheezing
  - Red or swollen skin or mouth blisters, skin tears or wounds
  - Severe weakness or tiredness
  - Stomach ache
- Before starting treatment with RoActemra, tell the doctor if you/your child have recently been vaccinated and talk to the doctor about any vaccinations that you/your child may need. Patients should be up-to-date with all their vaccinations before they start treatment with RoActemra
- Seek immediate medical advice if you/your child develop any signs/symptoms suggestive of a tuberculosis infection (such as persistent cough, wasting/weight loss, listlessness, mild fever) during or after treatment with RoActemra. You/your child should have been screened and found to have no active tuberculosis prior to treatment with RoActemra
- Younger children may be less able to communicate their symptoms; therefore parents/guardians/caregivers of younger children should contact the doctor immediately if their child is unwell for no apparent reason
- Seek guidance from your/your child's doctor about whether the next treatment should be delayed if you/your child have an infection of any kind (even a head cold) at the time of your scheduled treatment

Complications of diverticulitis

You/your child may develop complications of diverticulitis, which can become serious if not treated.

- **Seek immediate medical attention** if you/your child develop stomach pain or colic with a change in bowel habits and fever, or notice blood in your/your child's stool
- Inform the doctor if you/your child have or have had intestinal ulceration or diverticulitis (inflammation in parts of the large intestine)