

RoActemra® (tocilizumab) Patient Alert Card

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to minimise important selected risks

This patient alert card contains important safety information that patients and their parents/guardians need to be aware of before, during and after treatment with RoActemra. RoActemra treatment may be administered as an intravenous (IV) infusion or subcutaneous (SC) injection

- Show this card to ANY healthcare professional involved in you or your child's care
- Read the RoActemra Package Leaflet for more information

Date of preparation: December 2014 RXUKACTE00045

General

- As a Rheumatoid arthritis (RA) patient your treatment may be administered as an IV infusion or SC injection. As a polyarticular or systemic juvenile idiopathic arthritis (pJIA/sJIA) patient the treatment will be IV infusion only

Infections

RoActemra increases the risk of getting infections, which can become serious if not treated. You or your child should not receive RoActemra if you have an active serious infection.

- **Seek immediate medical attention** if you or your child develop signs/symptoms of infection such as:
 - Fever
 - Persistent cough
 - Weight loss
 - Throat pain or soreness
 - Wheezing
 - Red or swollen skin blisters, skin tears or wounds
 - Severe weakness or tiredness
- Seek medical advice if any signs/symptoms (such as persistent cough, wasting/weight loss, low-grade fever) suggestive of a tuberculosis infection occur during or after treatment with RoActemra. You or your child should have been screened and found to have no active tuberculosis prior to treatment with RoActemra
- Talk to your healthcare professional about any vaccinations You or your child may need before you start treatment with RoActemra
- Seek guidance from your healthcare professional about whether you or your child should delay your next treatment if you have an infection of any kind (even a head cold) at the time of your scheduled treatment
- Younger children with pJIA/sJIA may be less able to communicate their symptoms therefore parents/guardians of pJIA or sJIA patients should contact their healthcare professional immediately if their child is unwell for no apparent reason

Allergic reactions

Most allergic reactions occur during the injection/infusion, or within 24 hours of RoActemra administration, although allergic reactions can occur at any time.

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. Fatal anaphylaxis has been reported during treatment with intravenous RoActemra.

- During an IV infusion, your doctor or nurse will be monitoring you closely for any signs of an allergic reaction. If an anaphylactic reaction, serious infusion related reaction or other serious allergic reaction occurs, administration of RoActemra should be stopped immediately, appropriate medical treatment initiated and RoActemra should be permanently discontinued
- **Seek immediate medical attention** if you or your child notice any of the following signs or symptoms of allergic reactions:
 - Rash, itching or hives
 - Shortness of breath or trouble breathing
 - Swelling of the lips, tongue or face
 - Chest pain
 - Feeling dizzy or faint
 - Severe stomach pain or vomiting
 - Very low blood pressure

Always tell your doctor before your or your child's next dose if you or your child experience any allergic reaction symptoms after receiving RoActemra.

Complications of diverticulitis

Patients using RoActemra may develop complications of diverticulitis, which can become serious if not treated.

- **Seek immediate medical attention** if you or your child develop stomach pain or colic, or notice blood in your stool

If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44(0)1707 367554.

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

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

Dates of RoActemra treatment:*

Start:

Route of administration:

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

Patient's/Parent's/Guardian's name:

Doctor's name:

Doctor's phone number: