RoActemra® (tocilizumab) Patient Alert Card

This educational material is provided by Roche Products Ltd 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 you need to be aware of before, during and after treatment with RoActemra. Your treatment may be administered as an intravenous (IV) infusion or subcutaneous (SC) injection

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

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General

- Your treatment may be administered as an IV infusion or SC injection

Infections

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

- **Seek immediate medical attention** if you 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 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 may need before you start treatment with RoActemra
- Seek guidance from your healthcare professional about whether you should delay your next treatment if you have an infection of any kind (even a head cold) at the time of your scheduled treatment

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 after marketing authorisation 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 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

If you have experienced any allergic reaction symptoms after your last SC injection of RoActemra do not administer the next dose until you have informed your doctor and your doctor has told you to take the next dose.

Complications of diverticulitis

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

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

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. Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal and sent by email to postlicensing.medicinesauthority@gov.mt or posted to ADR Reporting, The Medicines Authority Post-Licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA. 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 with you for at least 3 months after the last RoActemra dose, since side effects could occur for some time after your last dose of RoActemra. If you 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 name: _____

Doctor's name: _____

Doctor's phone number: _____