RoActemra® (tocilizumab) Patient Alert Card

This card is for both paediatric and adult patients. Use accordingly.

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.

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This patient alert card contains important safety information that patients or parents/guardians of patients 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 your care
- Read the RoActemra Package Leaflet for more information

General

- As a Rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or systemic juvenile idiopathic arthritis (sJIA) patient, your treatment may be administered as an IV infusion or SC injection. As a Giant Cell Arteritis (GCA) patient, your treatment will be by SC injection only.

Infections

You should not receive RoActemra if you have an active serious infection. In addition, some previous infections may reappear with use of RoActemra.

- Seek medical advice if any signs/symptoms (such as persistent cough, wasting/weight loss, low-grade fever) suggestive of a tuberculosis (TB) infection occur during or after treatment with RoActemra. You should have been screened and found to have no active TB 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

- 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.

- During an IV infusion, your doctor or nurse will be monitoring you closely for any signs of an allergic reaction

- For treatment with SC injections, your doctor will assess your suitability to use RoActemra SC injections at home. If you are administering at home and you experience any allergic reaction symptoms after receiving RoActemra, do not take the next dose until you have informed your doctor AND your doctor has told you to take the next dose
- **Seek immediate medical attention** and stop RoActemra immediately and permanently discontinue 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

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 fever and persistent stomach pain or colic with change in bowel habits, or notice blood in your stool
- Inform your doctor if you have or have had intestinal ulceration or diverticulitis (inflammation in parts of your large intestine).

Keep this card 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.

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. 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.

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: _____