RoActemra® Patient Alert Card

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.

- Show this card to any healthcare professional involved in your or your child's care
- Read the *What You Should Know About RoActemra* Patient Brochure and the package leaflet for more information

This material is provided by Roche Products Limited as a licence requirement for this medicine and forms part of the Risk Management Plan

For more information on RoActemra please see the RoActemra package leaflet that comes with your medicine

If you have any further questions, please ask your doctor, nurse or pharmacist

Dates of RoActemra Treatment:*

Start: .....

Most recent: .....

Next scheduled: .....

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

Patient's Name: .....

Parent's/Guardian's Name: .....

Doctor's Name: .....

Doctor's Phone: .....

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

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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 or your child have a 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 that you or your child may need before you or your child start treatment with RoActemra
- If you or your child have an infection of any kind (even a head cold) at the time of your or your child's next treatment, the infusion should be delayed until you or your child are feeling better
- Younger children with pJIA or 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 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 with RoActemra.

- During an infusion, your doctor or nurse will be monitoring you or your child closely for any signs of an allergic reaction. If an anaphylactic reaction or other serious allergic reaction occurs, administration of RoActemra should be stopped immediately and appropriate medical treatment initiated
- **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

Always tell your doctor before your or your child's next dose if you or your child experience any symptoms of an allergic reaction 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 if there is blood in your or your child's stool

Suspected adverse reactions associated with the use of RoActemra should be reported to: Medicines Authority Post-licensing Directorate 203. Level 3. Rue D'Argens, Gzira GZR 1368, or at: http://www.medicinesauthority.gov.mt/adrportal. Suspected adverse events should also be reported to Roche by phone on +44 (0)1707 367554, fax on +44 (0)1707 367582 or e-mail at welwyn.uk_dsc@roche.com.