RoActemra® (tocilizumab) Patient 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 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 Patient Information Leaflet that comes with your medicine for more information available at www.medicines.org.uk

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

RoActemra may make an existing infection worse or increase the chance of getting a new infection. You should not receive RoActemra if you have an active serious infection. In addition, some previous infections may reappear with use of RoActemra.

Patients, and parents/ guardians of sJIA or pJIA patients should...

- Seek medical advice if any signs/symptoms (such as persistent cough, wasting/weight loss, low-grade fever) suggestive of a tuberculosis (TB) infection occurring 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
- Tell your doctor immediately if you experience signs or symptoms of an infection. Some infections might become very serious and may require immediate treatment and hospitalisation
- 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

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)

Hepatotoxicity

RoActemra treatment can often cause an increase in a specific set of blood laboratory tests called 'liver enzyme' tests which are used to measure the function of your liver. Changes in these liver enzyme blood tests will be monitored regularly while you are receiving RoActemra.

On rare occasions, patients have experienced serious life-threatening liver problems, some of which have required liver transplant.

Rare side effects, which may affect up to 1 in every 1,000 patients receiving RoActemra, include inflammation of the liver (hepatitis) and jaundice (yellowing of the skin).

Very rarely (affecting 1 in every 10,000 patients receiving RoActemra) patients can experience 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
- Tell your doctor if you have liver disease before you receive RoActemra

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

Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, or the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

You should also report side effects to Roche Products Ltd by emailing the Roche Drug Safety Centre at 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: IV SC

** 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: