FOR USE IN MALTA

RoActemra® (tocilizumab)

Important Safety Information for Patients

This brochure provides key information to assist patients and their caregivers in understanding the safe use of RoActemra. Please read this document, the RoActemra Package Leaflet, and the RoActemra Patient Alert Card information carefully and save them as references.

If any of the information is not clear to you ask the doctor, nurse, or pharmacist to explain it. The information that you receive in these documents complements the information that you will receive from the doctor, nurse, or pharmacist.

This Patient Brochure contains important safety information that you need to be aware of before and during treatment with RoActemra.

This Patient Brochure must be read together with the RoActemra Patient Alert Card (provided by the doctor) and the RoActemra Package Leaflet that comes with the medication (and is also available on www.medicines.ie) as it contains important information about RoActemra including Instructions for Use.

Note: this brochure is for use by RoActemra patients (or their parents/ guardians if the patient is a child).

Please read this material along with the Package Leaflet supplied with this medicine or also available on www.ema.europa.eu www.medicines.ie before taking this medicine.

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Contents

How is RoActemra given?

RoActemra is given either as an intravenous (into a vein) (IV) infusion with a needle or subcutaneous (under the skin) (SC) injection using a pre-filled syringe or pre-filled pen.

Indications for Intravenous and Subcutaneous Formulation (PFS & PFP)

- RoActemra is used to treat adults with moderate to severe active rheumatoid arthritis (RA), an autoimmune disease, if previous therapies did not work well enough. RoActemra is usually given in combination with methotrexate. However, RoActemra can be given alone if your doctor determines that methotrexate is inappropriate. RoActemra can also be used to treat adults who have not had previous methotrexate treatment if they have severe, active and progressive rheumatoid arthritis.

Indications for both Intravenous and Subcutaneous Formulation (PFS only)

- RoActemra is used to treat children and adolescents, aged 2 years and over, with active polyarticular juvenile idiopathic arthritis (pJIA), an inflammatory disease that causes pain and swelling in one or more joints. It is used to improve the symptoms of pJIA and can be given in combination with methotrexate or alone.

Indications for Intravenous Formulation only

- RoActemra is used to treat children and adolescents, aged 2 years and over, with active systemic juvenile idiopathic arthritis (sJIA), an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash. It is used to improve the symptoms of sJIA and can be given in combination with methotrexate or alone.
- RoActemra is used to treat adults and children aged 2 years and over with severe or life-threatening cytokine release syndrome (CRS), a side-effect in patients treated with chimeric antigen receptor (CAR) T-cell therapies used to treat certain types of cancer.

Indications for Subcutaneous Formulation only (PFS & PFP)

- RoActemra is used to treat adults with a disease of the arteries called giant cell arteritis (GCA) caused by inflammation of the body's largest arteries, especially those that supply blood to the head and neck.

Indications for Subcutaneous Formulation only (PFS only)

- RoActemra is used to treat children and adolescents, aged 1 year and over, with active systemic juvenile idiopathic arthritis (sJIA), an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash. It is used to improve the symptoms of sJIA and can be given in combination with methotrexate or alone.

Before starting treatment with RoActemra

Before starting RoActemra, tell the doctor or nurse if you/your child:

- Has any signs of an infection (such as a fever, cough or headache), has a skin infection with open sores (chicken pox or shingles), is being treated for an infection, or gets frequent infections. Has diabetes or other conditions that increase the chance for infections.
- Has had tuberculosis (TB) or has been in close contact with someone who has had TB. The doctor will check for signs and symptoms of TB before starting RoActemra.
- Has had intestinal ulcers or diverticulitis.
- Has/had liver disease or viral hepatitis.
- Has recently been vaccinated (immunised), such as against MMR, or is scheduled to be vaccinated. Patients should be brought up to date with all vaccinations (immunisations) before starting RoActemra. Certain types of vaccines should not be administered while on RoActemra.
- Has cancer. Discuss with the prescriber if you should receive RoActemra.
- Has cardiovascular risk factors such as high blood pressure or high cholesterol.
- Has had any allergic reactions to previous medications, including RoActemra.
- Are taking any other medications. This includes oral medications, such as NSAIDs (e.g. ibuprofen), corticosteroids, methotrexate (MTX) and biologic drugs.

In addition, for patients with sJIA, tell the doctor or nurse if you/your child:

- Has a history of macrophage activation syndrome (activation and uncontrolled proliferation of specific blood cells).

This is not an exhaustive list, please refer to the Package Leaflet for further information.

During treatment with RoActemra

What tests will be done when receiving treatment with RoActemra?

At each visit to see your doctor or nurse, they may test your blood to help guide your/your child's treatment. Here are some things they may look at:

- **Neutrophils**
  Having enough neutrophils is important to help our bodies fight infections. RoActemra works on the immune system and can cause the number of neutrophils, a form of white blood cells, to drop. For this reason, your doctor may test to make sure you/your child have enough neutrophils and monitor for signs and symptoms of infection. If you/your child have a drop in neutrophils the doctor may decide to interrupt treatment, or potentially stop treatment with RoActemra altogether.

- **Platelets**
  Platelets are small blood components that help stop bleeding by forming clots. Some people who have taken RoActemra have had a drop in the number of platelets in their blood. In clinical trials, the drop in platelets was not associated with any serious bleeding. If you/your child have a drop in platelets the doctor may decide to interrupt treatment, or potentially stop treatment with RoActemra altogether.

- **Liver enzymes**
  Liver enzymes are proteins produced by your liver which may be released into your blood, sometimes indicating liver damage or disease. Some people who have taken RoActemra have had a rise in liver enzymes, which could be a sign of liver damage. Rises in liver enzymes were seen more often when medications that could be harmful to the liver were used with RoActemra. If you/your child have a rise in liver enzymes, the doctor may decide to change the dose of RoActemra, or of other medication, or potentially stop treatment with RoActemra altogether.

- **Cholesterol**
  Some people who have taken RoActemra have had a rise in blood cholesterol, which is a type of lipid (fat). If you have an increase in cholesterol, your doctor may prescribe a cholesterol-lowering medication.

Can patients have vaccinations during treatment with RoActemra?

RoActemra is a medication that affects the immune system and may lower the body's ability to fight infection. Immunisation with live or live-attenuated vaccines (which contain very small amounts of the actual germ or weakened germs, such as the measles, mumps, rubella (MMR) vaccine), should not be given during treatment with RoActemra. Patients should be brought up to date with all vaccinations (immunisations) before starting RoActemra. Please consult your HCP for further information regarding vaccination and RoActemra treatment.

What are the potential serious side effects of RoActemra?

Infections

RoActemra is a medication that affects your immune system. The immune system is important because it helps you fight infections. RoActemra can reduce your/your child's ability to fight infections and may make an existing infection worse or increase the chance of getting a new infection. Some infections may become serious while on RoActemra. Serious infections may require treatment and hospitalisation and in some cases may lead to death.

Seek immediate medical attention if you or your child develop signs/ symptoms of infection such as:

- Fever and chills
- Persistent cough
- Weight loss
- Throat pain or soreness
- Wheezing
- Red or swollen skin or mouth blisters, skin tears or wounds
- Severe weakness or tiredness
- Stomach ache

Tell your doctor immediately if you or your child develop any signs/ symptoms suggestive of a tuberculosis infection (such as persistent cough, wasting/weight loss, listlessness, mild fever) during or after treatment with RoActemra.

Allergic reactions

Most allergic reactions occur during injection or within 24 hours of RoActemra administration, although allergic reactions can occur at any time. Serious allergic reactions including anaphylaxis (an acute allergic or hypersensitivity reaction) 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 RoActemra.

- If an anaphylactic 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/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 or chest tightness
    - Feeling dizzy or faint
    - Severe stomach pain or vomiting
    - Very low blood pressure
- If you/your child have experienced any allergic reaction symptoms after receiving RoActemra or if RoActemra is given at home and you/your child experience any symptoms suggestive of an allergic reaction:
  - **Do not take the next dose until you have informed the doctor AND the doctor has told you/your child to take the next dose**.
  - **Always tell the doctor before the next dose if you/your child experience any allergic reaction symptoms after receiving RoActemra**.

Complications of diverticulitis (inflammation in parts of the large intestine)

Patients taking RoActemra have uncommonly experienced serious side effects in their intestines. Symptoms may include fever and persistent abdominal (stomach) pain with unexplained change in bowel habits. **Seek immediate medical attention** if you/your child develop any of these symptoms or notice blood in your stool.

Malignancies

Medicines which act on the immune system, like RoActemra, may increase the risk of malignancy.

Hepatotoxicity

If you/your child has **liver disease**, tell your doctor. Before you use RoActemra, your doctor may do a blood test to measure your/your child's liver function. Increases in a specific set of blood laboratory tests called liver enzymes have been seen commonly in the blood of patients with RoActemra. You/your child will be monitored closely for changes in liver enzymes in the blood during treatment with RoActemra and appropriate action taken by your doctor.

Cases of liver failure resulting in liver transplantation have been reported. Patients should be advised to immediately seek medical help if they experience signs and symptoms of liver injury. Rare side effects may affect up to 1 in every 1,000 users and includes inflammation of the liver (hepatitis) and jaundice. Very rare side effects may affect up to 1 in every 10,000 users and can include 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. You/your child might not have any symptoms in which case this increase in liver enzymes will be detected during blood tests.

Summary and Contact Information

This patient brochure reviews some of the most important information about RoActemra. Medicines are sometimes prescribed for purposes other than those listed. Do not use RoActemra for a condition for which it was not prescribed. Tell your doctor, nurse or pharmacist about any side effect you experience, bothers you or that does not go away. These side effects listed in this brochure are not all of the possible side effects that you could experience with RoActemra. Ask your doctor, nurse or pharmacist for more information. Talk to your doctor, nurse or pharmacist if you have any questions or problems.

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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:
Post: The Drug Surveillance Centre, Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24.
Telephone: 00 353 (0)1 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at: http://www.medicinesauthority.gov.mt/adrportal, and by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

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