RoActemra® (tocilizumab)

Important Safety Information for Patients

This brochure provides key information to help patients understand the safe use of RoActemra therapy.

This educational material is provided by Roche Products (Ireland) Limited and is mandatory as a condition of the marketing authorisation of RoActemra.

For more information on RoActemra, please see the Patient Information Leaflet (PIL) that comes with your medicine. If you have any further questions, please ask your doctor, nurse or pharmacist.

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How is RoActemra given?

RoActemra is administered 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.

Intravenous Formulation – Adult Patients

- RoActemra is indicated for the treatment of moderate to severe active Rheumatoid Arthritis (RA) in adult patients. RoActemra can be given alone (in case of intolerance to methotrexate [MTX] or where treatment with MTX is inappropriate) or in combination with MTX and/or other disease-modifying anti-rheumatic drugs (DMARDs).
- RoActemra is indicated for chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS).

Subcutaneous Formulation – Adult Patients

- RoActemra is indicated for the treatment of moderate to severe active RA in adult patients, who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. RoActemra can be given alone (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX and/or other DMARDs.
- RoActemra is indicated for adult patients with giant cell arteritis (GCA).

Intravenous and Subcutaneous Formulations – Paediatric Patients

- RoActemra is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older (for RoActemra subcutaneous [SC]), and in patients 2 years of age and older (for RoActemra intravenous [IV]), who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoActemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.
- RoActemra in combination with MTX is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis; also referred to as Juvenile Idiopathic Polyarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX.

Before starting treatment with RoActemra

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

- Have signs of an infection (such as a fever, cough or headache, have a skin infection with open sores (chicken pox or shingles), are being treated for an infection, or get frequent infections. Have diabetes or other conditions that increase the chance for infections.
- Have tuberculosis (TB) or have been in close contact with someone who has had TB. Your doctor should test you for TB before starting RoActemra.
- Have had intestinal ulcers or diverticulitis (inflammation in parts of your large intestine).
- Have/had liver disease, viral hepatitis.
- Have recently had a vaccination (immunisation), such as that for measles, mumps, rubella (MMR), or are scheduled to have one. You should be brought up to date with all immunisations before starting RoActemra. Certain types of vaccines should not be administered while on RoActemra.
- Have cancer. Discuss with your doctor or nurse if you should receive RoActemra.
- Have heart or circulatory disease such as high blood pressure or high cholesterol.
- Have had any allergic reactions to previous medications, including RoActemra.
- Have had or now have impaired lung function (e.g. interstitial lung disease, where inflammation and scarring in the lungs make it difficult to get enough oxygen).

In addition, for patients with sJIA, also tell the doctor or nurse if you:

- Have a history of macrophage activation syndrome (MAS).
- Are taking any other medications to treat sJIA. This includes oral medications, such as NSAIDs (e.g. ibuprofen), corticosteroids, methotrexate and biologic drugs.

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 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 have enough neutrophils and monitor for signs and symptoms of infection.

Platelets

Platelets are small blood components that help stop bleeding by forming clots. Some people taking 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.

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 have a rise in liver enzymes, your doctor should take care of this right away. Your doctor may decide to change your 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 MMR vaccine), should not be given during treatment with RoActemra.

What are the potential serious side effects of RoActemra?

Infections

RoActemra is a medication that affects your immune system. Your immune system is important because it helps you fight infections. Your ability to fight infections may be lowered with RoActemra. Some infections may become serious while on RoActemra. Serious infections may require treatment and hospitalisation. It is very important to report any signs of infection to your doctor or nurse right away.

Seek immediate medical attention if you 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

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 after marketing authorisation during treatment with intravenous 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.

Your doctor will assess you (or your caregiver) for your suitability to use RoActemra injections at home.

Seek immediate medical attention if you notice any of the following signs or symptoms of allergic reactions after receiving RoActemra:

- 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

Abdominal pain

Patients taking RoActemra have on rare occasions experienced serious side effects in their stomach and intestines. Symptoms may include fever and persistent abdominal pain with change in bowel habits. **Seek immediate medical attention** if you develop stomach pain or colic, or notice blood in your stool.

If you experience any of the above side effects, **do not take the next dose until you have informed your doctor** AND your doctor has told you to take the next dose.

Malignancies

Medicines which act on the immune system, like RoActemra, may increase the risk of malignancy. Your doctor will help you decide whether RoActemra treatment is right for you.

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 RoActemra 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 it to:
The Drug Surveillance Centre, Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest, Naas Road, Dublin 24.
Tel: 00 353 (0)1 4690700; Fax: 00 353 (0)1 4690793
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, report to:
Pharmacovigilance Section at Post-Licensing Directorate,
Medicines Authority, Sir Temi Żammit Buildings,
Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Reporting forms and information can be found at
www.medicinesauthority.gov.mt/adrportal

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions, problems or for more information.

Detailed information on this medicine is available on the European Medicines Agency website (www.ema.europa.eu) and online at www.medicines.ie

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