Actemra (tocilizumab)

Important Safety Information for Patients

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

If any of the information is not clear to you ask your physician, nurse, or pharmacist for clarification. The information that you receive in these documents complements the information that you will receive from your physician, nurse, or pharmacist.]

This Patient Brochure [is a requirement of the Actemra product license and] contains important safety information that you need to be aware of before and during treatment with Actemra. This Patient Brochure must be read together with the Actemra Patient Alert Card [provided by your physician] and the Actemra Package Leaflet that comes with your medication (and is also available on <insert website address>) as it contains important information about Actemra including Instructions for Use.

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Actemra® (tocilizumab)

How is Actemra given?

Actemra 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

- **Actemra is used to treat adults** with moderate to severe active rheumatoid arthritis (RA), an autoimmune disease, if previous therapies did not work well enough. Actemra is usually given in combination with methotrexate. However, Actemra can be given alone if your doctor determines that methotrexate is inappropriate.

- Actemra can also be used to treat adults who have not had previous methotrexate treatment if they have severe, active and progressive rheumatoid arthritis.

- **Actemra is used to treat children with sJIA**. Actemra is used for children aged 2 years and over who have a***ctive systemic juvenile idiopathic arthritis (sJIA)***, an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash. Actemra is used to improve the symptoms of sJIA and can be given in combination withmethotrexate or alone.

- **Actemra is used to treat children with pJIA.** Actemra is used for children 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. Actemra is used to improve the symptoms of pJIA and can be given in combination with methotrexate or alone.

Before starting treatment with Actemra® (tocilizumab)

Before starting Actemra, tell the doctor or nurse if the patient:

- Has 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 tuberculosis (TB) or has been in close contact with someone who has had TB. Your doctor should test you for TB before starting Actemra
- Has had intestinal ulcers or diverticulitis

- Has/had liver disease, viral hepatitis
- Has recently had a vaccination (immunisation), such as that for MMR, or is scheduled to have one. Patients should be brought up to date with all immunisations before starting Actemra. Certain types of vaccines should not be administered while on Actemra.
- Has cancer. Discuss with your prescriber if you should receive Actemra
- Has heart or circulatory disease such as high blood pressure or high cholesterol
- Has had any allergic reactions to previous medications, including Actemra
- Has had or now has 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 the patient:

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

During treatment with Actemra® (tocilizumab)

What tests will be done when receiving treatment with Actemra?

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. Actemra 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 Actemra 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 Actemra 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 Actemra. 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 Actemra, or of other medication, or potentially stop treatment with Actemra altogether.
- **Cholesterol.** Some people who have taken Actemra 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 Actemra?

Actemra 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 flu vaccine or the measles, mumps, rubella (MMR) vaccine), should not be given during treatment with Actemra.

What are the potential serious side effects of Actemra?

Infections. Actemra 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 Actemra. Some infections may become serious while on Actemra. Serious infections may require treatment and hospitalisation and in some cases may lead to death.

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

Abdominal pain.

Patients taking Actemra 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.

Malignancies. Medicinal products which act on the immune system, like Actemra, may increase the risk of malignancy.

Hepatotoxicity

If you have **liver disease**, tell your doctor. Before you use Actemra, your doctor may do a blood test to measure your liver function.

Liver problems: increases in a specific set of blood laboratory tests called liver enzymes have been seen commonly in the blood of patients treated with tocilizumab. You will be monitored closely for changes in liver enzymes in the blood during treatment with Actemra (tocilizumab) and appropriate action taken by your doctor.

On rare occasions, patients have experienced serious life-threatening liver problems, some of which have required liver transplant. Rare side effects, these may affect up to 1 in every 1,000 users, are inflammation of the liver (hepatitis), jaundice. Very rare side effects, these may affect up to 1 in every 10,000 users, is 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 might not have any symptoms in which case this increase in liver enzymes will be picked up during blood tests.

Side effects in children and adolescents with sJIA or pJIA
Side effects in children and adolescents with sJIA or pJIA are generally similar to those in adults. Some side effects are seen more often in children and adolescents: inflamed nose and throat, headache, feeling sick (nausea) and lower white blood cell counts.

Children and adolescents
Actemra pre-filled pen (ACTPen®) is not recommended for use in children under 12 years of age. Actemra must not be given to children with sJIA weighing less than 10 kg.

If a child has a history of ***macrophage activation syndrome*** (activation and uncontrolled proliferation of specific blood cells), tell your doctor. Your doctor will have to decide if they can still be given Actemra.

Call for reporting

Talk to the doctor, nurse or pharmacist if you or the patient have any questions or have any problems.

If the patient experiences any side effects, talk to the doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you or the patient can help provide more information on the safety of this medicine.

You can report side effects directly to the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan via contacts presented below: address: RA, Yerevan 0051, 49/5 Komitas avenue, tel.: (374 60) 830073, (+374 10) 230896, hot line: (+374 10) 200505; (+374 96) 220505; or email: vigilance@pharm.am; or via website: www.pharm.am.

Also to contact to Gayane Ghazaryan, Local person for Pharmacovigilance for Hoffmann-La Roche products in Armenia Acti Group LLC., via mob.: +374 91 796688 or email address: gayaneh.ghazaryan@gmail.com; or Nune Karapetyan, Local backup for Pharmacovigilance of Roche Products in Armenia, via mob.: +374 91 721153 or email address: nune.karapetyan.roche@gmail.com.

Or to contact to Local Safety Responsible, Roche Georgia LLC via tel: +995 322 506284, +995 322 507284 or emailing to georgia.safety@roche.com.

Gayane Ghazaryan Gayaneh Ghazaryan
Local person for Pharmacovigilance for Hoffmann- La Roche products in Armenia, Acti Group LLC

Nino Ganugrava Nino Ganugrava
Country Medical Director for Georgia/Armenia, Roche Georgia LLC.