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 www.pharm.am) 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

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

Allergic reactions. Most allergic reactions occur during injection or within 24 hours of Actemra administration, although allergic reactions can occur at any time. Serious allergic reactions including anaphylaxis have been reported in association with Actemra. Such reactions may be more severe, and potentially fatal in patients who have experienced allergic reactions during previous treatment with Actemra. Fatal anaphylaxis has been reported during treatment with Actemra.

- If an anaphylactic reaction or other serious allergic reaction occurs, administration of Actemra should be stopped immediately, appropriate medical treatment initiated, and Actemra should be permanently discontinued.
- **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 or chest tightness
  - Feeling dizzy or faint
  - Severe stomach pain or vomiting
  - Very low blood pressure
- If you have experienced any allergic reaction symptoms after receiving Actemra or if you are administering Actemra at home and you experience any symptoms suggestive of an allergic reaction:

- **Do not take the next dose until you have informed your doctor AND your doctor has told you to take the next dose**
- **Always tell the doctor before your next dose if you experience any allergic reaction symptoms after you receive Actemra.**

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.

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.

You can also report side effects directly via [the national reporting system]. By reporting side effects, you or the patient can help provide more information on the safety of this medicine.

Please report side-effects to **Actemra via** the national reporting system to the SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELYAN CJSC via following contacts:

Address: 49/4 Komitas av., 0051 Yerevan, Armenia.

HOT LINE: (+ 374 10) 20-05-05, (+374 10) 22-05-05

Email: vigilance@pharm.am

Also you may provide your report to the Local Safety Responsible of F.Hoffmann La Roche products in Armenia, Gayane Ghazaryan via following contacts:

Tel.: +374 91 796688

Email: gayaneh.ghazaryan@gmail.com

Or back up, Nune Karapetyan via following contacts:

Tel.: +374 91 721153

Email: nune.karapetyan.roche@gmail.com

Or direct your reports to Roche Moscow DS Hub via following contacts:

Tel.: +7-495-229 2999, Fax: +7-495- 229 7999

Email: moscow.ds@roche.com; website: www.roche.ru.

For full information on all possible side effects please see the Actemra Package Leaflet, which can be found at the SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELYAN CJSC website: www.pharm.am.

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