Actemra ® (tocilizumab) (IV)

Patient Alert Card

[This Patient Alert Card[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 alert card must be read together with the Actemra Patient Brochure [provided by your physician] and the Actemra Package Leaflet that comes with your medication (and is also available on www.pharm.am website) as it contains important information about Actemra including Instructions for Use.]

[Health Authority Approval Date: August, 2022]

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Keep this card with you for at least 3 months after the patient's last Actemra dose since side effects could occur for some time after the patient's last dose of Actemra. If the patient experiences any untoward effects and have been treated with Actemra in the past, contact the healthcare professional for advice [insert contact number].

Dates of Actemra Treatment:*

Start:.....…

Most recent:…….....

Route of administration: Into the vein

(intravenous, IV) infusion

IV

Next scheduled administration:…….

* Please make sure you also bring a list of all your other medicines with you at any visit to a healthcare professional.

Contact Information

Patient's Name:.....

Doctor's Name:.....

Doctor's Phone:.....

Actemra Patient Alert Card

This patient alert card contains important safety information that you need to be aware of before and during treatment with Actemra.

- Show this card to ANY healthcare professional involved in the patient's care

This patient alert card must be read together with the Actemra Package Leaflet and Actemra Patient Brochure that comes with your medication (and are also available on www.pharm.am website address>) as they contain important information about Actemra including Instructions for Use.

Infections

You should not receive Actemra if you have an active serious infection. In addition, some previous infections may reappear with use of Actemra.

- Talk to the patient's healthcare professional about any vaccinations the patient may need before starting treatment with Actemra

- Patients and parents/guardians of sJIA or pJIA patients should be advised to seek medical advice if the patient develops any signs/symptoms (such as persistent cough, wasting/weight loss, low-grade fever) suggestive of a tuberculosis infection occurring during or after treatment with Actemra. The patient should have been screened and found to have no active tuberculosis prior to treatment with Actemra
- Younger children may be less able to communicate their symptoms; therefore parents/guardians/caregivers of younger children should contact their healthcare professional immediately if their child is unwell for no apparent reason
- Seek guidance from the patient's healthcare professional about whether the patient should delay the next treatment if the patient has an infection of any kind (even a head cold) at the time of your scheduled treatment

Complications of diverticulitis

Patients using Actemra may develop complications of diverticulitis, which can become serious if not treated.

- **Seek immediate medical attention** if the patient develops stomach pain or colic with a change in bowel habits, or notice blood in their stool
- Inform your doctor if the patient has or has had intestinal ulceration or diverticulitis (inflammation in parts of the large intestine)

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 Actemra. 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 effect, 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.

It is essential to report any Suspected Adverse Events. It allows to assess the safety/efficacy of the product. HCP can report any Adverse Event online to SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACADEMICIAN E. GABRIELYAN CJSC of MOH RA via following contacts: website address: www.pharm.am or call: hotline (+ 374 10) 20-05-05, (+374 10) 22-05-05, email: vigilance@pharm.am.

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

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

For full information on all possible side effects please see the Actemra Package Leaflet, which can be found at the www,pharm.am website.

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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

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