Actemra ® (tocilizumab) (IV)

Patient Alert Card

[This Patient Alert Card is a requirement of the Actemra product licence 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) as it contains important information about Actemra including Instructions for Use.]

Health Authority Approval Date: *January, Year*

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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:.....

[Design features and logo to be added in layout following previous alert card design if local policy allows]

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) 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

Allergic reactions

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.

IV infusion (in the clinic)
During the infusion, the doctor or nurse will be monitoring the patient closely for any signs of an allergic reaction.
The patient should seek immediate medical attention and Actemra should be stopped immediately and permanently discontinued if a severe hypersensitivity reaction (also known as anaphylaxis) occurs. Symptoms include the following: • 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.

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.

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

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By reporting side effects, you or the patient can help provide more information on the safety of this medicine. You can report side effects according to the local requirements 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 96) 22-05-05

Email: vigilance@pharm.am

Also, please report side-effects to the following company contact point: Gayane Ghazaryan, Medical Manager, Local Safety Responsible of Hoffmann-La Roche products in Armenia/ LSR: mob.: +374 91 796688/ email: gayaneh.ghazaryan@gmail.com, or to Nune Karapetyan, mob: +374 91 721153/ email: nune.karapetyan.roche@gmail.com. Morever, direct your reports to Roche Moscow DS Hub via following contacts: tel.: +7-495-229 2999, Fax: +7-495- 229 7999/ email: russia.pvhub@roche.com; website: www.roche.ru.

Sincerely,

Gayane Ghazaryan, _____ 13.01.2021
Medical Manager, Local Safety Responsible of
Hoffmann-La Roche products in Armenia

Nune Karapetyan _____ 13.01.2021
Commercial Lead of Hoffmann-La Roche products in Armenia

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