Actemra ® (tocilizumab) (IV)

Patient Alert Card

This educational material is mandatory as a condition of the marketing authorisation of Actemra in order to further minimise important selected risks.

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Keep this card with you for at least 3 months after your or your child's last Actemra dose, since side effects could occur for some time after your or your child's last dose of Actemra. If you or your child 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

Next scheduled:.....

* 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]

Actemra Patient Alert Card

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

- Show this card to ANY healthcare professional involved in your care, or the child you care for,

The following materials contain important information about treatment with Actemra. Please read them:

- *What You Should Know About Actemra* Patient Brochure,
- The Actemra package leaflet (Patient Information Leaflet = PIL)
- Instructions for Use for more information
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Infections

Actemra increases the risk of getting infections, which can become serious or result in death if not treated. You, or the child you care for should not receive Actemra if you have active serious infections

- **Seek immediate medical attention** if signs/symptoms of infection develop, 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
  -

- Talk to your, or your child's, healthcare professional about any vaccinations you, or the child you care for, may need before starting treatment with Actemra
- Seek medical advice if you, or the child you care for develops any signs/symptoms (such as persistent cough, wasting/weight loss, low-grade fever) suggestive of a tuberculosis infection occur during or after treatment with Actemra. You, or the child you care for, 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/carers of younger children should contact their healthcare professional immediately if their child is unwell for no apparent reason

- Seek guidance from your, or your child's, healthcare professional about whether your, or the child you care for should delay the next treatment if
  - you, or your child, has an infection of any kind (even a head cold) at the time of your scheduled treatment

Allergic reactions

Most allergic reactions occur during or within 24 hours of Actemra administration (injection or infusion), 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 after marketing authorisation during treatment with intravenous Actemra.

IV infusion (in the clinic)
During the infusion, your doctor or nurse will be monitoring you closely for any signs of an allergic reaction.
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 in you, or the child you care for:
  - 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

Always tell the doctor before the next dose if you, or the child you care for, experience any allergic reaction symptoms after receiving Actemra

Complications of diverticulitis

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

- **Seek immediate medical attention** if you, or the child you care for, develop fever and persistent stomach pain or colic with change in bowel habits, or notice blood in your, or your child's, stool
- Inform your doctor if you, or the child you care for, has, or has had, intestinal ulceration or diverticulitis (inflammation in parts of your large intestine)

Talk to the doctor, nurse or pharmacist if you have any questions or you or the child you care for has problems.

If you get any side effects, talk to your 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 can help provide more information on the safety of this medicine.

Call for reporting

Consult the SmPC before prescribing, preparing or administering Actemra

For full information on all possible adverse events please see the Summary of Product Characteristics (SmPC) or the Patient Information Leaflet, which can be found at the at the website of Scientific Centre of Drug and Medical Technology Expertise after Academician Emil Gabrielyan" JSC via following adress: www.pharm.am .

Adverse reactions should also be reported to Roche Medical Information via the Company contact point, that is provided below:

Drug Safety Department of Roche Moscow via contacts as follows: email: moscow.ds@roche.com, mobile phone: +7-495-229 2999, fax: +7-495- 229 7999 or try website: www.roche.ru

Company contact point :

Local Safety Responsible for Roche products in Armenia, Gayane Ghazaryan, via following contacts: +37491796688, email address: gayaneh.ghazaryan@gmail.com or Rima Davtyan tel: +010734643, email address: rima@pharmatech.am .

Vahan Arushanyan

General Director, PharmaTech CJSC 27.11.18 _____

date / signature

Gayane Ghazaryan , Safety Responsible

for Roche products in Armenia, PharmaTech CJSC 26.11.18 _____

date / signature