

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, or the child you care for, care

The following materials contain important information about your 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

Infections

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

- **Seek immediate medical attention** if you develop signs/symptoms of infection such as:
 - Fever
 - Persistent cough
 - Weight loss
 - Throat pain or soreness
 - Wheezing
 - Red or swollen skin blisters, skin tears or wounds
 - Severe weakness or tiredness
- 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
- Talk to your healthcare professional about any vaccinations that you, or the child you care for, may need before starting treatment with ACTEMRA
- Seek guidance from your, or your child's, healthcare professional about whether you should delay your next treatment if you, or your child, has an infection of any kind (even a head cold) at the time of your scheduled treatment
- Younger children with pJIA or sJIA may be less able to communicate their symptoms therefore parents/guardians of pJIA or sJIA patients should contact their healthcare professional immediately if their child is unwell for no apparent reason

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:
 - Rash, itching or hives
 - Shortness of breath or trouble breathing
 - Swelling of the lips, tongue or face
 - Chest pain
 - Feeling dizzy or faint
 - Severe stomach pain or vomiting
 - Very low blood pressure

Do not take the next dose until you have informed your or your child's doctor AND your or your child's doctor has told you to take the next dose if you or your child have experienced 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 your child develop stomach pain or colic, or notice blood in your or your child's stool
- Inform your doctor if you or your child have or have had intestinal ulceration or diverticulitis

Reporting of side effects

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 to PharmaTech Safety department via mobile phone: +37491796688, or email: gayaneh.ghazaryan@gmail.com or direct your report to Drug Safety Department of Roche Moscow via contacts below: email: moscow.ds@roche.com, mobile phone: +7-495-229 2999, fax: +7-495- 229 7999 or try website: www.roche.ru.

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

Vahan Arushanyan, director of Pharmatech CJSC

Signature: _____

Date: 27.03.18

Gayane Ghazaryan, Safety Responsible for Roche Products in Armenia,

PharmaTech CJSC

Signature: _____

Date: 27.03.18