

## MEDICATION GUIDE

### ACTEMRA® (AC-TEM-RA) (tocilizumab)

#### Solution for Intravenous Infusion

### ACTEMRA® (AC-TEM-RA) (tocilizumab)

#### Injection, Solution for Subcutaneous Administration

Read this Medication Guide before you start ACTEMRA, before each infusion, or each time you get a prescription refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

#### **What is the most important information I should know about ACTEMRA?**

#### **ACTEMRA can cause serious side effects including:**

##### **1. Serious Infections.**

ACTEMRA is a medicine that affects your immune system. ACTEMRA can lower the ability of your immune system to fight infections. Some people have serious infections while taking ACTEMRA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

Your doctor should test you for TB before starting ACTEMRA.

- Your doctor should monitor you closely for signs and symptoms of TB during treatment with ACTEMRA.

You should not start taking ACTEMRA if you have any kind of infection unless your healthcare provider says it is okay.

Before starting ACTEMRA, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection, with or without a fever, such as:
  - sweating or chills
  - muscle aches
  - cough
  - shortness of breath
  - blood in phlegm
  - weight loss
  - warm, red, or painful skin or sores on your body
  - diarrhea or stomach pain
  - burning when you urinate or urinating more often than normal
  - feel very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB
- live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidiomycosis, or blastomycosis). These infections may happen or become more severe if you use

ACTEMRA. Ask your healthcare provider, if you do not know if you have lived in an area where these infections are common.

- have or have had hepatitis B

After starting ACTEMRA, call your healthcare provider right away if you have any symptoms of an infection. ACTEMRA can make you more likely to get infections or make worse any infection that you have.

## **2. Tears (perforation) of the stomach or intestines.**

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking ACTEMRA get tears in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.
- Tell your healthcare provider right away if you have fever and stomach-area pain that does not go away, and a change in your bowel habits.

## **3. Changes in certain laboratory test results.**

Your healthcare provider should do blood tests before you start receiving ACTEMRA, after the first 4 to 8 weeks for rheumatoid arthritis (after which tests should be done every 3 months), every 4 to 8 weeks for PJIA and every 2 to 4 weeks for SJIA during treatment to check for the following side effects of ACTEMRA:

- low neutrophil count. Neutrophils are white blood cells that help the body fight off bacterial infections.
- low platelet count. Platelets are blood cells that help with blood clotting and stop bleeding.
- increase in certain liver function tests.

You should not receive ACTEMRA if your neutrophil or platelet counts are too low or your liver function tests are too high.

Your healthcare provider may stop your ACTEMRA treatment for a period of time or change your dose of medicine if needed because of changes in these blood test results.

- increase in blood cholesterol levels. You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider should do blood tests to check your cholesterol levels 4 to 8 weeks after you start receiving ACTEMRA, and then every 6 months after that.

## **4. Cancer.**

ACTEMRA may increase your risk of certain cancers by changing the way your immune system works. Tell your healthcare provider if you have ever had any type of cancer.

See “What are the possible side effects with ACTEMRA?” for more information about side effects.

### **What is ACTEMRA?**

ACTEMRA is a prescription medicine called an Interleukin-6 (IL-6) receptor antagonist. ACTEMRA is used to treat:

- Adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a Disease Modifying Anti-Rheumatic Drug (DMARD) has been used and did not work well.
- People with active polyarticular juvenile idiopathic arthritis (PJIA) ages 2 and above.
- People with active systemic juvenile idiopathic arthritis (SJIA) ages 2 and above.

ACTEMRA is not approved for subcutaneous use in people with PJIA or SJIA.

It is not known if ACTEMRA is safe and effective in children with PJIA or SJIA under 2 years of age or in children with conditions other than PJIA or SJIA.

### **Who should not take ACTEMRA?**

Do not take ACTEMRA if you are allergic to tocilizumab, or any of the ingredients in ACTEMRA. See the end of this Medication Guide for a complete list of ingredients in ACTEMRA.

### **What should I tell my healthcare provider before receiving ACTEMRA?**

ACTEMRA may not be right for you. **Before receiving ACTEMRA, tell your healthcare provider if you:**

- have an infection. See “What is the most important information I should know about ACTEMRA?”
- have liver problems
- have any stomach-area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines
- have had a reaction to tocilizumab or any of the ingredients in ACTEMRA before
- have or had a condition that affects your nervous system, such as multiple sclerosis
- have recently received or are scheduled to receive a vaccine.
  - All vaccines should be brought up-to-date before starting ACTEMRA.
  - People who take ACTEMRA should not receive live vaccines.
  - People taking ACTEMRA can receive non-live vaccines
- plan to have surgery or a medical procedure
- have any other medical conditions
- plan to become pregnant or are pregnant. It is not known if ACTEMRA will harm your unborn baby.

Pregnancy Registry: Genentech has a registry for pregnant women who take ACTEMRA. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ACTEMRA, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll.

- plan to breast-feed or are breast-feeding. You and your healthcare provider should decide if you will take ACTEMRA or breast-feed. You should not do both.

**Tell your healthcare provider about all of the medicines you take**, including prescription and non-prescription medicines, vitamins and herbal supplements. ACTEMRA and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- any other medicines to treat your RA. You should not take etanercept (Enbrel<sup>®</sup>), adalimumab (Humira<sup>®</sup>), infliximab (Remicade<sup>®</sup>), rituximab (Rituxan<sup>®</sup>), abatacept (Orencia<sup>®</sup>), anakinra (Kineret<sup>®</sup>), certolizumab (Cimzia<sup>®</sup>), or golimumab (Simponi<sup>®</sup>), while you are taking ACTEMRA. Taking ACTEMRA with these medicines may increase your risk of infection.
- medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

### **How will I receive ACTEMRA?**

#### **Into a vein (IV or intravenous infusion) for Rheumatoid Arthritis, PJIA, or SJIA:**

- If your doctor prescribes ACTEMRA as an IV infusion, you will receive ACTEMRA from a healthcare provider through a needle placed in a vein in your arm. The infusion will take about 1 hour to give you the full dose of medicine.
- For rheumatoid arthritis or PJIA you will receive a dose of ACTEMRA about every 4 weeks.
- For SJIA you will receive a dose of ACTEMRA about every 2 weeks.
- If you miss a scheduled dose of ACTEMRA, ask your healthcare provider when to schedule your next infusion.
- While taking ACTEMRA, you may continue to use other medicines that help treat your rheumatoid arthritis, PJIA, or SJIA such as methotrexate, non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as instructed by your healthcare provider.
- Keep all of your follow-up appointments and get your blood tests as ordered by your healthcare provider.

#### **Under the skin (SC or subcutaneous injection) for Rheumatoid Arthritis:**

- **See the Instructions for Use at the end of this Medication Guide for instructions about the right way to prepare and give your ACTEMRA injections at home.**
- ACTEMRA is available as a single-use Prefilled Syringe.
- You may also receive ACTEMRA as injection under your skin (subcutaneous). If your doctor decides that you or a caregiver can give your injections of ACTEMRA at home, you or your caregiver should receive training on the right way to prepare and inject ACTEMRA. Do not try to inject ACTEMRA until you have been shown the right way to give the injections by your healthcare provider.
- Your healthcare provider will tell you how much ACTEMRA to use and when to use it.

### **What are the possible side effects with ACTEMRA?**

#### **ACTEMRA can cause serious side effects, including:**

- See “What is the most important information I should know about ACTEMRA?”
- **Hepatitis B infection** in people who carry the virus in their blood. If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus may become active while you use ACTEMRA. Your doctor may do blood tests before you start treatment with ACTEMRA and while you are using ACTEMRA. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B infection:
  - feel very tired
  - skin or eyes look yellow
  - little or no appetite
  - vomiting
  - clay-colored bowel movements
  - fevers
  - chills
  - stomach discomfort
  - muscle aches
  - dark urine
  - skin rash

- **Serious Allergic Reactions.** Serious allergic reactions, including death, can happen with ACTEMRA. These reactions can happen with any infusion or injection of ACTEMRA, even if they did not occur with an earlier infusion or injection. Tell your healthcare provider before your next dose if you had hives, rash or flushing after your injection. Seek medical attention right away if you have any of the following signs of a serious allergic reaction:
  - shortness of breath or trouble breathing
  - swelling of the lips, tongue, or face
  - chest pain
  - feeling dizzy or faint
  - moderate or severe abdominal pain or vomiting
- **Nervous system problems.** While rare, Multiple Sclerosis has been diagnosed in people who take ACTEMRA. It is not known what effect ACTEMRA may have on some nervous system disorders.

Common side effects of ACTEMRA include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- increased blood pressure (hypertension)
- injection site reactions

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of ACTEMRA. For more information, ask your healthcare provider or pharmacist.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

You may also report side effects to Genentech at 1-888-835-2555.

### **General information about ACTEMRA.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about ACTEMRA.

If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about ACTEMRA that is written for health professionals.

For more information, go to [www.ACTEMRA.com](http://www.ACTEMRA.com) or call 1-800-ACTEMRA.

### **What are the ingredients in ACTEMRA?**

Active ingredient: tocilizumab

Inactive ingredients of Intravenous ACTEMRA: sucrose, polysorbate 80, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate.

Inactive ingredients of Subcutaneous ACTEMRA: L-arginine, L-arginine hydrochloride, L-methionine, L-histidine, L-histidine hydrochloride monohydrate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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**Genentech, Inc.**

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