Medication Guide

ACTEMRA® (AC-TEM-RA)
(tocilizumab) injection
for intravenous use

ACTEMRA® (AC-TEM-RA)
(tocilizumab) injection
for subcutaneous use

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 healthcare provider should assess you for TB before starting ACTEMRA (except if you have COVID-19).

   If you have COVID-19, your healthcare provider should monitor you for signs and symptoms of new infections during and after treatment with ACTEMRA.

   Your healthcare provider should monitor you closely for signs and symptoms of TB during and after 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
     - shortness of breath
     - warm, red, or painful skin or sores on your body
     - feel very tired
     - muscle aches
     - blood in phlegm
     - diarrhea or stomach pain
     - cough
     - weight loss
     - burning when you urinate or urinating more often than normal
   - 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 new onset stomach-area pain that does not go away, and a change in your bowel habits.

3. **Liver problems (Hepatotoxicity):** Some people have experienced serious life-threatening liver problems, which required a liver transplant or led to death. Your healthcare provider may tell you to stop taking ACTEMRA if you develop new or worse liver problems during treatment with ACTEMRA. Tell your healthcare provider right away if you have any of the following symptoms:
   - feeling tired (fatigue)
   - lack of appetite for several days or longer (anorexia)
   - weakness
   - nausea and vomiting

- yellowing of your skin or the whites of your eyes (jaundice)
- abdominal swelling and pain on the right side of your stomach-area
- light colored stools
- confusion
- dark “tea-colored” urine

4. **Changes in certain laboratory test results**. Your healthcare provider should do blood tests before you start receiving ACTEMRA. If you have rheumatoid arthritis (RA), giant cell arteritis (GCA), or systemic sclerosis-interstitial lung disease (SSc-ILD) your healthcare provider should do blood tests every 4 to 8 weeks after you start receiving ACTEMRA for the first 6 months and then every 3 months after that. If you have polyarticular juvenile idiopathic arthritis (PJIA) you will have blood tests done every 4 to 8 weeks during treatment. If you have systemic juvenile idiopathic arthritis (SJIA) you will have blood tests done every 2 to 4 weeks during treatment. These blood tests are 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.
   - 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.

   Your healthcare provider will determine how often you will have follow-up blood tests. Make sure you get all your follow-up blood tests done as ordered by your healthcare provider.
   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.
5. **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.
- To treat adults with giant cell arteritis (GCA).
- For slowing the rate of decline in lung function in adults with systemic sclerosis-associated interstitial lung disease (SSc-ILD) (also known as scleroderma associated ILD).
- To treat people with active PJIA ages 2 and above.
- To treat people with active SJIA ages 2 and above.
- To treat people age 2 years and above who experience severe or life-threatening Cytokine Release Syndrome (CRS) following chimeric antigen receptor (CAR) T cell treatment.
- To treat hospitalized adults with coronavirus disease 2019 (COVID-19) receiving systemic corticosteroids and requiring supplemental oxygen or mechanical ventilation.
- ACTEMRA is not approved for subcutaneous use in people with CRS or COVID-19.

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

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.

Before you receive ACTEMRA, tell your healthcare provider about all of your medical conditions, including 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, unless urgent treatment initiation is required.
- 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.
- are pregnant or plan to become pregnant. ACTEMRA may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with ACTEMRA.
- are breastfeeding or plan to breastfeed. It is not known if ACTEMRA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ACTEMRA.

Tell your healthcare provider about all of the medicines you take, including prescription, over-the-counter 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. 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, Giant Cell Arteritis, PJIA, SJIA, CRS or COVID-19:

- If your healthcare provider 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, giant cell arteritis 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.
- For CRS you will receive a single dose of ACTEMRA, and if needed, additional doses.
- For COVID-19, you will receive a single dose of ACTEMRA, and if needed one additional dose.
- While taking ACTEMRA, you may continue to use other medicines that help treat your rheumatoid arthritis, PJIA, SJIA or COVID-19 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, Giant Cell Arteritis, SSc-ILD, PJIA or SJIA:

- **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-dose Prefilled Syringe or single-dose prefilled ACTPen® autoinjector.
- You may also receive ACTEMRA as an injection under your skin (subcutaneous). If your healthcare provider 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.
- For PJIA or SJIA, you may self-inject with the Prefilled Syringe or prefilled ACTPen® autoinjector, or your caregiver can give you ACTEMRA, if both your healthcare provider and parent/legal guardian find it appropriate.
- 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 healthcare provider 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
  - vomiting
  - chills
  - dark urine
  - skin or eyes look yellow
  - clay-colored bowel movements
  - stomach discomfort
  - skin rash
  - little or no appetite
  - fevers
  - muscle aches
- **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. Stop taking ACTEMRA, contact your healthcare provider, and get emergency help right away if you have any of the following signs of a serious allergic reaction:

- swelling of your face, lips, mouth, or tongue
- trouble breathing
- wheezing
- severe itching
- skin rash, hives, redness, or swelling outside of the injection site area
- dizziness or fainting
- fast heartbeat or pounding in your chest (tachycardia)
- sweating

- **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.

The most 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 about any side effect that bothers you or does not go away. These are not all 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 the safe and effective use of ACTEMRA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not give ACTEMRA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ACTEMRA that is written for health professionals.

What are the ingredients in ACTEMRA?

Active ingredient: tocilizumab.
Inactive ingredients of Intravenous ACTEMRA: disodium phosphate dodecahydrate/sodium dihydrogen phosphate dihydrate buffered solution, polysorbate 80, sucrose, and water for Injection.
Inactive ingredients of Subcutaneous ACTEMRA: L-arginine hydrochloride, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, and water for Injection.

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For more information, go to www.ACTEMRA.com or call 1-800-ACTEMRA.

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