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(For additional information [see "Tocilizumab: Drug information"](#) and [see "Tocilizumab: Pediatric drug information"](#))

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Actemra; Actemra ACTPen

Brand Names: Canada

Actemra

Warning

- Very bad and sometimes deadly infections have happened in patients who take this drug. Most people who had these infections were taking other drugs to lower the immune system like methotrexate or steroid drugs. If you have any infection, are taking antibiotics now or in the recent past, or have had many infections, talk with your doctor.
- TB (tuberculosis) has been seen in patients started on this drug. These patients were exposed to TB in the past, but never got the infection. You will be tested to see if you have been exposed to TB before starting this drug.

What is this drug used for?

- It is used to treat some types of arthritis.
- It is used to treat a certain artery problem called giant cell arteritis (GCA).
- It is used to treat cytokine release syndrome (CRS).

- It is used to slow the progress of lung disease in some people.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have an infection.
- If you have liver disease or raised liver enzymes.
- If you are taking any of these drugs: Abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, or rituximab.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- If you have high blood sugar (diabetes), talk with your doctor. You may be more likely to get infections.
- If you have had hepatitis B before or carry the virus, talk with your doctor. This drug can cause the virus to become active again.
- Hepatitis B testing needs to be done as you were told by the doctor. Talk with

the doctor.

- Drugs that may suppress the immune system like this drug may raise the risk of cancer. If you have questions, talk with the doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- If possible, make sure all vaccines are up to date before treatment with this drug.
- Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- Treatment with this drug may lead to higher cholesterol and triglycerides. The effect of these changes on heart health is not known. Talk with the doctor.
- If your weight changes, talk with your doctor. The dose of this drug may need to be changed.
- Liver problems have happened with this drug. Sometimes, this has been severe and has led to a liver transplant or death. If you have questions, talk with the doctor.
- It is not known how this drug may affect some nervous system problems. However, multiple sclerosis (MS) has rarely happened in people taking this drug. Call your doctor right away if you have an abnormal burning, numbness, or tingling feeling; muscle stiffness or weakness; change in bladder or bowel habits; or change in eyesight.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Use some other kind of birth control also like a condom when taking this drug.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call

your doctor right away.

- If you used this drug when you were pregnant, tell your baby's doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

Infusion:

- Some people have unsafe allergic effects or bad side effects during the infusion or within 24 hours of the infusion. Talk with the doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Rarely, some allergic reactions have been deadly.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of high or low blood pressure like very bad headache or dizziness,

passing out, or change in eyesight.

- Feeling very tired or weak.
- Warm, red, or painful skin or sores on the body.
- A skin lump or growth.
- Change in color or size of a mole.
- Shortness of breath.
- Chest pain or pressure.
- Tears in the stomach or bowel wall have happened in certain people taking this drug. Call your doctor right away if you have swelling or pain in your stomach that is very bad, gets worse, or does not go away. Call your doctor right away if you throw up blood or have throw up that looks like coffee grounds; upset stomach or throwing up that does not go away; or black, tarry, or bloody stools.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Signs of a common cold.
- Nose or throat irritation.
- Irritation where the shot is given.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

Auto-injector shot and prefilled syringes:

- It is given as a shot into the fatty part of the skin.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- Take this drug out of the refrigerator and let it come to room temperature before you use it. Be sure you know how long to leave it at room temperature. Do not heat or microwave.
- Do not use if the solution is cloudy, leaking, or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Move the site where you give the shot with each shot.
- Do not give into a mole, scar, or skin that is irritated, tender, bruised, red, hard, or broken.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

Infusion:

- It is given as an infusion into a vein over a period of time.

What do I do if I miss a dose?

- Call your doctor to find out what to do.

How do I store and/or throw out this drug?

Auto-injector shot and prefilled syringes:

- Store in a refrigerator. Do not freeze.
- Store in the original container to protect from light.

- Keep dry.

Infusion:

- If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

All products:

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the

knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine. The use of this information is governed by the Lexicomp End User License Agreement, available at <https://www.wolterskluwer.com/en/solutions/lexicomp/about/eula>.

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