

# Tocilizumab Solution for injection

## U.S. Trade Names

Actemra

The list of names may not include all products that are available on the market.

This medicine can lower your body's ability to fight infections. You may get more infections while taking this medicine. Any infection you get could become serious and even deadly. Risk factors for this condition include: history of tuberculosis, taking medicine that makes your immune system weak, like methotrexate or corticosteroids. Report the following side effects to your healthcare provider immediately: general ill feeling (extreme tiredness, weakness or aches), low grade fever, symptoms of a cold (shortness of breath, cough, or sore throat).

## What is this medicine?

TOCILIZUMAB (TOE si LIZ ue mab) is used to treat rheumatoid arthritis and juvenile idiopathic arthritis. It is also used to treat giant cell arteritis and cytokine release syndrome.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

## What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:

- cancer
- diabetes
- heart disease
- hepatitis B or history of hepatitis B infection
- high blood pressure
- high cholesterol
- immune system problems
- infection (especially a virus infection such as chickenpox, cold sores, or herpes)
- liver disease
- low blood counts, like low white cell, platelet, or red cell counts
- multiple sclerosis
- recently received or scheduled to receive a vaccination
- scheduled to have surgery
- stomach or intestine problems
- stroke
- tuberculosis, a positive skin test for tuberculosis, or have recently been in close contact with someone who has tuberculosis
- an unusual or allergic reaction to tocilizumab, other medicines, foods, dyes, or preservatives
- pregnant or trying to get pregnant
- breast-feeding

## How should I use this medicine?

This medicine is for infusion into a vein or for injection under the skin. It is usually given by a health care professional in a hospital or clinic setting. If you get this medicine at home, you will be

taught how to prepare and give this medicine. Use exactly as directed. Take your medicine at regular intervals. Do not take your medicine more often than directed.

It is important that you put your used needles and syringes in a special sharps container. Do not put them in a trash can. If you do not have a sharps container, call your pharmacist or healthcare provider to get one.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. While the drug may be prescribed for children as young as 2 years for selected conditions, precautions do apply.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once. NOTE: This medicine is only for you. Do not share this medicine with others.

#### **What if I miss a dose?**

It is important not to miss your dose. Call your doctor or health care professional if you are unable to keep an appointment. If you give yourself the medicine and you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

#### **What may interact with this medicine?**

Do not take this medicine with any of the following medications:

- live virus vaccines

This medicine may also interact with the following medications:

- biologic medicines such as abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, rituximab, secukinumab, ustekinumab
- birth control pills
- certain medicines for cholesterol like atorvastatin, lovastatin, and simvastatin
- cyclosporine
- omeprazole
- steroid medicines like prednisone or cortisone
- theophylline
- vaccines
- warfarin

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

**What side effects may I notice from receiving this medicine?**

Side effects that you should report to your doctor or health care professional as soon as possible:

- allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- breathing problems
- changes in vision
- feeling faint or lightheaded, falls
- high blood pressure
- signs and symptoms of infection like fever or chills; cough; sore throat; pain or trouble passing urine
- signs and symptoms of liver injury like dark yellow or brown urine; general ill feeling or flu-like symptoms; light-colored stools; loss of appetite; nausea; right upper belly pain; unusually weak or tired; yellowing of the eyes or skin
- stomach pain
- tingling, numbness in the hands or feet
- unusual bleeding or bruising
- unusually weak or tired

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):

- dizziness
- headache
- pain, redness, or irritation at site where injected

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**What should I watch for while using this medicine?**

Your condition will be monitored carefully while you are receiving this medicine. Tell your doctor or healthcare professional if your symptoms do not start to get better or if they get worse. You may need blood work done while you are taking this medicine.

You will be tested for tuberculosis (TB) before you start this medicine. If your doctor prescribes any medicine for TB, you should start taking the TB medicine before starting this medicine. Make sure to finish the full course of TB medicine.

This medicine may increase your risk of getting an infection. Call your doctor or health care professional for advice if you get a fever, chills or sore throat, or other symptoms of a cold or flu. Do not treat yourself. Try to avoid being around people who are sick.

Talk to your doctor about your risk of cancer. You may be more at risk for certain types of cancers if you take this medicine.

**Where should I keep my medicine?**

Keep out of the reach of children.

If you are using this medicine at home, you will be instructed on how to store this medicine. Throw away any unused medicine after the expiration date on the label.

**NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.**

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