

Sarilumab Solution for injection

U.S. Trade Names

KEVZARA

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?

SARILUMAB (sar IL ue mab) is used to treat adults with rheumatoid arthritis (RA). This medicine helps reduce joint pain and swelling. This medicine is often used with other medicines.

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
- diverticulitis
- hepatitis B or history of hepatitis B infection
- 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, platelets, or red cell counts
- recently received or scheduled to receive a vaccine
- scheduled to have surgery
- stomach or intestinal problems
- 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 sarilumab, other medicines, foods, dyes or preservatives
- pregnant or trying to get pregnant
- breast-feeding

How should I use this medicine?

This medicine is for injection under the skin. 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, syringes, or pens 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. Special care may be needed.

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?

If 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, ofatumumab, rituximab, secukinumab, tocilizumab, tofacitinib, and ustekinumab
- birth control pills
- certain medicines for cholesterol like atorvastatin, lovastatin, and simvastatin
- certain medicines that treat or prevent blood clots like warfarin, apixaban, and rivaroxaban
- medicines that lower your chance of fighting infection
- steroid medicines like prednisone or cortisone
- theophylline

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

- chest pain
- feeling faint or lightheaded, falls
- low blood counts - this medicine may decrease the number of white blood cells, red blood cells, and platelets. You may be at increased risk for infections and bleeding
- 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
- sudden abdominal pain. vomiting

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

- pain, redness, or irritation at site where injected
- runny or stuffy nose

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?

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.

This medicine may increase your risk of getting an infection. Call your 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. This medicine decreases your body's ability to fight infections. Try to avoid being around people who are sick. Call your health care professional if you are around anyone with measles, chickenpox, or if you develop sores or blisters that do not heal properly.

Talk to your health care professional if you have not had chickenpox or the vaccine for chickenpox.

If you are going to need surgery or other procedure, tell your health care professional that you are using this medicine.

Talk to your doctor about your risk of cancer. You may be 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.

Store in the prefilled syringes or pens in the refrigerator at 2 to 8 degrees C (36 to 46 degrees F). Do not freeze. Do not shake. Keep in the original container to protect from light. Throw away any unopened and unused medicine that has been stored in the refrigerator after the expiration date.

If needed, the syringe or pen may be stored at room temperature up to 25 degrees C (77 degrees F) for up to 14 days. Keep in the original carton. Do not shake. Throw away any unused medicine that is stored at room temperature after 14 days.

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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