



What You Should Know About

 **RoACTEMRA**[®]
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What you should know about RoACTEMRA

Finding the right treatment for rheumatoid arthritis (RA) is very important. With today's RA drugs, many people find the relief they need. It is important to know about the benefits and the risks of any drug. Finding the balance between the two will lead you to a treatment that works best for you. RoACTEMRA might be that treatment.

RoACTEMRA, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, RoACTEMRA can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate. RoACTEMRA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX.

RoACTEMRA worked well in patients who were not helped by other drugs for RA, such as MTX, Arava® (leflunomide), Enbrel® (etanercept), Humira® (adalimumab) and Remicade® (infliximab).

This brochure will answer some questions you may have about the side effects and potential risks of RoACTEMRA. It will help you and your doctor decide if RoACTEMRA is the right treatment for you. This brochure does not take the place of speaking to your doctor or nurse.

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What you should know about RA and RoACTEMRA

What causes RA?

No one knows for sure. In RA, the body's immune system doesn't work the way it should. The immune system is supposed to only attack foreign substances like germs. But when it doesn't work right, it can also attack the body itself. Diseases in which this happens, like RA, are called autoimmune diseases. When the immune system attacks the body, it leads to the symptoms people with RA have. These include joint pain, swelling, stiffness and fatigue.

What is IL-6?

Interleukin 6 (IL-6) is a protein that is made by the immune system. The body uses IL-6 to manage infections. It also plays a major role in the signs and symptoms of RA. People with RA have too much IL-6.

What is RoACTEMRA?

RoACTEMRA is a drug that blocks the action of IL-6 in the body. It is used in adults to treat moderate to severe RA.

How has RoACTEMRA been studied?

RoACTEMRA has been widely studied in adults with RA. It has been studied alone and in combination with oral medications for RA.

How is RoACTEMRA used?

RoACTEMRA can be used concomitantly with MTX or as monotherapy in cases of intolerance to MTX or where continued treatment with MTX is inappropriate. RoACTEMRA has not been studied with and should not be used with other biologic drugs (the newest type of drug made from living cells) for RA that are injected because of the possibility of increased risk of infection. These include: Enbrel[®], Humira[®], Remicade[®], MabThera[®] (rituximab), Orencia[®] (abatacept) and Kineret[®] (anakinra).

How is RoACTEMRA given?

A doctor or nurse will give you RoACTEMRA. It is administered by an intravenous (IV) infusion with a needle. One dose will take 1 hour to infuse into a vein, most likely in your arm.

Dosing is based on your weight, so each person's dose may be different. Your doctor may change your dose based on how well RoACTEMRA works for you. RoACTEMRA is given every 4 weeks.

It is important that you do not miss your scheduled dose of RoACTEMRA. If you do, call your doctor. He or she will tell you when you should get your next dose.

At each visit, your doctor or nurse may test your blood to help guide your treatment. Here are some things they may look at:

- **Platelets.** Some people taking RoACTEMRA had a drop in the number of platelets in their blood. The body uses platelets to help stop bleeding. In clinical trials, the drop in platelets wasn't associated with any serious bleeding
- **White blood cells.** Having enough white blood cells is important to help your body fight infections. RoACTEMRA works on the immune system and can cause the number of white blood cells to drop. So your doctor may test to make sure you have enough white blood cells and monitor for signs and symptoms of infection
- **Liver enzymes.** Some people who have taken RoACTEMRA have had a rise in liver enzymes. This did not result in injury to the liver. Rises in liver enzymes were seen more often when drugs that could be harmful to the liver were used with RoACTEMRA. If this happens to you, your doctor should take care of this right away. Your doctor may decide to change your dose of RoACTEMRA, other medication, or potentially stop treatment altogether
- **Cholesterol.** Some people who have taken RoACTEMRA have had a rise in cholesterol. If this happens to you, your doctor may prescribe a cholesterol-lowering drug

What are the most common side effects of RoACTEMRA?

These were the most common side effects reported by patients in clinical trials that were usually mild and did not result in the patient having to stop using the drug.

- Upper respiratory tract infection (common cold, sinus infection)
- Headache
- Temporary rise in blood pressure
- Rash
- Dizziness
 - If you experience dizziness, you should not drive or use machines until it has resolved

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What are the serious side effects of RoACTEMRA?

Infections. RoACTEMRA is a drug that affects your immune system. Your immune system is important because it helps you fight infections. Your ability to fight infections may be lowered with RoACTEMRA. Some infections may become serious while on RoACTEMRA. This may require hospital treatment or may even lead to death. So it is very important to report any signs of infection to your doctor right away.

Allergic reactions. Most allergic reactions happen during infusion or within 24 hours after infusion. They can range from mild to severe.

- Mild to moderate reactions include:
 - Rise in blood pressure
 - Headache
 - Skin reactions, such as rash, hives and itching
- Severe reactions include:
 - Trouble breathing
 - Being lightheaded
 - Drop in blood pressure

Alert your doctor or nurse immediately if you are having any of these symptoms.

Abdominal pain. Rarely, patients taking RoACTEMRA have had serious side effects in their stomach and intestines. Symptoms may include fever and new onset of abdominal pain and change in bowel habits. Contact your doctor or nurse right away if you have any of these symptoms.

Malignancies. Not enough is known about the effect of RoACTEMRA on cancer. Long-term safety studies are ongoing.

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Before starting RoACTEMRA, tell your doctor if you:

- Have an infection or are being treated for an infection
- Have signs of an infection, such as a fever, cough, headache or are feeling unwell
- Have skin infections with open sores
- Get a lot of infections
- Have diabetes or other conditions that increase the chance for infections
- Have tuberculosis (TB), or if you have been in close contact with someone who has had TB. Your doctor should test you for TB before starting RoACTEMRA

Speak to your doctor if you have any questions about this information.

Tell your doctor about any side effects you may have. The side effects listed in this brochure are not all of the possible side effects with RoACTEMRA. Ask your doctor for more information.

RoACTEMRA may not be right for you. At each visit, tell your doctor or nurse if you:

- **Are taking other medicines. Tell your doctor or nurse about all the medicines you take. This includes prescription and over-the-counter drugs, vitamins and herbals.** You can take other drugs if your doctor has told you it is okay to take them while you are taking RoACTEMRA. RoACTEMRA may interact with some of your medications. This may affect the dose you need of that drug. Tell your doctor if you are taking medicines that contain:
 - atorvastatin, used to reduce cholesterol levels
 - calcium channel blockers (eg, amlodipine), used to treat raised blood pressure
 - theophylline, used to treat asthma
 - warfarin, used as a blood-thinning agent
 - phenytoin, used to treat convulsions
 - ciclosporin, used to suppress your immune system during organ transplants
 - benzodiazepines (eg, temazepam), used to relieve anxiety
- Are taking any other drugs to treat RA. This includes oral drugs, such as MTX, Arava®, and biologic drugs that are injected, such as Enbrel®, Humira®, Remicade®, MabThera®, Orencia® and Kineret®
- Are pregnant, may be pregnant, intend to become pregnant or are breast-feeding. Women of childbearing potential must use effective contraception during (and up to 3 months after) treatment. RoACTEMRA should not be used during pregnancy unless clearly necessary
- Have an infection
- Have had or now have viral hepatitis or any disease of the liver
- Have a history of stomach ulcers or diverticulitis (inflammation in parts of the large intestine)
- Just got a vaccine (such as a flu shot) or are scheduled to get one
- Have cancer, cardiovascular risk factors such as raised blood pressure and raised cholesterol levels or moderate to severe kidney function problems

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Summary and contact information

This brochure reviews some of the most important information about RoACTEMRA. Drugs are sometimes prescribed for purposes other than those listed. Do not use RoACTEMRA for a condition for which it was not prescribed.

If you have any questions or problems, always talk to your doctor or nurse.

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Important Safety Information

What is RoACTEMRA?

IL-6 plays an important role in the signs and symptoms of RA. People with RA have too much IL-6, which is made by the immune system.

RoACTEMRA is a medicine that blocks the action of IL-6 in the body and is used to treat adults with moderate to severe RA.

What is the most important information I should know about RoACTEMRA?

RoACTEMRA is a medicine that affects your immune system. Your immune system is important because it helps you fight infections. Your ability to fight infections may be lowered with RoACTEMRA. Some infections may become serious whilst on RoACTEMRA, leading to hospitalisation and/or death. Therefore, it is very important to report any signs of infection to your healthcare provider right away.

Before starting RoACTEMRA, tell your healthcare provider if you:

- Are experiencing an infection (fever, cough, headache, feeling unwell, or open skin sores) or receiving treatment for an infection
- Get a lot of infections or have diabetes or other conditions that increase the chance for infections
- Have TB, or if you have been in close contact with someone who has had TB
- Are taking any other medications to treat RA. This includes oral medication such as MTX and injectable medications such as Enbrel®, Humira®, Remicade®, MabThera®, Orencia® or Kineret®
- Have had or currently have viral hepatitis or any disease of the liver
- Have a history of diverticulitis (inflammation in parts of your large intestine) and/or gastrointestinal ulcers
- Recently received a live virus vaccination or are scheduled for any live virus vaccination
- Have cancer, cardiovascular risk factors such as raised blood pressure and raised cholesterol levels or moderate to severe kidney function problems

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

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Important Safety Information (continued)

RoACTEMRA can cause serious side effects. Possible side effects include:

- Serious infection, including TB
- Allergic reactions. Signs of an allergic reaction include trouble breathing, skin rash or swollen face
- Blood. Your body may have a reduced number of white blood cells, which help fight infections or platelets, which help stop bleeding. Symptoms include infection and bruising or bleeding very easily
- Liver. Some patients taking RoACTEMRA may have abnormal liver blood tests
- Increases in cholesterol levels. Some patients taking RoACTEMRA may have increases in their cholesterol levels
- Abdominal pain. Patients taking RoACTEMRA on rare occasions have experienced serious side effects in their stomach and intestines. Symptoms may include fever and persistent abdominal pain with change in bowel habits. Contact your healthcare provider right away if you develop these symptoms
- Malignancies. Not enough is known about the effect of RoACTEMRA on cancer. Long-term safety studies are ongoing

The most common side effects with RoACTEMRA are upper respiratory tract infections (common cold, sinus infections), headache, temporary increases in blood pressure, rash and dizziness.

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all of the possible side effects with RoACTEMRA. Ask your healthcare provider for more information.



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