



MEDICATION GUIDE

Get important facts about REMICADE® you can discuss with your doctor.

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How REMICADE® Works

Your immune system works around the clock to protect you from bacteria, viruses, and other foreign agents. When you have ulcerative colitis (UC), your immune system becomes overactive and produces excess amounts of a protein called tumor necrosis factor-alpha, or TNF-alpha.

The presence of excess TNF-alpha causes your immune system to attack healthy cells in your gastrointestinal tract. This leads to the inflammation you experience as the symptoms of UC. REMICADE® has been shown to block the action of TNF-alpha. This inhibits the underlying causes of inflammation.

See how REMICADE® works in the illustration below:



[CHOOSE ANOTHER CONDITION](#)

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- [How REMICADE® works](#)
- [Financial support options](#)
- [Talking to your doctor effectively](#)

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REMICADE® is not right for everyone.

SELECTED IMPORTANT SAFETY INFORMATION

REMICADE® can lower your ability to fight infections. Serious and sometimes fatal events can occur. There have been reports of serious infections including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that have spread throughout the body. Lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, and other cancers have been reported in children and adults taking REMICADE®. Some people with heart failure should not take REMICADE®. Other serious side effects include hepatitis B, liver injury, blood problems, allergic reactions, nervous system problems, or lupus-like syndrome. To learn more about these and other risks, please read the [Important Safety Information](#) and the [Medication Guide](#), and talk with your doctor.

Download the [Medication Guide](#) to learn more about REMICADE®. (Requires Adobe® Reader®. [Click here](#) to download.)

REMICADE® is given by IV infusion

Your doctor may perform certain tests to determine if you are able to receive REMICADE®. If your doctor decides REMICADE® is right for you, you'll receive it as an intravenous (IV) infusion from a healthcare professional over a 2-hour period. REMICADE® is the only medication of its kind to require as few as 6 treatments a year after 3 starter doses. That's once every 8 weeks.

Before starting the REMICADE® infusion, your doctor will assess your health and may decide to give you medication to prevent or lessen side effects. During the infusion, you'll be carefully monitored by a nurse or other healthcare provider. He or she will check in on you periodically to make sure you are comfortable and that the process is going smoothly. And because REMICADE® is infused, it goes directly into your blood stream and gets right to work. Plus, REMICADE® is non-sedating, so you should be able to resume your daily activities, as advised by your doctor.

For detailed information about the REMICADE® IV infusion process, download [Preparing for Your Infusion Treatment With REMICADE®](#)  (Requires Adobe® Reader®. [Click here](#) to download.)

Customized dosing based on body weight

Before each infusion, your doctor will calculate the right amount of medication for you, based on your weight and the severity of your UC.

How should I receive REMICADE®?

- You will be given REMICADE® through a needle placed in a vein ([IV or intravenous infusion](#) ) in your arm
- Your doctor may decide to give you medicine before starting the REMICADE® infusion to prevent or lessen side effects
- Only a healthcare professional should prepare the medicine and administer it to you
- REMICADE® will be given to you over a period of about 2 hours
- If you have [side effects from REMICADE®](#), the infusion may need to be adjusted or stopped. In addition, your healthcare professional may decide to treat your symptoms
- A healthcare professional will monitor you during the REMICADE® infusion and for a period of time afterward for side effects. Your doctor may do certain tests while you are taking REMICADE® to monitor you for side effects and to see how well you respond to the treatment
- Your doctor will determine the right dose of REMICADE® for you and how often you should receive it. Make sure to [discuss with your doctor](#) when you will receive infusions and to come in for all your infusions and follow-up appointments

Remember: If you have any questions or changes in your health status at any point during the infusion process, be sure to discuss them with the healthcare professional overseeing your treatment. This summary is a general example of how infusion treatments may occur. Your infusion treatment may differ based on your healthcare provider.

[NEXT: FAQs](#)

IMPORTANT SAFETY INFORMATION

Only your doctor can recommend a course of treatment after checking your health condition. REMICADE® (infliximab) can cause serious side effects such as lowering your ability to fight infections. Some patients, especially those 65 years and older, have had serious infections caused by viruses, fungi or bacteria that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with REMICADE®.

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking REMICADE® and azathioprine or 6-mercaptopurine. For children and adults taking TNF blockers, including REMICADE®, the chances of getting lymphoma or other cancers may increase.

You should discuss any concerns about your health and medical care with your doctor.

What should I tell my doctor before I take REMICADE®?

You should let your doctor know if you have or ever had any of the following:

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start REMICADE®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- Infections that keep coming back, have diabetes or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take REMICADE®.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV. Your doctor will test you for HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barré syndrome).

Also tell your doctor about any medications you are taking, including vaccines or Kineret (anakinra), Orencia (abatacept) or Actemra (tocilizumab) and if you are pregnant, plan to become pregnant or are nursing. Adults and children should not receive a live vaccine while taking REMICADE®. If you have a baby and you were using REMICADE® during your pregnancy, tell your baby's doctor about your REMICADE® use before the baby receives any vaccine.

What should I watch for and talk to my doctor about before or while taking REMICADE®?

The following serious (sometimes fatal) side effects have been reported in people taking REMICADE®.

You should tell your doctor right away if you have any of the signs listed below:

- Infections (like TB, blood infections, pneumonia)—fever, tiredness, cough, flu, or warm, red or painful skin or any open sores. REMICADE® can make you more likely to get an infection or make any infection that you have worse.
- Lymphoma, or any other cancers in adults and children.
- Heart failure—new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- Liver injury—jaundice (yellow skin and eyes), dark brown urine, right-sided abdominal pain, fever, or severe tiredness.
- Blood disorders—fever that doesn't go away, bruising, bleeding or severe paleness.

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- Nervous system disorders—numbness, weakness, tingling, changes in your vision or seizures.
- Allergic reactions during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, and fever or chills.
- Lupus-like syndrome—chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun. The more common side effects with REMICADE® are respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing and stomach pain.
- Psoriasis—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

Please download the [Medication Guide](#) and discuss it with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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