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 reported include skin cancer, cervical cancer, hepatitis B, heart problems or stroke within 24 hours of infusion, liver injury, blood problems, nervous system problems, allergic reactions, or lupus-like syndrome. To learn more about these and other risks, please read the Important Safety Information on pages 8-9. Please click here to read the Medication Guide and discuss any questions you have with your doctor.

The person depicted is a model used for illustrative purposes only.
GETTING STARTED

You and your doctor have chosen to treat your moderately to severely active Crohn’s disease or UC symptoms with REMICADE®. This brochure may help you better understand what to expect as you prepare for your first treatment with REMICADE®.

SELECTED IMPORTANT SAFETY INFORMATION

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hepatitis B, heart problems or stroke within 24 hours of infusion, liver injury, blood problems, nervous system problems, allergic reactions, or lupus-like syndrome. To learn more about these and other risks, please read the Important Safety Information on pages 8-9. Please [click here] to read the Medication Guide and discuss any questions you have with your doctor.

WHAT IS REMICADE®?

REMICADE® is a prescription medication given as an intravenous (IV) infusion to treat the signs and symptoms of moderately to severely active Crohn’s and UC in patients who haven’t responded to other therapies.

In clinical studies, patients treated with REMICADE® experienced symptom control in as few as 2 weeks for Crohn’s and 8 weeks for UC.

HOW DOES IT WORK?

REMICADE® blocks the action of a protein in your body called tumor necrosis factor-alpha (TNF-alpha). TNF-alpha is made by your body’s immune system. People with certain diseases, including Crohn’s and UC, have too much TNF-alpha, which causes the immune system to attack healthy parts of the body. REMICADE® may block TNF-alpha and the damage it causes.

REMICADE® isn’t right for everyone, and individual results may vary. Talk with your doctor to decide if REMICADE® is right for you.
SCHEDULING YOUR IV INFUSION

If your doctor decides that REMICADE® [infliximab] is right for you, it’s time to schedule your IV infusion. Some offices offer IV infusion services on-site, while others will refer you to an infusion center, usually in an area hospital.

Your healthcare provider’s office can help you schedule a year’s worth of IV infusion appointments in advance. If you need to reschedule an appointment, just call your infusion center—they’ll help to find an infusion time that works for you.

Janssen CarePath offers resources to help patients start and stay on REMICADE® as prescribed.

For more information, please call 877-CarePath (877-227-3728) or visit JanssenCarePath.com/patient/Remicade

GETTING READY FOR YOUR IV INFUSION

Your IV infusion time gives you the opportunity to sit back and relax. Here are a few steps you can take to make sure you feel comfortable during your infusion:

DRINK UP!
It’s a good idea to show up to your infusion well hydrated—drink plenty of water.

PACK UP!
REMICADE® is administered over a period of 2 hours. Bring a book, laptop, tablet, or other digital device...or just a pillow and take a nap to pass the time.

DRESS UP!
It’s important to dress for the occasion. Make comfort a priority: wear loose-fitting clothing and layers in case you get too warm or too cold.

REMICADE® isn’t right for everyone, and individual results may vary. Talk with your doctor to decide if REMICADE® is right for you.

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 reported include skin cancer, cervical cancer, hepatitis B, heart problems or stroke within 24 hours of infusion, liver injury, blood problems, nervous system problems, allergic reactions, or lupus-like syndrome. To learn more about these and other risks, please read the Important Safety Information on pages 8-9. Please click here to read the Medication Guide and discuss any questions you have with your doctor.
THE IV INFUSION PROCESS

BEFORE YOUR FIRST IV INFUSION

Prior to your first IV infusion, your doctor will ask about your medical history and any medical conditions you may currently have—including tuberculosis (TB), cancer, hepatitis B, and any allergy you may have to ingredients in REMICADE® (infliximab), and if you live or have lived in certain parts of the country where there is an increased risk for certain infections.

Before starting therapy with REMICADE®, your doctor will test you for TB and hepatitis B.

BEFORE EVERY IV INFUSION

To ensure there have been no changes since your last treatment with REMICADE®, your doctor will ask you about certain health issues before each infusion, including:

- Any change in your medical history
- New medications you may be taking
- Recent flu shots or other vaccines
- Any possibility of pregnancy
- Any infection or other symptom you’ve noticed
- Heart conditions
- Nervous system disorders

SELECTED IMPORTANT SAFETY INFORMATION

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To learn more about these and other risks, please read the Important Safety Information on pages 8-9. Please click here to read the Medication Guide and discuss any questions you have with your doctor.

STARTING YOUR IV INFUSION

When you arrive for your IV infusion, a healthcare professional will record your vital signs and check your weight, since the actual dose of REMICADE® you will receive is calculated based on body weight.

Your hand or arm will be sterilized with rubbing alcohol and an IV needle will be inserted and fastened with tape. Your doctor may decide to give you other medications before starting the REMICADE® infusion to help control side effects, some of which may cause drowsiness.

A healthcare professional will check in with you periodically throughout your infusion. The IV infusion takes about 2 hours.

Once your healthcare professional is done monitoring you for reactions, you are free to continue your day as normal, since REMICADE® does not cause drowsiness.

WHEN DO YOU NEED YOUR NEXT DOSE?

Your first 3 infusions, or induction doses, are scheduled close together, at Weeks 0, 2, and 6. After your induction doses, you’ll receive REMICADE® only once every 8 weeks.

REMICADE® isn’t right for everyone, and individual results may vary. Talk with your doctor to decide if REMICADE® is right for you.

[continued from previous page]
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 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 if you:
- Use the medicines Kineret (anakinra), Orencia (abatacept) or Actemra (tocilizumab) or other medicines called biologics used to treat the same problems as REMICADE®.
- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using REMICADE® during your pregnancy. Tell your baby's doctor about your REMICADE® use. If your baby receives a live vaccine within 6 months after birth, your baby may develop infections with serious complications that can lead to death.
- Recently received or are scheduled to receive a vaccine. Adults and children taking REMICADE® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking REMICADE®.

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.
- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- Lymphoma, or any other cancers in adults and children.
- Skin cancer—any changes in or growths on your skin.
- Cervical cancer—your doctor may recommend that you be regularly screened. Some women with rheumatoid arthritis, particularly those over 60, have developed cervical cancer.
- Heart failure—new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Other heart problems within 24 hours of infusion, including heart attack, low blood flow to the heart, or abnormal heart rhythm—chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, or severe palpitations.
- 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.
- Nervous system disorders—numbness, weakness, tingling, changes in your vision or seizures.
- Stroke within 24 hours of infusion—numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking; dizziness; loss of balance or coordination; or a sudden, severe headache.
- Allergic reactions during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, and fever or chills.
- Delayed allergic reactions (3 to 12 days after infusion)—fever, rash, headache, sore throat, muscle or joint pain, swelling of the face and hands, or difficulty swallowing.
- 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.
- Psoriasis—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

The most common side effects of REMICADE® include respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing and stomach pain.

Please click here to read the Medication Guide and discuss any questions you have 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.
Savings Program for REMICADE®

Get Started

Eligible patients using commercial or private insurance to pay for REMICADE® medication costs

PAY $5 PER INFUSION

$20,000 maximum program benefit per calendar year. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. There is no income requirement. Program does not cover the cost to give you your infusion. See full eligibility requirements.

Before the calendar year ends, you will receive information and eligibility requirements for continued participation in the program.

Please read the Important Safety Information for REMICADE® on pages 8–9. Please click here to read the Medication Guide and discuss any questions you have with your doctor.