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 to 9 of this brochure and the Medication Guide and discuss any questions you have with your doctor.

Understanding Resources for Patients on REMICADE®

Learn about resources and programs that are available to support your REMICADE® treatment

Whether you’re just getting started with your REMICADE® treatment or looking for options to help you stay on treatment, we want you to have access to the information, programs, and support that you need.
Preventing for Your REMICADE® Infusion

Once you and your doctor have decided that REMICADE® is right for you, your doctor’s office or infusion center will schedule your appointments. REMICADE® is given through a needle placed in your vein, usually in your arm. For detailed information about the REMICADE® infusion process and questions, please talk to your doctor. The tips below will help guide and prepare you for your infusion.

Before you arrive

**Drink Up!**
It’s a good idea to show up to your infusion well hydrated.

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

**Dress Up!**
It’s important to dress for the occasion. Wear loose-fitting clothing and layers in case you get too warm or cold.

During your intravenous (IV) infusion

When you arrive, your healthcare professional will check your vital signs, ask you questions about your overall health, and provide you with the Medication Guide to read before each infusion.

A healthcare professional will determine the right amount of medication for you based on your weight and will be there to give you your treatment. Your doctor may decide to give you other medications before starting the REMICADE® infusion to prevent or lessen side effects.

A healthcare professional will check in with you during your infusion. The infusion is given over a period of about 2 hours.

After your IV infusion

You will be monitored at the doctor’s office or infusion center for a period of time afterward just to make sure you are not having a reaction, and then you will be free to leave. You should be able to continue your normal schedule, as advised by your doctor.

Visit Remicade.com to view a video of a real patient talking about her infusion experience.

Finding an Infusion Center

Some doctors offer IV infusion services on-site. If your doctor’s office doesn’t, it’s easy to find an infusion center near you. Visit 2infuse.com to find treatment locations that are close to your home or workplace.

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Cost Support Resources

Get Support for REMICADE®

Once you and your doctor have decided that REMICADE® is right for you, Janssen CarePath will help you find the resources you may need to get started and stay on track.

Paying for REMICADE®

Janssen CarePath can identify cost support options that may help with managing your out-of-pocket costs—whether you have commercial or private health insurance, government coverage such as Medicare or Medicaid, or no insurance coverage.

Getting Started

Janssen CarePath can review your health plan benefits and insurance coverage for REMICADE® and offer treatment education resources.

Staying on Track

We understand how important it is for you to take REMICADE®, Janssen CarePath provides ongoing support that may help you stay on track with your REMICADE® treatment.

Affording Treatment With REMICADE®

At Janssen, we don’t want cost to get in the way of treatment you need. We can help you explore options to lower your out-of-pocket cost for REMICADE®.

If you have commercial or private health insurance and need help paying for REMICADE®, the Janssen CarePath Savings Program may be able to help. See page 5.

If you don’t have commercial or private health insurance, Janssen CarePath can provide information about other resources that may help with your out-of-pocket medication costs. You may also find help from the programs and resources found on JanssenPrescriptionAssistance.com.

Janssen CarePath Savings Program for REMICADE®

For patients using commercial insurance to pay for REMICADE®

Eligible patients using commercial insurance can save on out-of-pocket medication costs with the Janssen CarePath Savings Program.

ELIGIBLE PATIENTS 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. See full eligibility requirements at Remicade.JanssenCarePathSavings.com.

3 ways to enroll in the Janssen CarePath Savings Program

Online at MyJanssenCarePath.com
To access the enrollment site, you will need to create an account if you don’t already have one.

Over the Phone
877-CarePath (877-227-3728)
Monday–Friday, 8:00 AM–8:00 PM ET.

By Mail or Fax
Download and print the enrollment form. Complete, sign, and mail or fax to the address or fax number on the form. You will be enrolled in the program upon receipt of enrollment confirmation by mail.

Please read the Important Safety Information on pages 8 to 9 and the Medication Guide and discuss any questions you have with your doctor.
What Conditions Is REMICADE® Used to Treat?

REMICADE® is a prescription medication used to treat:

- **Crohn’s Disease**: Can reduce signs and symptoms and induce and maintain remission in adult patients with moderately to severely active Crohn’s disease who haven’t responded well to other therapies.
- **Pediatric Crohn’s Disease**: Can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active Crohn’s disease who haven’t responded well to other therapies.
- **Ulcerative Colitis**: Can reduce signs and symptoms, induce and maintain remission, promote intestinal healing, and reduce or stop the need for steroids in adult patients with moderately to severely active ulcerative colitis who haven’t responded well to other therapies.
- **Pediatric Ulcerative Colitis**: Can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active ulcerative colitis who haven’t responded well to other therapies.
- **Rheumatoid Arthritis**: Can reduce signs and symptoms, help stop further joint damage, and improve physical function in patients with moderately to severely active rheumatoid arthritis, in combination with methotrexate.
- **Psoriatic Arthritis**: Can reduce signs and symptoms of active arthritis, help stop further joint damage, and improve physical function in patients with psoriatic arthritis.
- **Ankylosing Spondylitis**: Can reduce signs and symptoms in patients with active ankylosing spondylitis.
- **Plaque Psoriasis**: Approved for the treatment of adult patients with chronic severe (extensive and/or disabling) plaque psoriasis under the care of a physician who will determine if REMICADE® is appropriate considering other available therapies.

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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 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, fluttering or pounding in your chest, and/or a fast or a slow heartbeat.
- 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.
- 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 read the full Prescribing Information and Medication Guide for REMICADE® 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.
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