IS YOUR CHILD READY FOR SYMPTOM CONTROL?

PEDIATRICS

For children ages 6-17 with moderately to severely active Crohn’s disease or ulcerative colitis (UC) who haven’t responded well to other therapies

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 hepatosplenetic 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.
REMICADE® (infliximab) 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.

REMICADE® can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active ulcerative colitis (UC) who haven’t responded well to other therapies.

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REMICADE® was studied in separate 1-year clinical studies for pediatric patients with moderately to severely active Crohn’s or UC.

Children treated in these trials experienced symptom relief and some achieved remission, or a period of few to no symptoms.

**IN CROHN’S,** almost 9 out of 10 children (88%) experienced symptom control at Week 10.

**IN UC,** more than 7 out of 10 children (73%) experienced symptom control at Week 8.

At 1 year, almost 6 out of 10 children (56%) with Crohn’s and almost 4 out of 10 children (38%) with UC achieved remission.

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

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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.
HOW IS REMICADE® ADMINISTERED?

REMICADE® (infliximab) is an intravenous (IV) infusion given under the supervision of a healthcare professional. When you arrive for your child’s infusion, a healthcare professional will record his or her vital signs and weight, since the dose of REMICADE® is calculated based on body weight.

Your child’s hand or arm will be sterilized with rubbing alcohol and an IV needle will be inserted and fastened with tape. Your child may be given other medications with their IV infusion to help control side effects. Some of these medications may cause drowsiness.

A healthcare professional will check in with your child periodically throughout the infusion to monitor for side effects. The IV infusion process takes about 2 hours, and you can stay with your child throughout the infusion.

Your healthcare professional will monitor your child for possible side effects following the IV infusion. If your child has not received any medications that may cause drowsiness, he or she can continue their day as normal, since REMICADE® does not cause drowsiness.

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WHEN WILL YOUR CHILD NEED HIS OR HER NEXT DOSE?

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

WHAT SHOULD YOU WATCH FOR?

REMICADE® can cause serious side effects, including infections and certain types of cancer. In pediatric patients, common side effects included blood disorders, redness or blushing, viral infections, bone fractures, bacterial infections, and respiratory-related allergic reactions.

The MEDICATION GUIDE [click here to read] and the IMPORTANT SAFETY INFORMATION, found on pages 8-9, include more information about side effects and safety concerns you may have about REMICADE®.

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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.
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MORE INFORMATION ABOUT REMICADE®

REMICADE®
Learn more about Crohn’s disease, UC, and REMICADE® (infliximab).
For more information, visit www.remicade.com

Janssen CarePath Savings Program for REMICADE®
Janssen CarePath Savings Program can help with out-of-pocket costs for your child’s treatment, if you are eligible.
For more information, visit REMICADE.JanssenCarePathSavings.com

Janssen CarePath for REMICADE®
Care Coordinators are available to help answer questions about insurance coverage, provide educational materials, and assist you with appointment reminders.
For more information, call 877-CarePath (877-227-3728) or visit JanssenCarePath.com/REMICADE

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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.
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.**

- **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 tenderness.

- **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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.
COST SUPPORT with Janssen CarePath Savings Program for REMICADE® (infliximab)

Eligible patients enrolled in the Janssen CarePath Savings Program

PAY JUST $5 PER INFUSION*†‡

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

To learn more, visit www.JanssenCarePath.com/REMICADE

*This program is only available to individuals using private or commercial health insurance to cover a portion of medication costs. This program is not available to individuals who use any state or federal government subsidized healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration. Patients confirm that they will not seek reimbursement from any of these programs or from pharmaceutical patient assistance foundations and accounts such as a Flexible Spending Account (FSA), Healthcare Savings Account (HSA), or Health Reimbursement Account (HRA).

†Eligible patients pay $5 per infusion, with up to $20,000 maximum benefit each calendar year. For Massachusetts residents only, this offer is subject to change per state legislation.

‡Janssen CarePath Savings Program rebates are determined by medication cost only. Rebate amounts are not determined by costs associated with administration of the IV infusion.

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.