

## Understanding Your Treatment With REMICADE® or Infliximab

## Resources available to support your Johnson & Johnson therapy

Whether you're just getting started with your REMICADE® or Infliximab 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.

### **SELECTED IMPORTANT SAFETY INFORMATION**

REMICADE<sup>®</sup> and Infliximab 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 or cause infections in certain areas. Lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, and other cancers have been reported in children and adults taking either REMICADE<sup>®</sup> or Infliximab. Some people with heart failure should not take either REMICADE<sup>®</sup> or Infliximab. 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 9-11 and the <u>Medication Guide</u> for REMICADE<sup>®</sup> and the <u>Medication Guide</u> for Infliximab and discuss any questions you have with your doctor.

## Johnson&Johnson

## Indications

#### REMICADE® (infliximab) and Infliximab are prescription medications 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 adult 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 adult patients with psoriatic arthritis

### Ankylosing Spondylitis

Can reduce signs and symptoms in adult 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® or Infliximab is appropriate considering other available therapies

Legacy



For **25 years**, patients have been our focus

## ALL 3+ MILLION OF THEM GLOBALLY

Our **Focus** Remains Our **Commitment** Continues

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## Infliximab: An Unbranded Biologic Option

## Unbranded Infliximab is REMICADE® without the brand name

## Unbranded Infliximab manufactured by Johnson & Johnson is:

A prescription medicine that is the **same product** as the biologic medicine REMICADE®

Approved to treat the **same** conditions as REMICADE®

Available in the **same** strength and **same** dosage form as REMICADE<sup>®</sup>, and given intravenously the **same** as REMICADE<sup>®</sup>



Same as REMICADE<sup>®</sup> except for the brand name and package

## Unbranded Infliximab can support the treatment plan you and your doctor have chosen



Insurance companies may ask some patients to switch their therapy even though they may be doing well medically on their current therapy



If your coverage for REMICADE® has changed, unbranded Infliximab offers you a treatment option that is the same product as REMICADE®

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## **Infusion Resources**



## **Preparing for Your Infusion**

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



## After your IV infusion

prevent or lessen side effects.

You will be monitored at the doctor's office or infusion center for a period of time afterward to be 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.

GATHER YOUR MEDICAL HISTORY AND A LIST OF YOUR CURRENT MEDICATIONS TO BRING WITH YOU TO YOUR INFUSION APPOINTMENT.

## **Patient Support Resources**

## Get Support for Your Johnson & Johnson Medicine

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

J&J withMe

### **Cost Support Options**

J&J withMe 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**

J&J withMe can review your health plan benefits and insurance coverage for REMICADE® or Infliximab and offer treatment education resources.

## Staying on Track



We understand how important it is for you to take REMICADE® or Infliximab as your doctor prescribed. J&J withMe provides ongoing support that may help you stay on track with your REMICADE® or Infliximab treatment.

## Paying for REMICADE® or Infliximab

At Johnson & Johnson, 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® or Infliximab.

If you have commercial or private health insurance and need help paying for REMICADE® or Infliximab, the J&J withMe Savings Program may be able to help. See page 7.

If you don't have commercial or private health insurance, J&J withMe 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 **JNJwithMe.com**.



## J&J withMe Savings Program

## For patients using commercial insurance to pay for REMICADE® or Infliximab

Eligible patients using commercial or private insurance can save on out-of-pocket medication costs for REMICADE® or Infliximab. Depending on your health insurance plan, savings may apply toward co-pay, co-insurance, or deductible.

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**\$5** PER INFUSION

Maximum program benefit per calendar year shall apply. 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. Offer may change or end without notice. Restrictions, including monthly maximums, may apply. Program does not cover the cost to give you your infusion. See program requirements at **Remicade.JNJwithMeSavings.com**.

## To enroll in the J&J withMe Savings Program



### Online at Account.JNJwithMe.com

Create an online account, check your eligibility, enroll in the Savings Program, manage your Savings Program benefits, and receive timely alerts and program updates.

**Over the Phone 877-227-3728** Monday–Friday, 8:00 AM–8:00 PM ET

The support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

To learn more about these and other risks, please read the Important Safety Information on pages 9-11 and the <u>Medication Guide</u> for REMICADE<sup>®</sup> and the <u>Medication Guide</u> for Infliximab and discuss any questions you have with your doctor.

## **Exploring Options for Staying on Therapy**

## If Your Health Plan No Longer Covers Your Johnson & Johnson Medicine

- Your first step should be to work with your doctor to understand your options for remaining on REMICADE<sup>®</sup> or Infliximab
- Your doctor will likely need to go through the exception or appeal process given that your coverage has changed. This will require your doctor to submit a letter of medical necessity to your health plan, providing further information to support why you need to stay on REMICADE<sup>®</sup> or Infliximab. The timeframe for this process will depend on your health plan
- J&J withMe can provide your doctor and your doctor's office with additional information, if requested
- You and your doctor have the right to ask your health plan to explain its decision and consider making REMICADE® or Infliximab available for you as an exception to its policies
- In addition, if you and your doctor would like to learn about patient advocacy groups and the resources they may have available to you, you can find this information at <u>Remicade.JNJwithMe.com</u>.

The support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.



If you are currently being treated with REMICADE<sup>®</sup> and are being asked to switch medications, download a discussion guide that can help you talk with your doctor about your treatment and your options available on <u>Remicade.com</u> in the Additional Resources section.

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## IMPORTANT SAFETY INFORMATION



Only your doctor can recommend a course of treatment after checking your health condition. REMICADE® and 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 which include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body or caused infections in certain areas (such as skin). Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with either REMICADE® or Infliximab.

Unusual cancers have been reported in children and teenage patients taking tumor necrosis factor (TNF) blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in male teenagers or young men with Crohn's disease or ulcerative colitis who were taking either REMICADE® or Infliximab and azathioprine or 6-mercaptopurine. For children and adults taking TNF blockers, including either REMICADE® or Infliximab, the chances of getting lymphoma or other cancers may increase. You should discuss any concerns about your health and medical care with your doctor.

It is not known if REMICADE<sup>®</sup> and Infliximab are safe and effective in children under 6 years of age.

### What should I tell my doctor before I take either REMICADE® or Infliximab?

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 either REMICADE® or Infliximab.
- Lived in a region where certain fungal infections like histoplasmosis, coccidioidomycosis, or blastomycosis 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 either REMICADE® or Infliximab.
- 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).

### Important Safety Information continued on next page.

## IMPORTANT SAFETY INFORMATION (cont'd)

#### What should I tell my doctor before I take either REMICADE<sup>®</sup> or Infliximab? (cont'd)

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® and Infliximab.
- Are pregnant, plan to become pregnant, are breast-feeding or plan to breastfeed, or have a baby and were using either REMICADE® or Infliximab during your pregnancy. Tell your baby's doctor about your use of either REMICADE® or Infliximab. 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 either REMICADE® or Infliximab should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking either REMICADE® or Infliximab.

# What should I watch for and talk to my doctor about before or while taking either REMICADE<sup>®</sup> or Infliximab?

The following serious (sometimes fatal) side effects have been reported in people taking either REMICADE® or Infliximab. You should tell your doctor right away if you have any of the signs listed below:

- Serious infections (like TB, blood infections, pneumonia)—fever, tiredness, cough, flu-like symptoms, or warm, red or painful skin or any open sores. REMICADE® and Infliximab 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 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, pain on the right side of your stomach area, fever, or severe tiredness.

# Remicade<sup>®</sup> Infliximab

# What should I watch for and talk to my doctor about before or while taking either REMICADE® or Infliximab? (cont'd)

- Blood problems—fever that doesn't go away, bruising, bleeding or severe paleness.
- Nervous system disorders—changes in your vision, numbness or tingling in any part of your body, seizures, or weakness in your arms or legs.
- 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 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 more common side effects of REMICADE<sup>®</sup> and Infliximab include respiratory infections (such as sinus infections and sore throat), headache, coughing and stomach pain.

Please read the full <u>Prescribing Information</u>, including Boxed Warning and <u>Medication Guide</u> for REMICADE<sup>®</sup> and the full <u>Prescribing Information</u>, including Boxed Warning and <u>Medication Guide</u> for Infliximab and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.

## Get to Know REMICADE<sup>®</sup> and Unbranded Infliximab from Johnson & Johnson



If you have questions about your treatment options, please talk to your doctor about what might be right for you.



Johnson & Johnson has been making and providing REMICADE® to patients since 1998

For questions about REMICADE®, visit <u>Remicade.com</u> Unbranded Infliximab from Johnson & Johnson is the **same product** as REMICADE®

For questions about Infliximab, visit Infliximab.com



REMICADE<sup>®</sup> and unbranded Infliximab offer the **same** affordability and support programs

For questions about cost, coverage, and treatment support visit JNJwithMe.com

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