



Together you and your doctor chose REMICADE<sup>®</sup>, but your health plan may be asking that you switch to another medicine. This discussion guide may help you work with your doctor to learn more about why you're being asked to switch and what options are available. **Print this guide, identify questions you'd like to ask, and bring it to your next appointment.** 

1. Why am I being asked to switch?

| 2. Do I have to switch my medication?   |
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| 3. Which medication might I be switched to?   |
| 4. Would you explain to me the risks and benefits of the medication to which I might switch?  |
| 5. How can I have a say in my treatment decision?   |
| <ul> <li>6. If REMICADE<sup>®</sup> is still right for me, what are the next steps?</li> <li>What do I need to do?</li> <li>What do you need to do?</li> <li>Who from your office can help me?</li> </ul> |
| 7. If you are being asked to switch to a biosimilar: What is a biosimilar?  |

8. Can you tell me about the support programs for this product?



When it comes to selecting a treatment, it's important to know the facts about your medication. Talk with your doctor to see if REMICADE<sup>®</sup> is still right for you and about your options for staying on treatment.

# **SELECTED IMPORTANT SAFETY INFORMATION**

REMICADE<sup>®</sup> 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 REMICADE<sup>®</sup>. Some people with heart failure should not take REMICADE<sup>®</sup>. 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 3-4 and 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 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® 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 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 REMICADE<sup>®</sup>.

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 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.

# It is not known if REMICADE® is safe and effective in children under 6 years of age.

# 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<sup>®</sup>.
- 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 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<sup>®</sup>.
- Are pregnant, plan to become pregnant, are breast-feeding or plan to breastfeed, 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®.

Please read additional Important Safety Information on page 4 and the Medication Guide and discuss any questions you have with your doctor.



# 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<sup>®</sup>. 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® 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.
- 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> include respiratory infections (such as sinus infections and sore throat), headache, coughing and stomach pain.

Please read the full Prescribing Information and Medication Guide for REMICADE<sup>®</sup> 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.