Remicade

Generic Name: Infliximab (in-FLIX-i-mab)

Brand Name: Remicade

Patients who use Remicade have an increased risk of infection. Severe and sometimes fatal infections, including tuberculosis (TB), invasive <u>fungal infections</u>, and sepsis, have occurred in patients who use Remicade . Before receiving Remicade , patients should be tested for TB infection with a skin test. TB should be treated before starting Remicade . Tell your doctor right away if you develop symptoms of infection such as fever, persistent sore throat, unusual vaginal discharge, or painful or frequent urination while you use Remicade .

Rarely, teenagers and young adults using Remicade to treat Crohn disease have developed a certain type of lymphoma (cancer). This <u>type of cancer</u> is usually fatal. Patients who developed this cancer were using Remicade along with certain other medicines (azathioprine or 6-mercaptopurine).

Remicade is used for:

Reducing signs and symptoms of moderate to severe rheumatoid arthritis when used along with another medicine (methotrexate). It is also used to reduce symptoms of moderate to severe ankylosing spondylitis, psoriatic arthritis, and certain types of skin psoriasis. Remicade is used to reduce symptoms of moderate to severe Crohn disease or <u>ulcerative colitis</u> in patients who have not received relief from other treatments. It may also be used for other conditions as determined by your doctor.

Remicade is a monoclonal antibody. It blocks the action of a substance in the body called tumor necrosis factor (TNF). This may reduce the inflammation and immune responses caused by TNF.

Do NOT use Remicade if:

- you are <u>allergic</u> to any ingredient in Remicade , including mouse-derived (murine) proteins
- you have moderate to severe <u>heart failure</u> and you need doses higher than 5 mg/kg of Remicade
- if you have an active serious infection
- you are taking anakinra

Contact your doctor or health care provider right away if any of these apply to you.

Before using Remicade:

Some medical conditions may interact with Remicade . Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you <u>have allergies</u> to medicines, foods, or other substances
- if you have any type of infection, including bacterial or viral infection, <u>skin</u> <u>infection</u>, fungal infection (eg, histoplasmosis, coccidiomycosis), or TB infection, or have a history of chronic or recurrent infections, a positive TB test, or if you have recently been around someone who might have TB
- if you were born in an area where TB is common or if you have visited or lived in an area where TB, histoplasmosis, or coccidiomycosis infections are common
- if you have a history of hepatitis B or other liver problems, heart problems (eg, congestive heart failure), nervous system problems (eg, seizures, multiple sclerosis, Guillain-Barre syndrome, CNS demyelinating disease), blood disorders, bone marrow problems, lymphoma, or cancer
- if you have had phototherapy to treat psoriasis or other skin conditions
- if you have recently received or are scheduled to receive a vaccine
- if you have chronic <u>obstructive pulmonary disease</u> (COPD) or a history of smoking

Some MEDICINES MAY INTERACT with Remicade. Tell your health care provider if you are taking any other medicines, especially any of the following:

Costimulation modulators (eg, abatacept), immunosuppressants (eg, cyclosporine), or interleukin-1 receptor antagonists (eg, anakinra) because side effects, such as increased risk of severe infection and <u>low white blood cells</u> counts, may occur

This may not be a complete list of all interactions that may occur. Ask your health care provider if Remicade may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How to use Remicade:

Use Remicade as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Remicade comes with an extra patient information sheet called a Medication Guide. Read it carefully. Read it again each time you get Remicade refilled.
- Remicade is usually given as an injection at your doctor's office, hospital, or clinic.
- If you miss a dose of Remicade, contact your doctor immediately.

Ask your health care provider any questions you may have about how to use Remicade .

Important safety information:

- Remicade may cause dizziness. This effect may be worse if you take it
 with alcohol or certain medicines. Use Remicade with caution. Do not
 drive or perform other possibly unsafe tasks until you know how you react
 to it.
- Do not receive a live vaccine (eg, measles, mumps) while you are taking Remicade. Talk with your doctor before you receive any vaccine.
- Tell your doctor if you live in or have recently visited an area where
 histoplasmosis or coccidioidomycosis infections are common. Ask your
 doctor if you have questions about whether these infections are common
 in a particular area.
- Tell your doctor or dentist that you take Remicade before you receive any medical or <u>dental care</u>, emergency care, or surgery.
- Remicade may lower the ability of your body to fight infection. Avoid
 contact with people who have colds or infections. Do not touch your eyes
 or the inside of your nose unless you have thoroughly washed your hands
 first. If you develop a fever, feel very tired, have a cough, or have flu-like
 symptoms, these could be signs that you may be getting an infection. If
 any of these symptoms occur, contact your doctor at once.
- Remicade may reduce the number of clot-forming cells (platelets) in your blood. Avoid activities that may cause bruising or injury. Tell your doctor if

- you have unusual bruising or bleeding. Tell your doctor if you have dark, tarry, or bloody stools.
- Remicade may increase the risk of developing lymphoma (blood cancer) or other cancer. Tell your doctor if you have ever had lymphoma or another cancer. Contact your doctor right away if any symptoms appear, such as unusual lumps or swelling (eg, in your neck, armpit, or groin), night sweats, recurring fever, unusual tiredness, unexplained cough or breathlessness, persistent unexplained itching, or unexplained weight loss.
- Rarely, severe liver problems have occurred with use of Remicade.
 These liver problems may occur more than a year after starting Remicade.
 Contact your doctor right away if you develop dark urine, severe or persistent stomach pain, or yellowing of the skin or eyes.
- Allergic reactions have occurred up to 12 days after the use of Remicade.
 Tell your doctor if symptoms such as fever, rash, headache, or muscle or joint pain occur.
- Lab tests, including liver function and complete blood cell counts, may be performed while you use Remicade. These tests may be used to monitor your condition or check for side effects. Be sure to keep all doctor and lab appointments.
- Use Remicade with caution in the ELDERLY; they may be more sensitive to its effects, especially the risk of infection.
- Remicade should be used with extreme caution for Crohn disease in CHILDREN younger than 6 years old; safety and effectiveness in these children have not been confirmed.
- Remicade should be used with extreme caution for other diseases in CHILDREN; safety and effectiveness for other diseases in children have not been confirmed.
- Children may be more sensitive to Remicade 's effects, especially blood problems, infection, blood in the stool, flushing, and certain allergic reactions.
- PREGNANCY and BREAST-FEEDING: It is not known if Remicade can cause harm to the fetus. If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using Remicade while you are pregnant. It is not known if Remicade is found in breast milk. Do not breast-feed while taking Remicade.

Possible side effects of Remicade:

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

Back pain; headache; pain, redness, or swelling at the injection site; runny or stuffy nose; stomach pain or upset; tiredness.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); change in the amount of urine produced; chest pain; cough; dark brown-colored urine; dizziness; fainting; fast, slow, or irregular heartbeat; fever, chills, or sore throat; flu-like symptoms; flushing; joint or muscle pain; numbness or tingling of the skin, arms, or legs; painful urination; rash on the cheeks or arms that gets worse in the sun; red, warm, or painful skin; seizures; severe or persistent stomach or back pain; severe tiredness or weakness; shortness of breath; sudden unexplained weight gain or loss; suicidal thoughts or attempts; swelling of the hands, legs, or ankles; trouble swallowing; unexplained loss of appetite; unusual bruising or bleeding; unusual lumps; unusual vaginal discharge or odor; upper respiratory tract infection; very pale skin; vision changes; weakness in arms or legs; white patches or sores in the mouth; yellowing of the skin or eyes.

If OVERDOSE is suspected:

Contact 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (http://www.aapcc.org/findyour.htm), or emergency room immediately.

Proper storage of Remicade:

Remicade is usually handled and stored by a health care provider. If you are using Remicade at home, store Remicade as directed by your pharmacist or health care provider. Keep Remicade out of the reach of children and away from pets.

General information:

- If you have any questions about Remicade, please talk with your doctor, pharmacist, or other health care provider.
- Remicade is to be used only by the patient for whom it is prescribed. Do not share it with other people.
- If your symptoms do not improve or if they become worse, check with your doctor.

This information is a summary only. It does not contain all information about Remicade . If you have questions about the medicine you are taking or would like more information, check with your doctor, pharmacist, or other health care provider.

Issue Date: April 2, 2008 Database Edition 08.2.1.001

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