MEDICATION GUIDE
REMICADE® (Rem-eh-kaid)
(infliximab)

Read the Medication Guide that comes with REMICADE before you receive the first treatment, and before each time you get a treatment of REMICADE. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about REMICADE?

REMICADE may cause serious side effects, including:

1. Risk of infection

REMICADE is a medicine that affects your immune system. REMICADE can lower the ability of your immune system to fight infections. Serious infections have happened in patients receiving REMICADE. These infections include tuberculosis (TB) and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some patients have died from these infections.

- Your doctor should test you for TB before starting REMICADE.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with REMICADE.

Before starting REMICADE, tell your doctor if you:

- think you have an infection. You should not start taking REMICADE if you have any kind of infection.
- are being treated for an infection
- have signs of an infection, such as a fever, cough, flu-like symptoms
- have any open cuts or sores on your body
- get a lot of infections or have infections that keep coming back
- have diabetes or an immune system problem. People with these conditions have a higher chance for infections.
- Have TB, or have been in close contact with someone with TB
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may develop or become more severe if you take REMICADE. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your doctor.
- have or have had hepatitis B
- use the medicines KINERET (anakinra), ORENCIA (abatacept), ACTEMRA (tocilizumab), or other medicines called biologics used to treat the same conditions as REMICADE.

Reference ID: 3403013

After starting REMICADE, if you have an infection, any sign of an infection including a fever, cough, flu-like symptoms, or have open cuts or sores on your body, call your doctor right away. REMICADE can make you more likely to get infections or make any infection that you have worse.

2. Risk of Cancer

- There have been cases of unusual cancers in children and teenage patients using TNF-blocking agents.
- For children and adults taking TNF-blocker medicines, including REMICADE, the chances of getting lymphoma or other cancers may increase.
- Some patients with Crohn's disease or ulcerative colitis have developed Hepatosplenic T-cell Lymphoma, a rare type of cancer. Most of the patients were teenage or young adult males. This type of cancer results in death. All of these patients had received medicines known as azathioprine or 6-mercaptopurine together with REMICADE.
- People who have been treated for rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis for a long time may be more likely to develop lymphoma. This is especially true for people with very active disease.
- Some people treated with REMICADE have developed certain kinds of skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with REMICADE, tell your doctor.
- Patients with COPD (a specific type of lung disease) may have an increased risk for getting cancer while being treated with REMICADE.
- Tell your doctor if you have ever had any type of cancer. Discuss with your doctor any need to adjust medicines you may be taking.

See the section "**What are the possible side effects of REMICADE?**" below for more information.

What is REMICADE?

REMICADE is a prescription medicine that is approved for patients with:

- Rheumatoid Arthritis - adults with moderately to severely active rheumatoid arthritis, along with the medicine methotrexate
- Crohn's Disease - children 6 years and older and adults with Crohn's disease who have not responded well to other medicines
- Ankylosing Spondylitis
- Psoriatic Arthritis
- Plaque Psoriasis - adult patients with plaque psoriasis that is chronic (doesn't go away) severe, extensive, and/or disabling.
- Ulcerative Colitis - children 6 years and older and adults with moderately to severely active ulcerative colitis who have not responded well to other medicines.

REMICADE blocks the action of a protein in your body called tumor necrosis factor-alpha (TNF-alpha). TNF-alpha is made by your body's immune system. People with certain diseases have too much TNF-alpha that can cause the immune system to

attack normal healthy parts of the body. REMICADE can block the damage caused by too much TNF-alpha.

Who should not receive REMICADE?

You should not receive REMICADE if you have:

- heart failure, unless your doctor has examined you and decided that you are able to take REMICADE. Talk to your doctor about your heart failure.
- had an allergic reaction to REMICADE, or any of the other ingredients in REMICADE. See the end of this Medication Guide for a complete list of ingredients in REMICADE.

What should I tell my doctor before starting treatment with REMICADE?

Your doctor will assess your health before each treatment.

Tell your doctor about all of your medical conditions, including if you:

- have an infection (see "**What is the most important information I should know about REMICADE?**").
- have other liver problems including liver failure.
- have heart failure or other heart conditions. If you have heart failure, it may get worse while you take REMICADE.
- have or have had any type of cancer.
- have had phototherapy (treatment with ultraviolet light or sunlight along with a medicine to make your skin sensitive to light) for psoriasis. You may have a higher chance of getting skin cancer while receiving REMICADE.
- have COPD (Chronic Obstructive Pulmonary Disease), a specific type of lung disease. Patients with COPD may have an increased risk of getting cancer while taking REMICADE.
- have or have had a condition that affects your nervous system such as
  - multiple sclerosis, or Guillain-Barré syndrome, or
  - if you experience any numbness or tingling, or
  - if you have had a seizure.
- have 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). Children should have all of their vaccines brought up to date before starting treatment with REMICADE.
- are pregnant or planning to become pregnant. It is not known if REMICADE harms your unborn baby. REMICADE should be given to a pregnant woman only if clearly needed. Talk to your doctor about stopping REMICADE if you are pregnant or planning to become pregnant.
- are breast-feeding or planning to breast-feed. It is not known whether REMICADE passes into your breast milk. Talk to your doctor about the best way to feed your baby while taking REMICADE. You should not breast-feed while taking REMICADE.

If you have a baby and you were using REMICADE during your pregnancy, it is important to tell your baby's doctor and other health care professionals about your REMICADE use so they can decide when your baby should receive any vaccine. Certain vaccinations may cause infections.

If you received REMICADE while you were pregnant, your baby may be at higher risk for getting an infection for at least six months after the last dose of REMICADE you received during your pregnancy.

How should I receive REMICADE?

- You will be given REMICADE through a needle placed in a vein (IV or intravenous infusion) in your arm.
- Your doctor may decide to give you medicine before starting the REMICADE infusion to prevent or lessen side effects.
- Only a healthcare professional should prepare the medicine and administer it to you.
- REMICADE will be given to you over a period of about 2 hours.
- If you have side effects from REMICADE, the infusion may need to be adjusted or stopped. In addition, your healthcare professional may decide to treat your symptoms.
- A healthcare professional will monitor you during the REMICADE infusion and for a period of time afterward for side effects. Your doctor may do certain tests while you are taking REMICADE to monitor you for side effects and to see how well you respond to the treatment.
- Your doctor will determine the right dose of REMICADE for you and how often you should receive it. Make sure to discuss with your doctor when you will receive infusions and to come in for all your infusions and follow-up appointments.

What should I avoid while receiving REMICADE?

Do not take REMICADE together with medications such as KINERET (anakinra), ORENCIA (abatacept), ACTEMRA (tocilizumab), or other medicines called biologics that are used to treat the same conditions as REMICADE.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. These include any other medicines to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis or psoriasis.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

What are the possible side effects of REMICADE?

REMICADE can cause serious side effects, including:

See "**What is the most important information I should know about REMICADE?**".

Serious Infections

- Some patients, especially those 65 years and older have had serious infections while receiving REMICADE. These serious infections include TB and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients die from these infections. If you get an infection while receiving treatment with REMICADE your doctor will treat your infection and may need to stop your REMICADE treatment.
- Tell your doctor right away if you have any of the following signs of an infection while taking or after taking REMICADE:
  - a fever
  - feel very tired
  - have a cough
  - have flu-like symptoms
  - warm, red, or painful skin
- Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with REMICADE and during treatment with REMICADE.
- Even if your TB test is negative, your doctor should carefully monitor you for TB infections while you are taking REMICADE. Patients who had a **negative** TB skin test before receiving REMICADE have developed active TB.
- If you are a chronic carrier of the hepatitis B virus, the virus can become active while you are being treated with REMICADE. In some cases, patients have died as a result of hepatitis B virus being reactivated. Your doctor should do a blood test for hepatitis B virus before you start treatment with REMICADE and occasionally while you are being treated. Tell your doctor if you have any of the following symptoms:
  - feel unwell
  - poor appetite
  - tiredness (fatigue)
  - fever, skin rash and/or joint pain

Heart Failure

If you have a heart problem called congestive heart failure, your doctor should check you closely while you are taking REMICADE. Your congestive heart failure may get worse while you are taking REMICADE. Be sure to tell your doctor of any new or worse symptoms including:

- shortness of breath
- swelling of ankles or feet
- sudden weight gain

Treatment with REMICADE may need to be stopped if you get new or worse congestive heart failure.

Liver Injury

In rare cases, some patients taking REMICADE have developed serious liver problems. Tell your doctor if you have

- jaundice (skin and eyes turning yellow)
- dark brown-colored urine
- pain on the right side of your stomach area (right-sided abdominal pain)
- fever
- extreme tiredness (severe fatigue)

Blood Problems

In some patients taking REMICADE, the body may not make enough of the blood cells that help fight infections or help stop bleeding. Tell your doctor if you

- have a fever that does not go away
- bruise or bleed very easily
- look very pale

Nervous System Disorders

In rare cases, patients taking REMICADE have developed problems with their nervous system. Tell your doctor if you have

- changes in your vision
- weakness in your arms and/or legs
- numbness or tingling in any part of your body
- seizures

Allergic Reactions

Some patients have had allergic reactions to REMICADE. Some of these reactions were severe. These reactions can happen while you are getting your REMICADE treatment or shortly afterward. Your doctor may need to stop or pause your treatment with REMICADE and may give you medicines to treat the allergic reaction. Signs of an allergic reaction can include:

- hives (red, raised, itchy patches of skin)
- difficulty breathing
- chest pain
- high or low blood pressure
- fever
- chills

Some patients treated with REMICADE have had delayed allergic reactions. The delayed reactions occurred 3 to 12 days after receiving treatment with REMICADE. Tell your doctor right away if you have any of these signs of delayed allergic reaction to REMICADE:

- fever
- rash
- headache
- sore throat
- muscle or joint pain
- swelling of the face and hands
- difficulty swallowing

Lupus-like Syndrome
Some patients have developed symptoms that are like the symptoms of Lupus. If you develop any of the following symptoms, your doctor may decide to stop your treatment with REMICADE.

- 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
Some people using REMICADE had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps on the skin that are filled with pus. Your doctor may decide to stop your treatment with REMICADE.

The most common side effects of REMICADE include:

- respiratory infections, such as sinus infections and sore throat
- headache
- coughing
- stomach pain

Infusion reactions can happen up to 2 hours after your infusion of REMICADE. Symptoms of infusion reactions may include:

- fever
- chills
- chest pain
- low blood pressure or high blood pressure
- shortness of breath
- rash
- itching

Children who took REMICADE in studies for Crohn's disease showed some differences in side effects compared with adults who took REMICADE for Crohn's disease. The side effects that happened more in children were: anemia (low red blood cells), leukopenia (low white blood cells), flushing (redness or blushing), viral infections, neutropenia (low neutrophils, the white blood cells that fight infection), bone fracture, bacterial infection and allergic reactions of the breathing tract. Among patients who took REMICADE for ulcerative colitis in clinical studies, more children had infections as compared with adults.

Tell your doctor about any side effect that bothers you or does not go away.

These are not all of the side effects with REMICADE. Ask your doctor or pharmacist for more information.

General information about REMICADE

Medicines are sometimes prescribed for purposes that are not mentioned in Medication Guides or patient information sheets. Do not use REMICADE for a condition for which it was not prescribed.

This information sheet summarizes the most important information about REMICADE. You can ask your doctor or pharmacist for information about REMICADE that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For more information go to www.remicade.com, or call 1-800-JANSSEN (1-800-526-7736).

What are the ingredients in REMICADE?

The active ingredient is Infliximab.
The inactive ingredients in REMICADE include: sucrose, polysorbate 80, monobasic sodium phosphate monohydrate, and dibasic sodium phosphate dihydrate. No preservatives are present.

Manufactured by:
Janssen Biotech, Inc. U.S. License No. 1864
Horsham, PA 19044

Revised November 2013

This Medication Guide has been approved by the U.S. Food and Drug Administration