JUST FOR KIDS
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

DO I NEED A NEW MEDICINE?

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 hepatosplenic 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 8-11. Please click here to read the Medication Guide and discuss any questions you have with your doctor.
REMICADE® is approved in moderately to severely active Crohn’s disease and ulcerative colitis (UC) to reduce signs and symptoms and induce and maintain remission in children (ages 6-17) who haven’t responded well to other therapies.

REMICADE® (infliximab) is a prescription medicine that may help you feel better. Your doctor and parents will decide if it is okay for you to take REMICADE®.

DO YOU NEED A NEW MEDICINE?
If you take medicine and still feel sick, you might need a new one. Your doctor will talk to you and your parents about other medicines (like REMICADE®) that can help you feel better.

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HOW DO YOU GET REMICADE®?
Your doctor or nurse will place a needle in your hand or arm. The needle will be connected to a bag containing REMICADE®. The medicine takes about 2 hours to go into your blood.

WILL SOMEONE WATCH YOU?
A doctor or nurse will watch you the whole time to make sure you’re okay. Your mom or dad can stay with you during the treatment, too. If you feel funny or get sick during your treatment, tell a nurse or doctor so they can help.

WHAT SHOULD YOU DO DURING YOUR TREATMENT?
Take a nap, listen to music, watch a movie, or play games. You can also do your homework or read a book.

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WHEN SHOULD YOU TELL YOUR FRIENDS YOU ARE SICK?

The best time to tell your friends you are sick is when you are ready to. Telling a friend why you are sick can be hard. There are ways to make it easier.

IF YOU TELL A FRIEND, IT MIGHT HELP TO:

- Talk about how you feel
- Tell them what makes you feel sick
- Answer your friend’s questions
- Have your mom or dad help you

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CROHN’S DISEASE:
You might hear your parents or doctor call this Crohn’s. Crohn’s disease makes one or more areas of your gut swollen (or inflamed). It can also lead to bleeding in your gut. Crohn’s disease is NOT contagious!

ULCERATIVE COLITIS:
You might hear your parents or doctor call this UC. Ulcerative colitis also makes your gut swollen (or inflamed). You might see blood in your diarrhea because of UC. Like Crohn’s, UC is NOT contagious!

SYMPTOMS:
The things that make you feel bad. Stomach aches and going to the bathroom a lot are both symptoms.
FLARE:
A flare is when you suddenly feel worse than normal. You should always tell your parents and doctor when you have a flare.

RELAPSE:
When you feel better for a little while and then get sick again. Relapses can be scary.

REMISSION:
A time when your symptoms disappear and you feel better. Remission can last for days or years.

GASTROINTESTINAL TRACT:
Your gastrointestinal tract, or GI tract, is all of the parts of the body that help you digest your food.

GASTROENTEROLOGIST:
A special kind of doctor that knows all about Crohn’s and UC. Your gastroenterologist can give you special medicines to help you feel better.

SMALL INTESTINE:
There are lots of little parts of the small intestine. It works to help you digest food. The small intestine is very long. If you stretched it out, it would be almost 22 feet long!

LARGE INTESTINE:
You might hear this called a colon, too. They’re the same thing! It helps turn your stool from a liquid into a solid.
INDICATIONS

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.

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®.

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IMPORTANT SAFETY INFORMATION (CONT’D)

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.

- 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 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 tiredness.

- 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, or call 1-800-FDA-1088.
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