



Talking to Your Child's Doctor About Pediatric Crohn's Disease (PCD)

If your child experiences any of the symptoms of moderately to severely active PCD and has not responded well to other therapies, make sure you speak to a gastroenterologist as soon as possible. Remember, only a qualified physician can make a diagnosis and help you make an appropriate treatment choice for your child.

Use the questions on the following page to guide your discussion with the gastroenterologist about the ways PCD may be affecting your child. When the discussion turns to treatment options, ask your doctor if REMICADE® is right for your child.

REMICADE® 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. **Please read the Important Safety Information for REMICADE® below.**

Making the most of your child's appointment.

The following tips can help you give your doctor a more complete picture of your child's condition:

1. **Write it all down.** Before the appointment, make a note of your child's symptoms, medications taken, allergies, and disease history. Show this list to your child's doctor.
 2. **Discuss your child's feelings and the impact on his or her life.** Describe the symptoms that bother your child the most. Mention if he or she has missed school or activities due to PCD symptoms. Encourage your child to share details of his or her experience with PCD.
 3. **Discuss side effects.** Describe anything unusual your child experiences, such as stomach problems or skin rashes. This will help your doctor develop the right treatment plan for your child.
 4. **Ask why early treatment is important.** Early and effective treatment is important in order to control the symptoms of Crohn's disease.
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Suggested questions for your child's gastroenterologist:

Let your doctor know at the beginning of the appointment that you have questions, so there will be time to answer all of them.

1. What health and developmental problems can PCD lead to?
2. How do I know if my child's PCD is under control?
3. What treatment options are there for PCD?
4. Is there any kind of food or fitness plan that can help my child manage PCD?
5. If my child is being treated and still has flares, is the disease really under control?
6. What are biologics?
7. Is REMICADE® right for my child?
8. What are the benefits and risks of treatment with REMICADE®?
9. How often is REMICADE® given?
10. My child has _____ flares per month/year. What should my child do during a flare?
11. What could happen if I do not treat my child's PCD symptoms?

Have some questions of your own?

If you have more questions you'd like to ask, use the space below to write them down.

IMPORTANT SAFETY INFORMATION FOR REMICADE® (INFLIXIMAB)

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.

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IMPORTANT SAFETY INFORMATION FOR REMICADE® (INFLIXIMAB) (continued)

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 about any medications you are taking, including vaccines or Kineret (anakinra), Orencia (abatacept) or Actemra (tocilizumab) and if you are pregnant, plan to become pregnant or are nursing. Adults and children should not receive a live vaccine while taking REMICADE®. If you have a baby and you were using REMICADE® during your pregnancy, tell your baby's doctor about your REMICADE® use before the baby receives any vaccine.

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.
- Lymphoma, or any other cancers in adults and children.
- Heart failure—new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- 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.
- Allergic reactions during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, and fever or chills.
- 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. The more common side effects with REMICADE® are respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing and stomach pain.
- Psoriasis—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

Click here to read the [Medication Guide](#) for REMICADE® and discuss it with your doctor.
Click here for full [Prescribing Information](#).

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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