



Medication Fact Sheet

Generic Name: Infliximab

Trade Name: Remicade®

What is Remicade and how does it work?

Remicade® is a protein that blocks the action of a substance in your child's body called tumor necrosis factor (TNF).

TNF is made by certain blood cells and too much TNF increases inflammation.

Remicade® does not cure pediatric Crohn's disease or ulcerative colitis, but may reduce inflammation and symptoms and bring on remission in children who have had an inadequate response to conventional therapy.

Your child's immune system and Remicade®

Remicade® can lower your child's ability to fight infections.

Taking Remicade® can make your child more prone to getting infections or it can make infections he or she already has worse.

Let your child's healthcare provider know right away if you think they may have an infection.

What are the side effects of Remicade®?

Serious Side effects include:

Serious infections – Some patients have died from these infections.

They include tuberculosis, and infections caused by viruses, fungi or bacteria that have spread throughout the body.

Let your child's healthcare provider know if your child shows signs of infection such as fever, fatigue, cough or flu like symptoms.

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Allergic Reactions – Some children have had severe allergic reactions to Remicade®. These reactions can happen while your child is getting a Remicade® infusion or shortly afterwards.

Symptoms may include hives, difficulty breathing, chest pain and high or low blood pressure. Your child's doctor may decide to stop Remicade® treatment and give a medicine to treat the reaction.

Some children have had reactions 3 to 12 days after a treatment.

The symptoms may include

- fever
- rash
- headache
- muscle or joint pain

Call your child's healthcare provider right away if he or she develops these or any other unusual symptoms.

Nervous system disorders – There have been rare cases where children taking Remicade® or other TNF blockers have developed disorders that affected their nervous system.

Symptoms may include visual changes, weakness in arms and or legs, and numbness or tingling in any part of the body.

Call your child's healthcare provider right away if he or she develops these or any other unusual symptoms.

Cancer – In clinical studies, more cancers were seen in patients who took Remicade and other medicines that block TNF than in patients who did not receive these treatments.

There have been reports of hepatosplenic T-cell lymphoma in six Crohn's disease patients ranging in age from age 12 to 31 years treated.

Five of these reports were in children between 12 and 19 years of age and all had received either azathioprine or 6-Mercaptopurine along with Remicade®. Five of the six patients died as a result of their lymphoma.

In those patients for whom the duration of Remicade® use was reported, exposure ranged from one to two infusions of Remicade to approximately four years of maintenance therapy.

Liver Injury – There have been rare cases of liver problems.

Symptoms may include, jaundice (skin and eyes turning yellow), dark brown colored urine, right sided abdominal pain, fever and severe

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fatigue. Contact your child's healthcare provider immediately if he or she develops any of these symptoms.

Blood problems – In some patients the body may fail to produce enough of the blood cells that help your child's to fight infections or help their body to stop bleeding. Some of the patients have died from this failure to produce blood cells. If your child develops a fever that doesn't go away, bruise or bleed very easily or look very pale, call the doctor right away.

Lupus-like symptoms – Some patients have developed symptoms that can resemble a disease called lupus. Lupus-like symptoms may include chest discomfort or pain that doesn't go away, shortness of breath, joint pain, or a rash on the cheeks or arms that gets worse in the sun. Contact your child's healthcare provider if he or she develops any of these symptoms.

Common side effects of Remicade

- upper respiratory infections
- sinus infections
- sore throat
- coughing
- stomach pain

Who should not take Remicade?

Your child should not take Remicade if he or she has:

- had an allergic reaction previously to Remicade or any other product made with murine (mouse) proteins
- any kind of infection, open cut or sore. Minor infections should be discussed with your child's healthcare provider
- had tuberculosis, or if your child has recently been with anyone who might have TB
- lived or visited an area of the country where an infection called histoplasmosis or coccidioidomycosis (an infection caused by a fungus that affects the lung) is common
- had a condition that affects the nervous system, like multiple sclerosis, or Guillain-Barre syndrome, or if your child experiences any numbness, or tingling, or has had a seizure
- recently received a live vaccine



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How will Remicade® be given to my child?

Remicade® is given intravenously by a healthcare professional. Your child will need to have a tuberculosis test prior to receiving the first dose of Remicade and once a year after.