

Infliximab (Remicade®)

Remicade® (REM eh kade) is the brand name for infliximab (in FLICKS eh mab). This medicine blocks the action of a protein in the body called TNF-alpha (tumor necrosis factor-alpha). TNF-alpha is made by the body's immune system. People with certain diseases like Crohn's disease or ulcerative colitis produce too much TNF-alpha. This can cause inflammation. Remicade® blocks the damage caused by too much TNF-alpha.

The FDA has approved Remicade® to treat children 6 years and older who have ulcerative colitis (UC) and moderate to severe active Crohn's disease.

How the medicine is given

Your child will be given Remicade® by IV infusion (a needle placed in a vein in your child's arm). The medicine will be given at the hospital over a period of 1 to 4 hours.

Testing before and during treatment

- Before starting Remicade®, the doctor will examine your child and test for tuberculosis (TB). Testing may include a TB skin test, blood work, and a chest X-ray.
- During treatment, other tests may be done to check for side effects and to see how well your child is responding to Remicade® treatment.
- The doctor will decide the right dose of medicine for your child and how often your child should receive it.

Be sure to talk with your child's doctor about the schedule for receiving infusions. It is **very important to keep all of your child's appointments** for infusions and for follow-up.

Things to avoid

- If possible, all of your child's vaccines should be brought up to date **BEFORE** starting Remicade®. Tell your pediatrician that your child is on Remicade®. Your child **SHOULD NOT receive live vaccines** while taking this medicine.
- Remicade® affects the body's immune system, so your child will be less able to fight infections during treatment. Your child should try to avoid contact with people who are sick or have colds or flu. However, he or she may go to school and take part in sports and other school activities.

Possible side effects

As with most medicines, there are side effects from taking Remicade®. We may not yet know all of the possible side effects. However, the **most common side effects** are:

- Infusion reactions such as flushing and “shortness of breath”
- Minor sinus infections and colds.

Rare but serious side effects have also been reported. These include, but are not limited to:

- **Serious infections** – including TB and other infections caused by viruses, fungi or bacteria that have spread all through the body. If your child gets a serious infection, Remicade® treatment may be stopped while the infection is treated.
- **Cancer** – In drug studies, there were more cancers in patients who took Remicade® and other medicines that block TNF than in those who did not get this type of medicine. Some patients with Crohn’s disease who received Remicade® developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer usually causes death.
- **Low blood counts** – In some cases, the body may not make enough of the blood cells that help fight infections or help stop bleeding.
- **Allergic reactions** – Some reactions occur right away - or shortly after - the infusions. Signs of an allergic reaction may include hives, trouble breathing, chest pain, fever or chills. Delayed reactions can occur 3 to 12 days after receiving Remicade®. Signs of a delayed reaction may include fever, rash, headache, sore throat, muscle or joint pain.
- Other possible side effects include liver injury, nervous system problems, heart failure and a condition that resembles lupus.

When to call the doctor

Be sure to tell the doctor if your child has any of these signs:

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| ▪ Fever | ▪ Feeling very tired |
| ▪ A cough | ▪ Flu-like symptoms |
| ▪ Joint pain | ▪ Skin rash (warm, red, or painful skin) |
| ▪ Stomach pain | ▪ Any side effect that bothers you or does not go away |

Do not hesitate to call the doctor with any questions or concerns.

More information about Remicade® can be found on the Food and Drug Administration website - <http://www.fda.gov/cder/drug/infopage/infliximab/default.htm>

Your child’s medicine comes with a Med Guide from the FDA. Make sure the nurse gives it to you and that you read it.

