

Rx INFLIXIMAB
(It is used to relieve the symptoms of certain autoimmune disorders)



Why is this medication prescribed?

Infliximab is used to relieve the symptoms of certain autoimmune disorders (conditions in which the immune system attacks healthy parts of the body and causes pain, swelling, and damage) including:

1. rheumatoid arthritis (a condition in which the body attacks its own joints, causing pain, swelling, and loss of function) that is also being treated with methotrexate (Rheumatrex, Trexall)
2. Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever) that has not improved when treated with other medications
3. ulcerative colitis (condition that causes swelling and sores in the lining of the large intestine) that has not improved when treated with other medications,
4. ankylosing spondylitis (a condition in which the body attacks the joints of the spine and other areas causing pain and joint damage),
5. psoriasis (a skin disease in which red, scaly patches form on some areas of the body), 6. psoriatic arthritis (joint pain and swelling and scales on the skin).

Infliximab is in a class of medications called tumor necrosis factor-alpha (TNF-alpha) inhibitors. It works by blocking the action of TNF-alpha, a substance in the body that causes inflammation.

How should this medicine be used?

1. Infliximab comes as a powder to be mixed with sterile water and administered intravenously (into a vein) by a doctor or nurse. It is usually given in a doctor's office every 2-8 weeks. It will take about 2 hours for you to receive your entire dose of infliximab.

2. Infliximab may cause serious allergic reactions during an infusion and for 2 hours afterward. A doctor or nurse will monitor you during this time to be sure you are not having a serious reaction to the medication. You may be given other medications to treat or prevent reactions to infliximab. Tell your doctor or nurse immediately if you experience any of the following symptoms during or shortly after your infusion: hives; rash; itching; swelling of the face, eyes, mouth, throat, tongue, lips, hands, feet, ankles, or lower legs; difficulty breathing or swallowing; flushing dizziness; fainting; fever; chills; seizures; and chest pain.

3. Infliximab may help control your symptoms, but it will not cure your condition. Your doctor will watch you carefully to see how well infliximab works for you. If you have rheumatoid arthritis or Crohn's disease, your doctor may increase the amount of medication you receive, if needed. If you have Crohn's disease and your condition has not improved after 14 weeks, your doctor may stop treating you with infliximab. It is important to tell your doctor how you are feeling during your treatment.

Other uses for this medicine

Infliximab is also sometimes used to treat juvenile arthritis (joint pain and swelling that begins in childhood), and Behcet's syndrome (ulcers in the mouth and on the genitals and inflammation of various parts of the body). Talk to your doctor about the possible risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow? Before using infliximab,

1. tell your doctor and pharmacist if you are allergic to infliximab, any medications made from murine (mouse) proteins, or any other medications. Ask your doctor or pharmacist if you don't know whether a medication you are allergic to is made from murine proteins.

2. tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the **IMPORTANT WARNING** section, anakinra (Kineret) and etanercept (Enbrel). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

3. tell your doctor if you have or have ever had congestive heart failure (condition in which the heart cannot pump enough blood to other parts of the body). Your doctor may tell you not to use infliximab.

4. tell your doctor if you have ever been treated with phototherapy (a treatment for psoriasis that involves exposing the skin to ultraviolet light) and if you have or have ever had a disease that affects your nervous system, such as multiple sclerosis (MS; loss of coordination, weakness, and numbness due to nerve damage), Guillain-Barre syndrome (weakness, tingling, and possible paralysis due to sudden nerve damage) or optic neuritis (inflammation of the nerve that sends messages from the eye to the brain); numbness, burning or tingling in any part of your body; seizures; chronic obstructive pulmonary disease (COPD; a group of diseases that affect the lungs and airways); any type of cancer; bleeding problems or diseases that affect your blood; or heart disease.

5. tell your doctor if you have or have ever had hepatitis B (a viral liver infection), have been told that you are a carrier (you are not sick, but the virus is still in your blood) of hepatitis B, or have been in close contact with someone who has hepatitis B. If you are a carrier of hepatitis B, your doctor will watch you carefully to be sure you do not develop an active infection while you are taking infliximab.

6. tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using infliximab, call your doctor. You should not breast-feed while using infliximab.

7. if you are having surgery, including dental surgery, tell the doctor or dentist that you are using infliximab.

8. do not have any vaccinations without talking to your doctor. Tell your doctor if you have recently received a vaccine. If your child will be using infliximab, be sure that your child has received all the shots that are required for children of his or her age before he or she begins treatment with infliximab.

9. if you were treated with infliximab in the past and you are now starting a second course of treatment, you may have a delayed allergic reaction 3-12 days after you receive infliximab. Tell your doctor if you experience any of the following symptoms several days or longer after your treatment: muscle or joint pain; fever; rash; hives; itching; swelling of the hands, face, or lips; difficulty swallowing; sore throat; and headache.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss an appointment to receive an infliximab infusion, call your doctor as soon as possible.

What side effects can this medication cause?

Infliximab may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

1. stomach pain
2. nausea
3. heartburn
4. headache
5. runny nose
6. back pain
7. white patches in the mouth
8. vaginal itching, burning, and pain or other signs of a yeast infection
9. flushing

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them, or those listed in the IMPORTANT WARNING section, call your doctor immediately:

1. any type of rash, including a rash on the cheeks or arms that gets worse in the sun
2. chest pain
3. swelling of the feet, ankles, stomach, or lower legs
4. sudden weight gain
5. shortness of breath
6. blurred vision or vision changes
7. weakness in arms or legs
8. muscle or joint pain
8. numbness or tingling in any part of the body
9. seizures
10. yellowing of the skin or eyes

11. dark colored urine
12. loss of appetite
13. pain in the upper right part of the stomach
14. unusual bruising or bleeding
15. blood in stool
16. pale skin

Studies have shown that people who use infliximab or similar medications may be more likely to develop lymphoma (cancer that begins in the cells that fight infection) than people who do not take these medications. Patients who have autoimmune diseases are more likely to develop certain types of cancer than people who do not have these conditions. This is especially true if their disease is very active. Using infliximab may increase this risk. People who have COPD may have a higher risk of developing cancer while they are using infliximab than people who do not have this condition. Talk to your doctor about the risk of using infliximab.

Infliximab may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

IMPORTANT WARNING

Infliximab injection may decrease your ability to fight infection and increase the risk that you will get a serious or life-threatening bacterial, viral, or fungal infections that may spread throughout the body. Tell your doctor if you have any type of infection now, including minor infections (such as open cuts or sores), infections that come and go (such as cold sores) and chronic infections that do not go away, or if you often get any type of infection such as bladder infections. Also tell your doctor if you have diabetes or any condition that affects your immune system and tell your doctor if you live or have ever lived in areas such as the Ohio or Mississippi river valleys where severe fungal infections are more common. Ask your doctor if you do not know if infections are more common in your area. Also tell your doctor if you are taking medications that suppress the immune system such as azathioprine (Imuran), cancer chemotherapy medications, cyclosporine (Neoral, Sandimmune), oral corticosteroids 6-mercaptopurine (Purinethol); methotrexate (Rheumatrex), sirolimus (Rapamune), and tacrolimus (Prograf). If you experience any of the following symptoms during or shortly after your treatment with infliximab injection, call your doctor immediately: weakness; sweating; difficulty breathing; sore throat; cough; fever; extreme tiredness; flu-like symptoms; warm, red, or painful skin; or other signs of infection.

You may be infected with tuberculosis (TB, a severe lung infection) but not have any symptoms of the disease. In this case, infliximab injection may increase the risk that your infection will become more serious and you will develop symptoms. Your doctor will perform a skin test to see if you have an inactive TB infection. If necessary, your doctor will give you medication to treat this infection before you start using infliximab injection. Tell your doctor if you have or have ever had TB, if you have lived in or visited a place where TB is common, or if you have been around someone who has TB.

Keep all appointments with your doctor. Your doctor will monitor your health carefully to be sure you do not develop a serious infection.

Some children and teenagers who received infliximab injection and similar medications developed severe or life-threatening cancers including lymphoma (cancer that begins in the cells that fight infection). However, most of these children and teenagers had autoimmune disorders (conditions in which the immune system attacks a healthy part of the body) that may have also increased the risk that they would develop cancer. If your child develops any of these symptoms during his treatment, call his doctor immediately: unexplained weight loss; swollen glands in the neck, underarms, or groin; or easy bruising or bleeding. Talk to your child's doctor about the risks of giving infliximab injection to your child.

Some children and teenagers with Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever) who used infliximab injection developed a rare and life-threatening type of cancer called hepatosplenic T-cell lymphoma. These patients were also taking azathioprine (Imuran) or 6-mercaptopurine (Purinethol) when they developed this cancer.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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