

The Washington University Inflammatory Bowel Disease Clinic Medication Information Sheet for Adalimumab (Humira) and Certolizumab Pegol (Cimzia)

Drug Class: Tumor necrosis factor (alpha) blocker

What do these medications do?

Used for the treatment of moderately to severely active Crohn's disease or ulcerative colitis (currently only Adalimumab is FDA approved for ulcerative colitis) by partially inhibiting (suppressing) the activity of the immune system. This medication works by blocking a substance called tumor necrosis factor, which is made by certain white blood cells in your body. Both Adalimumab and Certolizumab Pegol may decrease the inflammation caused by too much tumor necrosis factor.

Possible Side Effects:

Humira is injected subcutaneously (just below the skin) and has been associated with hypersensitivity reactions (allergic reaction), and/or an autoimmunity reaction (lupus-like syndrome). You may be more prone to developing infections while on these medications. If you develop lupus-like syndrome or have a severe hypersensitivity reaction, you will need to discontinue using Adalimumab or Certolizumab Pegol

A hypersensitivity reaction may occur at various times in relation to when the treatment begins and can occur soon after the injection, or even 3-12 days after the injection. Hypersensitivity reactions occur because part of the Humira or Certolizumab Pegol drug is made from monoclonal antibodies and your body may recognize this as a foreign substance. You may also already be on Imuran, 6-MP or methotrexate as part of your treatment and these drugs help prevent hypersensitivity reactions.

A lupus-like syndrome may also occur and have symptoms such as: chest discomfort or pain that does not go away, shortness of breath, joint pain, and/or a rash on the cheeks or arms that gets worse in the sun.

Regular laboratory studies including at least complete blood count (CBC) and liver (hepatic) function panel will be required on this medication at least monthly to every 3 months depending on your physician's preference.

Please let your doctor know if you have:

- Ever had an infusion of Remicade or are using Enbrel
- An active infection, fevers or night sweats or a dry cough which does not go away
- Exposure to or previous infection with tuberculosis (TB) or a positive PPD (TB test)
- Multiple sclerosis, Guillain-Barre syndrome, any numbness or tingling or seizures

Please call your doctor to discuss any of these side effects:

- Headache
- Rash
- Injection site reaction
- Injection site pain

Call you doctor immediately if you have any of these side effects:

- Fever, chills, sore throat or other signs of infection
- Allergic reaction (itching or hives, swelling in face or hands, swelling or tingling in the mouth or throat, tightness in your chest, trouble breathing, difficulty swallowing)
- Injection site reactions (redness, itching, swelling, bruising)
- Muscle aches
- Joint aches

Warnings:

- You may get infections more easily while taking this medicine. Stay away from people with colds, flu, or other infections.
- Talk to your doctor before getting immunized with live virus vaccines (flu shot, measles)

Dosage and Administration:

The Adalimumab dosage comes as 40mg/0.8mL in pre-filled syringes or pens. You will inject this medication subcutaneously (SQ) once every 14 days after initial dosing. You will inject into your abdomen or your thighs, being sure to rotate the injection sites in order to prevent severe injection site reactions.

The Certolizumab dosage comes as 200mg/ml pre-filled syringe. You will inject either 2 syringes (400mg) monthly or 1 syringe (200mg) every 14 days after an initial dosing. You will inject into your abdomen or your thighs, being sure to rotate the injection sites in order to prevent severe injection site reactions.

- Please call before injecting Adalimumab or Certolizumab Pegol if you are ill and/or running a fever
- You will be tested for TB prior to receiving Adalimumab or Certolizumab Pegol using a Mantoux test (PPD) and then yearly while taking this medicine. You may also be required to have a chest X-ray. If you have TB, you will need to be treated before starting Adalimumab or Certolizumab Pegol.