Massachusetts General Hospital Founding Member, Mass General Brigham

Certolizumab Pegol - Medication Information

What is certolizumab pegol?

Certolizumab pegol (brand name: Cimzia®) is a medication used to treat Crohn's disease. It is in a class of medications called anti-TNFs, which are immunosuppressants that slow down the immune system's activity to heal inflammation.

How is certolizumab pegol given?

Certolizumab pegol is an injection, or shot, that you can give yourself subcutaneously (just under the skin). In some cases, your doctor or nurse can give you the injection at their office.

It usually comes as a pre-filled syringe with a needle. It is usually given on your thighs or stomach area. An IBD nurse will show you how to do the injections at your first appointment.

When you first start on certolizumab pegol, 400 mg (2 syringes total, 200 mg each) will be given every 2 weeks: on the first day (week 0), week 2, and week 4. After that, 400 mg will be given every 4 weeks.

When can I expect certolizumab pegol to work?

Some patients may feel an improvement in symptoms as soon as 1-2 weeks of starting certolizumab pegol. Typically, up to 6 weeks is required to see a benefit.

Certolizumab pegol works for most patients. The medication may stop working in up to 10% (1 in 10) of patients every year. To make sure that it keeps working, it is important to stay on track with your injection schedule and do not miss any injections. In some cases, your doctor may also have you start a second immunosuppressive medication along with certolizumab pegol to help it work better and remain effective longer.

Studies have shown that early effective treatment for Crohn's disease is associated with long-term benefits including lowering the likelihood of needing surgery or hospitalization for health problems related to Crohn's disease.

What tests are needed while I am on certolizumab pegol?

Before beginning certolizumab pegol treatment, you will need blood tests to check for hepatitis B and tuberculosis infections. You may also need to test for tuberculosis every year. Blood tests to check your blood count and liver function are done every 4 months while on certolizumab pegol. At times, your doctor may also check your certolizumab pegol level to make sure the dose is working well for you.

What are the potential side effects of certolizumab pegol?

Side effects with certolizumab pegol are uncommon, but may include:

Allergic reaction: Patients may develop allergic reactions to certolizumab pegol as with any other medication. Reactions may include rash, hives, swelling of the lips or throat. This is uncommon and can be treated with steroid and antihistamine medications.

Injection site reaction: A small number of patients may develop an injection site reaction such as pain, redness, or swelling where the injection was given. This usually goes away within 2-3 days after each injection and sometimes can be treated with antihistamine medications.

Infection: As with other medications that act on the immune system, certolizumab pegol can increase your risk of infections. Serious infections are uncommon, but serious medical conditions like uncontrolled diabetes or lung disease may increase this risk.



Lymphoma: Certolizumab pegol can also increase the risk of lymphoma, a form of cancer of the lymph node. In the general population, about 2 out of 10,000 people get diagnosed with lymphoma every year. With certolizumab pegol, this risk may increase to 3-4 out of 10,000 people.

Opposite immune reaction: Rarely, certolizumab pegol may cause an opposite immune reaction such as psoriasis or lupus. These occur in 1-3% of patients.

Skin cancer: Certolizumab pegol may also increase the risk for skin cancer. This is rare, but taking proper precautions to lower skin cancer risk is recommended such as wearing protective clothing, applying sunscreen, and avoiding being outside for extended periods of time when the UV index is high.

Medical history: Individuals with demyelinating diseases (like multiple sclerosis or optic neuritis), active cancer, history of melanoma, or history of congestive heart failure should discuss the safety of certolizumab pegol with their gastroenterologist (GI doctor).

Please see the medication package insert for the full list of potential side effects.

Is certolizumab pegol safe during pregnancy and breastfeeding?

Women and men on certolizumab pegol have not been associated with fertility problems, miscarriages, birth defects, preterm births, stillbirths, or other pregnancy-related problems. Most patients continue the treatment during their pregnancy. Certolizumab pegol does not cross the placenta and is safe to take during the entire pregnancy up until delivery. It is also safe to breastfeed while on certolizumab pegol. This has not been shown to have any negative impacts on the baby.

It is important to discuss with your provider about continuing certolizumab pegol before, during, and after pregnancy.

How can I take care of my health while on certolizumab pegol?

It is important to be up to date with your health maintenance while on certolizumab pegol. This includes being current on all the recommended vaccines such as the flu, COVID-19, pneumococcal, and shingles vaccines. You should not get any live virus vaccines while on certolizumab pegol or for 3 months after stopping it.

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and skin check-ups for both men and women.

Speak to your primary care doctor about whether you are up to date on all your vaccines and cancer screening.

What if my out-of-pocket costs are high with this treatment?

Our pharmacy team will work with you to see if you qualify for patient assistance and help with the application process.

The manufacturer of certolizumab pegol has a patient assistance program called Cimplicity for patients on the medication. Please go to <u>cimzia.com/join-cimplicity</u> for more information on this program.

What if I have questions about certolizumab pegol?

Talk with your provider about any questions or concerns you may have about certolizumab pegol.

This document has been reviewed for plain language by Blum Center staff.

