

CERTOLIZUMAB PEGOL

What is Certolizumab pegol?

Certolizumab pegol (Cimzia®) is an antibody against a pro-inflammatory protein (cytokine) called tumor necrosis factor α (anti-TNF). It is approved for the treatment of Crohn's disease.

How is it administered?

Certolizumab pegol is a self-administered subcutaneous injection. It is usually given using a pre-filled syringe with a needle. The common sites of administration are your thighs or in your abdomen. In some cases, you can receive the injection at your healthcare providers office.

Certolizumab is dosed at 400mg (2 syringes) administered at week 0, 2, and 4, followed by 400mg every 4 weeks.

You will receive teaching on how to do the injections at your first appointment which will be with an IBD nurse.

When can I expect to respond to Certolizumab pegol?

Some patients may feel a benefit within 1-2 weeks of initiating therapy. Typically, up to 6 weeks is required to see a benefit, though many notice an improvement in the symptoms with the first two injections of Certolizumab pegol.

Approximately 6 out of 10 patients will respond to Certolizumab pegol. The medication may stop working in up to 10% of patients every year. To ensure that it remains effective, it is important to be regular in your injection schedule without gaps in treatment. Sometimes your doctor will also start a second immunosuppressive medication along with Certolizumab pegol to help it work better and remain effective longer.

Studies have shown that early effective therapy for Crohn's disease or ulcerative colitis is associated with long-term benefit including decreasing likelihood of needing surgery or hospitalization for these conditions.

What testing is needed on Certolizumab pegol therapy?

You will need blood testing to check for exposure to hepatitis B and tuberculosis infection prior to beginning treatment with Certolizumab pegol. You may also need testing for tuberculosis exposure annually. Blood counts and liver tests are routinely drawn every 4 months while on Certolizumab pegol. At times, your doctor may also check your Certolizumab pegol level to ensure that you are receiving adequate dosing.

What are the potential side effects related to Certolizumab pegol?

Side effects with Certolizumab pegol are uncommon. Patients may develop allergic reactions to Certolizumab pegol as with any other medication. This is uncommon and can be treated with steroids and anti-histamines.

Fewer than 10% of patients may develop an injection site reaction which involves pain, redness, and swelling at the site of the injection. This usually does not last longer than 2-3 days after each injection and sometimes can be treated with anti-histamine medications.

As with other medications that act on the immune system, Certolizumab pegol can increase your risk of infections. Serious infections are uncommon, occurring in fewer than 2 or 3 out of 100 people. Significant medical conditions like uncontrolled diabetes or lung disease may increase this risk.

Certolizumab pegol can also increase the risk of lymphoma, a form of cancer of the lymph node. The frequency of this in the general population is estimated to be around 2 out of 10,000 people. In those on Certolizumab pegol, this risk may increase to 3-4 in 10,000. Rarely, Certolizumab pegol may cause paradoxical immune mediated reaction such as psoriasis or lupus. These occur in 1-3% of patients.

Individuals with demyelinating diseases (like multiple sclerosis or optic neuritis), untreated active malignancy, prior history of melanoma, or history of congestive heart failure should discuss the safety of Certolizumab pegol with their gastroenterologists.

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

Is Certolizumab pegol safe during pregnancy and breast feeding?

Maternal and paternal use of Certolizumab pegol has not been associated with impairment of fertility, miscarriage, birth defects, preterm birth, still births, or other adverse pregnancy outcomes. Certolizumab pegol® does not cross the placenta and is safe to take during the entire pregnancy up till delivery. It is safe to breastfeed while on Certolizumab pegol. This has not been shown to have any adverse impact of the baby. It is important to discuss with your provider about continuing Certolizumab pegol before and during and after pregnancy, but most patients will continue the treatment during their pregnancy.

Health maintenance on Certolizumab pegol therapy

It is important to be up to date with your health maintenance while on Certolizumab pegol therapy. This includes being current on all the recommended vaccines including annual influenza vaccine and pneumococcal vaccines. You should not receive live virus vaccines while on Certolizumab pegol therapy or within 3 months of stopping (or starting it).

It is also important to be up to date in your general cancer screening including mammograms and pap smears for women, and dermatologic (skin check-ups) for both men and women. Make sure to speak to your primary care doctor about whether you are up-to-date on all your cancer screening and immunizations.

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

There are a number of foundations that provide assistance to cover cost for patients on Certolizumab pegol therapy. The manufacturer of Certolizumab pegol has a patient assistance program for patients on Certolizumab pegol, called Cimplicity. Please go to

<https://www.cimzia.com/join-cimplicity> for more information on this program.