Certolizumab Pegol (Cimzia®)

Certolizumab pegol (Cimzia®) binds to human tumor necrosis factor alpha (TNFα), a pro-inflammatory cytokine with a central role in inflammatory processes. Certolizumab pegol does not contain a fragment crystallizable (Fc) region, which is normally present in a complete antibody. Certolizumab pegol neutralizes both soluble and transmembrane forms of TNFα, blocking the binding of TNFα to its receptors and inhibiting the biologic activity of TNFα.

Resources from Manufacturer

Cimzia Patient Medication Guide

Cimzia Full Prescribing Information

Cimzia Co-pay Assistance Program

USB Patient Assistance Foundation

Indications and Dosing in Rheumatology

Certolizumab is indicated for:

- Adults with moderately to severely active rheumatoid arthritis (RA)
- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with active ankylosing spondylitis (AS)
- Adult patients with non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Adult patients with moderately to severely active Crohn's disease

Dosing:

Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), and non-radiographic axial spondyloarthritis (nr-axSpA)

- Loading dose: Subcutaneous injection of 400 mg (given as two injections of 200 mg each) initially at week 0, week 2, and week 4
- Maintenance dose: Subcutaneous injection of 200 mg every 2 weeks, or 400 mg every 4 weeks

Contraindications

Hypersensitivity reaction to certolizumab pegol or any of the excipients.

ACR/ARP Medication Guide

American College of Rheumatology
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Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

Warnings and Precautions

- Serious Infections–Do not initiate certolizumab pegol during an active infection. If a serious infection develops, discontinue certolizumab pegol until the infection is controlled.
- Hepatitis B reactivation–Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop certolizumab pegol and begin anti-viral therapy.
- Malignancies–Patients with highly active forms of rheumatoid arthritis and other chronic inflammatory diseases who are exposed to immunosuppressant therapy may be at a higher risk for developing lymphomas than the general population. Risks and benefits of treatment should be evaluated in patients with a known malignancy.
- Congestive heart failure (CHF)–Closely monitor patients with CHF that are initiated on certolizumab pegol. Discontinue therapy if new or worsening signs of CHF appear.
- Neurologic reactions–New onset or exacerbation of demyelinating disorders may occur; use caution in patient with pre-existing or recent onset demyelinating disorders.
- Lupus-like syndrome–Discontinue if symptoms occur.
- Use with abatacept, anakinra, natalizumab, and rituximab–Not recommended due to increased risk of serious infections.
- Hematologic cytopenia–Caution should be taken in patients who have or have had significant cytopenias, including leukopenia, pancytopenia, and thrombocytopenia.
- Live vaccination–Avoid use with certolizumab pegol
- Hypersensitivity reaction–Discontinue certolizumab pegol if anaphylaxis or other serious allergic reaction occurs

Adverse Reactions

Most common adverse reactions (≥ 7%):

- Upper respiratory tract infections
- Rash
- Urinary tract infection

Medication Strength and Preparations

- Single-dose pre-filled syringe: 200 mg/mL
- Lyophilized powder in single-dose vial (for SC injection): 200 mg

Medication Administration and Storage

- Store in original carton to protect from light
- Store in refrigerator at 2°C to 8°C (36°F to 46°F) – do not freeze
- Needle cover of pre-filled syringe contains latex

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Subcutaneous Administration

- Before administration, allow syringe to warm to room temperature for 30 – 90 minutes
- Inject subcutaneously into front of thigh or lower abdomen (avoid injecting within 2 inches of navel)
- When a 400 mg dose is needed (given as two separate injections of 200 mg), injections should occur at separate sites
- Do not administer into tender, bruised, red or hard skin
- Rotate injection sites (≥ 1 inch apart)

Subcutaneous Medication Preparation of Lyophilized Powder

1. Unopened certolizumab pegol vials may be stored at room temperature (up to 25°C, or 77°F) for 6 months, but not exceeding the original expiration date. If stored at room temperature, do not place back in refrigerator and write the new expiration date on the carton.
2. Remove certolizumab pegol from the refrigerator and allow the vial(s) to sit at room temperature for 30 minutes before reconstituting.
3. Reconstitute the vial(s) with 1 mL of Sterile Water for Injection, USP using the 20-gauge needle provided, with the sterile water directed at the vial wall rather than the powder.
4. Gently swirl each vial as gently as possible and without shaking to avoid creating a foaming effect for about one minute.
5. Continue swirling every 5 minutes as long as non-dissolved particles are observed. Full reconstitution may take as long as 30 minutes.
6. The final reconstituted solution contains 200 mg/mL, should be clear to opalescent, colorless to pale yellow, and free from particulates.

Subcutaneous Medication Administration of Reconstituted Lyophilized Powder

7. Once reconstituted, certolizumab pegol can be stored in the vials for up to 24 hours prior to injection.
8. Prior to injection, ensure reconstituted solution is at room temperature, but not more than 2 hours prior to administration.
9. Withdraw the reconstituted solution into a 1 mL syringe. Replace the needle on the syringe with a 23-gauge needle for subcutaneous administration into the thigh or abdomen.
10. When a 400 mg dose is needed, 2 injections of 200 mg each are required with administration into separate sites.

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