certolizumab pegol (ser-to-liz-u-mab peg-gol)

Cimzia

Classification
Therapeutic: gastrointestinal anti-inflammatories, antirheumatics
Pharmacologic: tumor necrosis factor blockers, DMARDs, monoclonal antibodies

Pregnancy Category B

Indications
Moderately-to-severely active Crohn’s disease when response to conventional therapy has been inadequate. Moderately-to-severely active rheumatoid arthritis. Active psoriatic arthritis. Active ankylosing spondylitis.

Action
Neutralizes tumor necrosis factor (TNF), a prime mediator of inflammation; pegylation provides a long duration of action.

Therapeutic Effects:
Decreased signs/symptoms of Crohn’s disease. Decreased pain and swelling, decreased rate of joint destruction and improved physical function in rheumatoid arthritis. Decreased joint swelling and pain in psoriatic arthritis. Decreased spinal pain and inflammation in ankylosing spondylitis.

Pharmacokinetics
Absorption: 80% absorbed following SC administration.
Distribution: Unknown.
Metabolism and Excretion: Unknown.
Half-life: 14 days.

TIME/ACTION PROFILE (blood levels)
ROUTE ONSET PEAK DURATION
Subcut unknown 50–120 hr 2–4 wk

Contraindications/Precautions
Contraindicated in: Active infection (including localized); Concurrent use of anakinra.
Use Cautiously in: History of chronic or recurrent infection or underlying illness/treatment predisposing to infection; History of exposure to tuberculosis; History of opportunistic infection; Patients responding, or who have responded, to biologic therapies, methotrexate, cyclosporine, or radiation; History of inflammatory bowel disease; History of demyelinating disorders (may exacerbate); History of heart failure, CVA, MI; 6 wk of infection; GI: Use in pregnancy only if clearly needed; avoid breastfeeding; OB: Use in pregnancy only if clearly needed; breast feeding; Pedi: Safety not established; q risk of lymphoma (including hepatosplenic T-cell lymphoma [HSTCL] in patients with Crohn’s disease), leukemia, and other malignancies.

Adverse Reactions/Side Effects
Derm: psoriasis, skin reactions (rarely severe).
Hemat: hematologic reactions.
MS: arthralgia.
Misc: hypersensitivity reactions including ANAPHYLAXIS AND ANGIOEDEMA, infections (including reactivation tuberculosis, hepatitis B reactivation, and other opportunistic infections due to bacterial, invasive fungal, viral, mycobacterial, and parasitic pathogens), malignancies (including lymphoma, HSTCL, leukemia, and skin cancer), lupus-like syndromes.

Interactions
Drug-Drug: Concurrent use with anakinra: risk of serious infections (contraindicated). Concurrent use with azathioprine and/or methotrexate may q risk of HSTCL. May q antibody response to or q risk of adverse reactions to live vaccines (contraindicated).

Route/Dosage
Crohn’s Disease
Subcut (Adults): 400 mg initially, repeat 2 and 4 wk later; may be followed by maintenance dose of 400 mg every 4 wk.

Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis
Subcut (Adults): 400 mg initially, repeat 2 and 4 wk later; then maintenance dose of 200 mg every 2 wk (400 mg every 4 wk may be used alternatively).

NURSING IMPLICATIONS
Assessment
Crohn’s Disease: Assess abdominal pain and frequency, quantity, and consistency of stools at beginning and during therapy.

Use Cautiously: History of chronic or recurrent infection or underlying illness/treatment predisposing to infection; History of exposure to tuberculosis; History of opportunistic infection; Patients responding, or who have responded, to biologic therapies, methotrexate, cyclosporine, or radiation; History of inflammatory bowel disease; History of demyelinating disorders (may exacerbate); History of heart failure, CVA, MI; 6 wk of infection; GI: Use in pregnancy only if clearly needed; avoid breastfeeding; OB: Use in pregnancy only if clearly needed; breast feeding; Pedi: Safety not established; q risk of lymphoma (including hepatosplenic T-cell lymphoma [HSTCL] in patients with Crohn’s disease), leukemia, and other malignancies.
● Arthritis/Ankylosing Spondylitis: Assess pain and range of motion before and periodically during therapy.

● Assess for signs of infection (fever, sore throat, dyspnea, WBC) prior to and during therapy. Monitor all patients for active TB during therapy, even if initial test was negative. Do not begin certolizumab during an active infection, including chronic or localized infections. If infection develops, monitor closely and discontinue certolizumab if infection becomes serious.

● Evaluate patients at risk for hepatitis B virus (HBV) infection for prior evidence of HBV infection before initiating therapy. Monitor carriers of HBV closely for clinical and lab signs of active HBV infection during and for several months following discontinuation of therapy. If HBV reactivation occurs, discontinue certolizumab and initiate antiviral therapy.

● Monitor for signs of hypersensitivity reactions (angioedema, dyspnea, hypotension, rash, urticaria). If reactions occur, discontinue certolizumab immediately.

● Assess for signs and symptoms of systemic fungal infections (fever, malaise, weight loss, sweats, cough, dyspnea, pulmonary infiltrates, serious systemic illness with or without concomitant shock). Ascertain if patient lives in or has traveled to areas of endemic mycoses. Consider empiric antifungal treatment for patients at risk of histoplasmosis and other invasive fungal infections until the pathogens are identified. Consult with an infectious diseases specialist. Consider stopping certolizumab until the infection has been diagnosed and adequately treated.

● Lab Test Considerations: May cause anemia, leukopenia, pancytopenia, and thrombocytopenia.

● Monitor CBC with differential periodically during therapy. May cause leukopenia, neutropenia, thrombocytopenia, and pancytopenia. Discontinue certolizumab if symptoms of blood dyscrasias (persistent fever) occur.

● May cause QT prolongation.

● May cause erythromelalgia. | APTT.

Potential Nursing Diagnoses

Risk for infection (Side Effects)

Implementation

Perform test for latent TB. If positive, begin treatment for TB prior to starting certolizumab therapy. Monitor for TB throughout therapy, even if latent TB test is negative.

Bring medication to room temperature prior to reconstituting. Reconstitute 2 vials for each dose by adding 1 ml of Sterile Water for injection to each vial, using a 20-gauge needle, for a concentration of 200 mg/mL. Gently swirl so all powder comes into contact with sterile water; do not shake. Leave vials unattached for as long as 30 min to fully reconstitute. Solution is clear and colorless to pale yellow; do not administer solutions that are discolored or contain particulate matter. Do not leave reconstituted solution at room temperature for > 2 hr prior to injection. May be refrigerated for up to 24 hr prior to injection; do not freeze.

Subcut: Bring solution to room temperature prior to injection. Using a new 23-gauge needle for each vial, withdraw reconstituted solution into 2 separate syringes each containing 1 mL (200 mg/mL) of certolizumab. Switch each 23-gauge needle to a 25-gauge needle and inject the full contents of each syringe subcut into separate sides of the abdomen or thigh.

Patient/Family Teaching

● Advise patient of potential benefits and risks of certolizumab. Advise patient to read the Medication Guide prior to starting therapy.

● Inform patient of risk of infection. Advise patient to notify health care professional if symptoms of infection (fever, cough, flu-like symptoms, or open cuts or sores), including TB or reactivation of HBV infection, occur.

● Counsel patient about possible risk of lymphoma and other malignancies while receiving certolizumab.

● Advise patient to notify health care professional if signs of hypersensitivity reactions (rash, swelling face, difficulty breathing); or new or worsening medical conditions such as heart or neurological disease or autoimmune disorders occur and to report signs of bone marrow depression (bruising, bleeding, or persistent fatigue).

● Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and to consult health care professional prior to taking any Rx, OTC, vitamins, or herbal products.

● Advise patient to notify health care professional of pregnancy or if breast feeding.

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Evaluation/Desired Outcomes
- Decrease in signs and symptoms of Crohn’s disease.
- Decreased pain and swelling with decreased rate of joint destruction in patients with rheumatoid arthritis.
- Decreased joint swelling and pain in psoriatic arthritis.
- Decreased spinal pain and inflammation in ankylosing spondylitis.

Why was this drug prescribed for your patient?