cimzia®
(certolizumab pegol)

PRESCRIBING INFORMATION PATIENT POPULATION REFERENCE GUIDE

CIMZIA is indicated for:

- **Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy**
- **Treatment of adults with moderately to severely active rheumatoid arthritis**
- **Treatment of adult patients with active psoriatic arthritis**
- **Treatment of adults with active ankylosing spondylitis**
- **Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation**
- **Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy**

The following provides a quick reference guide with information about specific patient populations that can be found in the CIMZIA Prescribing Information (PI). These sections of the PI do not include all the information needed to prescribe CIMZIA safely and effectively. Please see the full Prescribing Information for CIMZIA provided by your sales representative.

For more information on CIMZIA use in:

- Patients with **moderate-to-severe Crohn's disease**, refer to PI sections 1.1 for Indication and Usage, 2.1 for Dosing and Administration, and 14.1 for Clinical Studies (Study CD1, Study CD2)
- Patients with **moderate-to-severe rheumatoid arthritis**, refer to PI sections 1.2 for Indication and Usage, 2.2 for Dosing and Administration, and 14.2 for Clinical Studies (Study RA-I, RA-II, RA-III, and RA-IV)
- Patients with **active psoriatic arthritis**, refer to PI sections 1.3 for Indication and Usage, 2.3 for Dosing and Administration, and 14.3 for Clinical Studies (Study PsA001)
- Patients with **active ankylosing spondylitis**, refer to PI sections 1.4 for Indication and Usage, 2.4 for Dosing and Administration, and 14.4 for Clinical Studies (Study AS-1)
- Patients with **active non-radiographic axial spondyloarthritis**, refer to PI sections 1.5 for Indication and Usage, 2.5 for Dosing and Administration, and 14.5 for Clinical Studies (Study nr-axSpA-1)
- Patients with **moderate-to-severe plaque psoriasis**, refer to PI sections 1.6 for Indication and Usage, 2.6 for Dosing and Administration, and 14.6 for Clinical Studies (Study PS-1, PS-2 and PS-3)
- Patients who are pregnant or considering pregnancy, refer to PI section 8 Use in Specific Populations, section 8.1 for **Pregnancy**
- Patients who are breastfeeding or considering breastfeeding, refer to PI section 8 Use in Specific Populations, section 8.2 for **Lactation**
- Pediatric patients, refer to PI section 8 Use in Specific Populations, section 8.4 for **Pediatric Use**
- Geriatric patients, refer to PI section 8 Use in Specific Populations, section 8.5 for **Geriatric Use**

Please see Important Safety Information on pages 2-4.
Please refer to the full Prescribing Information provided by the UCB representative, and visit CIMZIAhcp.com.

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IMPORTANT SAFETY INFORMATION

INDICATIONS

CIMZIA is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), and active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. CIMZIA is also indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PSO) who are candidates for systemic therapy or phototherapy, and for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adults with moderately to severely active disease who have had an inadequate response to conventional therapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

SERIOUS INFECTIONS

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

Please see Important Safety Information continued on next page.

IMPORTANT SAFETY INFORMATION (cont)

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.
- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Exercise caution and monitor carefully.

HYPERSENSITIVITY

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

Please see Important Safety Information continued on next page.

IMPORTANT SAFETY INFORMATION (cont)

NEUROLOGIC REACTIONS

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDS.

AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

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