CIMZIA (certolizumab pegol)

- Meet Oliver
- At 12 Weeks
- At 24 Weeks
- At 48 Weeks
- At 4 Years

Important Safety Information

Full Prescribing Information

CIMZIA IS INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS (PSA).

CIMZIA can help real **biologic-experienced patients**, like Oliver, improve joint symptoms and get

BACK TO ACTIVE[2]

Give Patients Control of Their Psoriatic Symptoms With CIMZIA

Scroll to learn more about Oliver's treatment journey.

Actor Portrayal

IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. 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.

CIMZIA has demonstrated safety and efficacy data in 1 pivotal study in adult patients with active psoriatic arthritis[1]

In psoriatic arthritis patients, the primary efficacy end point at Week 12 in RAPID-PsA was ACR20, with 58% of CIMZIA patients achieving ACR20 at Week 12 vs 24% of placebo patients. Similar results were seen in the 20% of patients with prior biologic experience[3,4]

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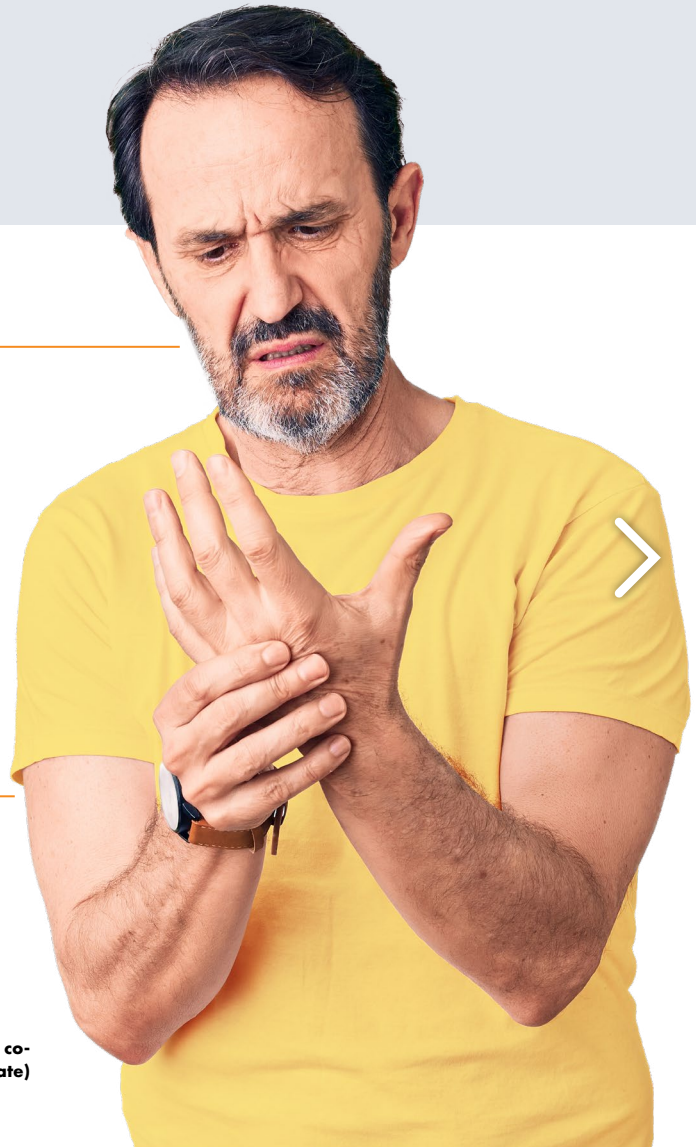
Meet Oliver

Age: 50 **Height:** 5′7″ **Weight:** 135 lbs

Occupation: Physical laborer at a railyard

Treatment goals: Reduce joint pain and improve his skin's appearance



Skin Symptoms

- plaques on arms, legs, sacrum, scalp, and nails
- BSA = 35%
- PGA = 3

Joint Symptoms

- pain in fingers, hands, wrists, hips, and feet
- started having joint pain 10 years ago; diagnosed with psoriatic arthritis after exam

Medication history

- topicals
- oral systemics
- anti-TNF

Infection and vaccine history

- TB screening = negative
- infections = none
- current on all vaccinations

With psoriatic arthritis, even a 6-month delay in diagnosis can result in irreversible joint damage.[3]

A population-based study from 2000 to 2017 reported >50% of patients had a diagnostic delay of >2 years, making early detection and treatment critically important for improving long-term patient outcomes.[4]

BSA, body surface area; PGA, Physicians Global Assessment; TB, tuberculosis; TNF, tumor necrosis factor.

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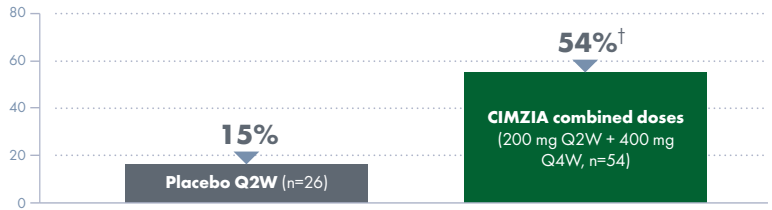
At 12 Weeks

"I'm starting to feel better and the joint pain in my wrists and feet is improved."

RAPID-PsA

Improvements in Joint Pain and Stiffness at Week 12 in Patients With Prior Anti-TNF Experience

ACR20 responder rates at Week 12[5]*



ACR20 response rates were stratified by baseline prior anti-TNF exposure, which was a prespecified secondary end point

*Prespecified secondary analysis of a primary end point; primary nonresponders excluded
†P<0.001[2]

To quickly recognize specific characteristics of psoriatic arthritis, remember **PSA**:

Pain | **S**tiffness | **A**xial involvement

ACR20, American College of Rheumatology criteria for 20% response; TNF, tumor necrosis factor; Q2W, every 2 weeks; Q4W, every 4 weeks.

IMPORTANT SAFETY INFORMATION

Cases of lymphoma and other malignancies have been observed among patients receiving TNF blockers, including children, adolescents, and young adults. Acute and chronic cases of leukemia have also been reported. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including CIMZIA. Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-antagonists, including CIMZIA. Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

At 24 Weeks

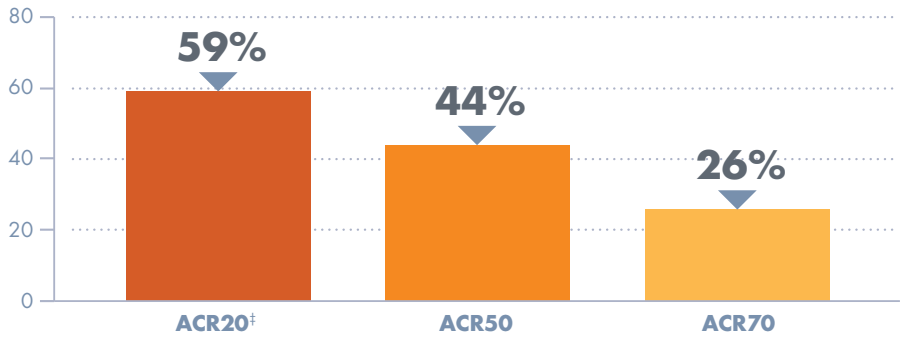
"The pain in my wrists, hands, and feet continues to get better, and I even feel relief in my fingers and hips."

RAPID-PsA

CIMZIA Provides Symptom Relief at Week 24 in Patients With Prior Anti-TNF Experience[6]

ACR responder rates at Week 24[6]*

anti-TNF experienced CIMZIA combined dose (n=54)†



In the placebo prior anti-TNF group (n=26), patients achieved ACR 20/50/70 rates of 12%, 4%, and 4%, respectively

*Randomized set. Nonresponder imputation

†CIMZIA combined dose included patients receiving CIMZIA 200 mg Q2W and patients receiving CIMZIA 400 mg Q4W

‡ACR20 response rates were stratified by baseline prior anti-TNF exposure, which was a prespecified secondary end point

ACR20, American College of Rheumatology criteria for 20% response; ACR50, American College of Rheumatology criteria for 50% response; ACR70, American College of Rheumatology criteria for 70% response; TNF, tumor necrosis factor; Q2W, every 2 weeks; Q4W, every 4 weeks.

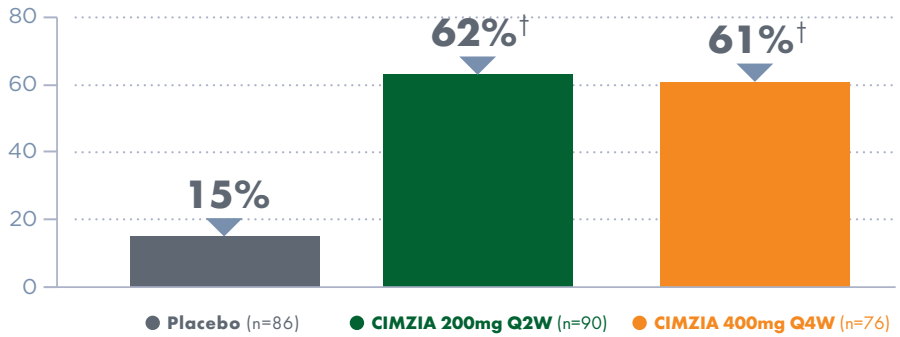
At 24 Weeks

"My skin is significantly clearer!"

RAPID-PsA

Skin Improvement at Week 24 in a Subpopulation of CIMZIA Patients with PsA[6]

PASI 75 responder rates in patients with ≥3% BSA at baseline at Week 24*



Baseline psoriatic skin involvement was ≥3% of BSA and median PASI at baseline was 7.1 for placebo and 7.0 for CIMZIA. 62% of patients receiving CIMZIA and 61% of patients receiving placebo had skin manifestations at baseline

*Randomized set. Nonresponder imputation

†Nominal *P*-value <0.005 vs placebo

BSA, body surface area; PASI, Psoriasis Area and Severity Index.

IMPORTANT SAFETY INFORMATION

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers.

CIMZIA® (certolizumab pegol)

Meet Oliver

At 12 Weeks

At 24 Weeks

At 48 weeks

At 4 Years

Important Safety Information

Full Prescribing Information

At 48 Weeks

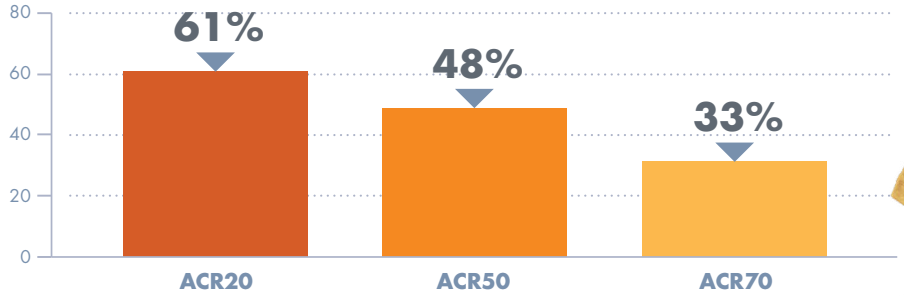
"The pain in the joints of my fingers, hands, wrists, hips, and feet has gotten significantly better since starting treatment."

RAPID-PsA

Sustained Relief of Joint Pain and Stiffness at Week 48 in Patients With Prior Anti-TNF Experience[2]

ACR responder rates at Week 48 open-label extension (OLE)*

anti-TNF experienced CIMZIA combined dose (n=54)†



Limitations of OLE data: ACR responder rates do not have a long-term placebo comparator beyond Week 24

*Randomized set. Nonresponder imputation

†CIMZIA combined dose included patients receiving CIMZIA 200 mg Q2W and patients receiving CIMZIA 400 mg Q4W

ACR20, American College of Rheumatology criteria for 20% response; ACR50, American College of Rheumatology criteria for 50% response; ACR70, American College of Rheumatology criteria for 70% response; TNF, tumor necrosis factor; Q2W, every 2 weeks; Q4W, every 4 weeks.

IMPORTANT SAFETY INFORMATION

Anaphylaxis or serious allergic reactions may occur. Some of these reactions occurred after the first administration of CIMZIA. Hypersensitivity reactions have been reported rarely following CIMZIA administration. 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.

CIMZIA (certolizumab pegol)

Meet Oliver

At 12 Weeks

At 24 Weeks

At 48 Weeks

At 4 Years

Important Safety Information

Full Prescribing Information

At 4 Years

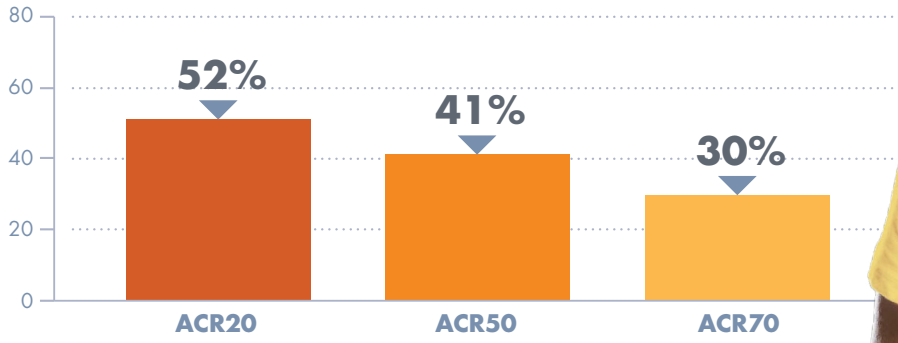
"I've been feeling great—I rarely have joint pain and am better able to do many tasks!"

RAPID-PsA

Long-Term Relief of Joint Pain and Stiffness Through 4 Years in Patients With Prior Anti-TNF Experience[2]

ACR responder rates at Week 216*

anti-TNF experienced CIMZIA combined dose (n=54)†



Limitations of open-label extension (OLE) data: ACR responder rates do not have a long-term placebo comparator beyond Week 24

*Randomized set. Nonresponder imputation

†CIMZIA combined dose included patients receiving CIMZIA 200 mg Q2W and patients receiving CIMZIA 400 mg Q4W

ACR20, American College of Rheumatology criteria for 20% response; ACR50, American College of Rheumatology criteria for 50% response; ACR70, American College of Rheumatology criteria for 70% response; TNF, tumor necrosis factor; Q2W, every 2 weeks; Q4W, every 4 weeks.

IMPORTANT SAFETY INFORMATION

Use of TNF blockers, including CIMZIA, has been associated with reactivation of hepatitis B virus in patients who are chronic carriers of the virus. In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal.

CIMZIA (certolizumab pegol)

Meet Oliver

At 12 Weeks

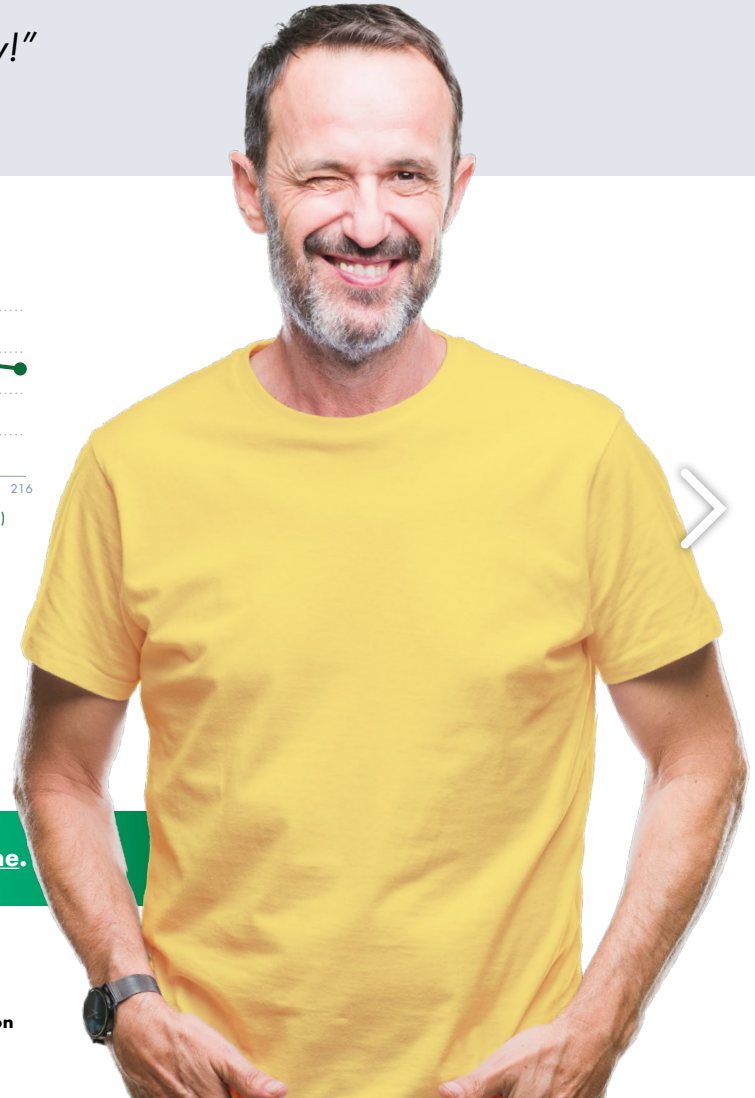
At 24 Weeks

At 48 Weeks

At 4 Years

At 4 Years

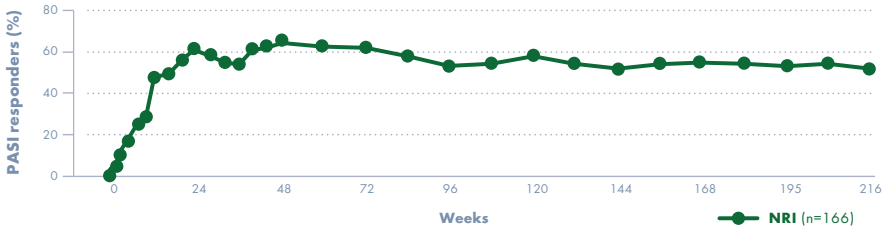
"I'm comfortable with my skin now!"



RAPID-PsA

Long-Term Skin Improvement in a Subpopulation of CIMZIA Patients[2]

PASI 75 responder rates in patients with ≥3% BSA at baseline[2]



Combined doses (CIMZIA 200 mg Q2W + CIMZIA 400 mg Q4W)

Baseline psoriatic skin involvement was ≥3% of BSA (62% overall) and median PASI at baseline was 7.1 for placebo and 7.0 for CIMZIA

Limitations of open-label extension (OLE) data: PASI responder rates do not have a long-term placebo comparator beyond Week 24

Data are shown for the randomized set. PASI responder rates are given for patients with baseline skin involvement (≥3% BSA affected by psoriasis). Patients were treated with CIMZIA from Week 0

Actor Portrayal

CIMZIA also helped a biologic-naïve psoriasis patient.[5,7] **Meet Joanne.**

BSA, body surface area; PASI, Psoriasis Area and Severity Index; Q2W, every 2 weeks; Q4W, every 4 weeks.

IMPORTANT SAFETY INFORMATION

Use of TNF blockers, including CIMZIA, has been associated with reactivation of hepatitis B virus in patients who are chronic carriers of the virus. In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal.

Important Safety Information

Full Prescribing Information

Indications

- CIMZIA (certolizumab pegol) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- CIMZIA is indicated for the treatment of adults with active psoriatic arthritis.

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.

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

Important Safety Information (continued)

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.

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-Barre 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%).

Please click to access full **Prescribing Information**, or visit **CIMZIAhcp.com**.

References: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc. **2.** van der Heijde D, Deodhar A, FitzGerald O, et al. 4-year results from the RAPID-PsA phase 3 randomised placebo-controlled trial of certolizumab pegol in psoriatic arthritis. *RMD Open.* 2018;4(1):e000582. 20. **3.** Haroon M, Gallagher P, FitzGerald O. Diagnostic delay of more than 6 months contributes to poor radiographic and functional outcome in psoriatic arthritis. *Ann Rheum Dis.* 2015;74(6):1045-1050. **4.** Karmacharya P, Wright K, Achenbach S, Bekele D, Crowson C, Ogdie A, Duarte-Garcia A, Ernste F, Tollefson M, Davis J. Diagnostic delay in psoriatic arthritis: a population based study [abstract]. *Arthritis Rheumatol.* 2021;jrheum.201199. **5.** Data on file. UCB, Inc.; Smyrna, GA. **6.** Mease PJ, Fleischmann R, Deodhar AA, et al. Effect of certolizumab pegol on signs and symptoms in patients with psoriatic arthritis: 24-week results of a phase 3 double-blind randomised placebo-controlled study (RAPID-PsA). *Ann Rheum Dis.* 2014;73(1):48-55. **7.** Gordon KB, Warren RB, Gottlieb AB, et al. Long-term efficacy of certolizumab pegol for the treatment of plaque psoriasis: 3-year results from two randomized phase III trials (CIMPASI-1 and CIMPASI-2). *Br J Dermatol.* Published online September 9, 2020:bjd.19393. doi:10.1111/bjd.19393.

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