PRESCRIBING INFORMATION FOR HCP'S IN REPUBLIC OF IRELAND AND NORTHERN IRELAND (Please consult the Summary of Product Characteristics (SPC) before prescribing).

Cimzia® (Certolizumab Pegol) Active Ingredient: Certolizumab pegol 200 mg in one ml in a pre-filled syringe, pre-filled pen or dose dispenser cartridge **Indication(s):** *Rheumatoid arthritis (RA):* Cimzia, in combination with methotrexate (MTX), is indicated for moderate to severe, active RA in adult patients with inadequate response to disease-modifying antirheumatic drugs (DMARDs) including MTX. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Cimzia in combination with methotrexate (MTX), is also indicated in severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX. *Axial spondyloarthritis:* Cimzia is indicated in adult patients with severe active axial spondyloarthritis, comprising: *Ankylosing spondylitis (AS):*Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). *Axial spondyloarthritis without radiographic evidence of AS:* Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs. *Psoriatic arthritis:* Cimzia in combination with MTX, is indicated for active psoriatic arthritis in adults with inadequate response to previous DMARD therapy. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. *Plaque psoriasis:* Cimzia is indicated in moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Dosage and Administration:** Should be initiated and supervised by specialist experienced physicians. Provide patients with the reminder alert card. For RA and psoriatic arthritis, continue MTX during treatment with Cimzia where appropriate. *Loading dose:* Recommended starting dose is 400 mg (2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4. *Maintenance dose: RA and Psoriatic Arthritis:* Recommended maintenance dose is 200 mg every 2 weeks. Once clinical response confirmed, can consider an alternative maintenance dose of 400 mg every 4 weeks. *Axial spondyloarthritis:* Recommended maintenance dose is 200 mg every 2 weeks or 400 mg every 4 weeks. After at least 1 year of treatment, in axSpA patients with sustained remission, can consider a reduced maintenance dose of 200 mg every 4 weeks. (see SPC). For indications above, carefully reconsider continued therapy in patients with no evidence of therapeutic benefit in the first 12 weeks of treatment. *Plaque psoriasis:* Recommended maintenance dose is 200 mg every 2 weeks. Can consider 400 mg every 2 weeks if insufficient response. Carefully reconsider continued therapy in patients with no evidence of therapeutic benefit in first 16 weeks of treatment. *Missed dose:* Advise patients to inject the next dose as soon as they remember and inject subsequent doses as originally instructed. **Contraindications:** Hypersensitivity to active substance or any excipients; active tuberculosis or other severe infections such as sepsis or opportunistic infections; moderate to severe heart failure (NYHA classes III/IV). **Warnings & Precautions:** Before starting Cimzia, screen for active and inactive tuberculosis and record results on the patient reminder alert card. If a past history of latent tuberculosis, use of anti-tuberculosis therapy must be started before initiation of Cimzia. If active tuberculosis diagnosed before or during treatment, Cimzia must not be initiated and must be discontinued. Some patients who have been successfully treated for active tuberculosis have redeveloped tuberculosis while being treated with Cimzia. Advise patients to seek advice if sign/symptoms of tuberculosis occur during/after therapy. Consult SPC for details. Monitor patients closely for signs of infection before, during and up to 5 months after treatment. Must not initiate if clinically important active infection until infection controlled. Monitor if develops new infection during treatment and discontinue if develops serious new infection until infection controlled. Serious infections and opportunistic infections have been reported with some fatal outcomes. Caution in patients with a history of recurring or opportunistic infections including those on concomitant corticosteroid or immunosuppressive medications or elderly. Test for HBV infection before starting Cimzia. If HBV carriers are treated with Cimzia, monitor throughout and after treatment. HBV reactivation has occurred in chronic carriers with some fatal outcomes. If develop HBV reactivation, discontinue Cimzia and initiate antiviral therapy and supportive treatments. Possible risk for lymphomas, leukaemia or other malignancies with TNF-antagonist treatment cannot be excluded. Caution if history of malignancy and when considering continuing therapy in patients who develop malignancy. Melanoma and Merkel cell carcinoma have been reported. Periodic skin exam recommended, especially if risk factors for skin cancer. Advise patients to seek immediate medical attention if they develop signs and symptoms suggestive of tuberculosis, blood dyscrasias or infection. Medical significant cytopaenia has been reported with Cimzia. Advise patients to seek immediate medical advice if signs/symptoms suggestive of blood dyscrasias or infection. Consider discontinuation if confirmed significant haematological abnormalities. Rare cases reported of demyelinating disease including multiple sclerosis. Consider benefit-risk if pre-existing or recent onset demyelinating disorder. Rare cases of neurological disorders reported with Cimzia. Rare reports of severe hypersensitivity reactions, some after first Cimzia administration – discontinue Cimzia immediately and treat appropriately. Use with caution if history of severe hypersensitivity to another TNF-antagonist. Cimzia has been associated with formation of antinuclear antibodies (ANA) and development of a lupus-like syndrome. If patient develops lupus-like syndrome, discontinue treatment. Use with caution in mild heart failure; discontinue if new or worsening symptoms of congestive heart failure. Use with caution in COPD patients and those with history of heavy smoking due to increased risk for malignancy. Patients receiving Cimzia may receive vaccination except live vaccines. Cimzia may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities. The needle shield contains a natural rubber latex derivative which may cause allergic reactions. Record name and batch number of administered product to improve traceability of biological products. **Interactions:** The combination of Cimzia and anakinra or abatacept is not recommended. **Fertility, pregnancy and lactation:** The use of adequate contraception to prevent pregnancy should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last Cimzia dose due to its elimination rate, but the need for treatment of the woman should also be taken into account. Data from more than 1300 prospectively collected pregnancies exposed to Cimzia with known pregnancy outcomes, including more than 1000 pregnancies exposed during the first trimester, does not indicate a malformative effect of Cimzia. Further data are being collected as the available clinical experience is still limited to conclude that there is no increased risk associated with Cimzia administration during pregnancy. Due to its inhibition of TNF alpha, Cimzia administered during pregnancy could affect normal immune response in the newborn. Cimzia should only be used during pregnancy if clinically needed. In a clinical study, 16 women were treated with certolizumab pegol during pregnancy. Certolizumab pegol plasma concentrations measured in 14 infants at birth were Below the Limit of Quantification (BLQ) in 13 samples; one was 0.042 µg/ml with an infant/mother plasma ratio at birth of 0.09%. At Week 4 and Week 8, all infant concentrations were BLQ. The clinical significance of low levels certolizumab pegol for infants is unknown. In a clinical study in 17 lactating women treated with Cimzia, minimal transfer of certolizumab pegol from the plasma to breast milk was observed. The percentage of the maternal Cimzia dose that reaches an infant during a 24-hour period was estimated to 0.04% to 0.3%. In addition, since certolizumab pegol is a protein that is degraded in the gastrointestinal tract after oral administration, the absolute bioavailability is expected to be very low in a breastfed infant. Consequently, Cimzia can be used during breastfeeding. **Effects on ability to drive:** Dizziness (including vertigo, vision disorder, fatigue) may occur after Cimzia administration. **Side Effects:** Common adverse-effects (≥ 1/100 to <1/10): bacterial and viral infections, eosinophilic disorders, leukopenia, headaches, sensory abnormalities, hypertension, nausea, hepatitis (including hepatic enzyme increased), rash, pyrexia, pain, asthenia, pruritus (any site), injection site reactions. **Serious Side effects**: Infections including sepsis, tuberculosis, fungal infections, blood and lymphatic system malignancies, solid organ tumours, non-melanoma skin cancers, pre-cancerous lesions, benign tumours and cysts, gastrointestinal tumours, melanoma, Merkel cell carcinoma, Kaposi's sarcoma, eosinophilic disorders, leukopaenia (including neutropaenia, lymphopaenia), anaemia, lymphadenopathy, thrombocytopaenia, thrombocytosis, pancytopaenia, splenomegaly, erythrocytosis, vasculitides, lupus erythematosus, drug hypersensitivity (including anaphylactic shock), angioneurotic oedema, sarcoidosis, thyroid disorders, haemosiderosis, suicide attempt, delirium, mental impairment, anxiety disorders, sensory abnormalities, peripheral neuropathies, seizure, cranial nerve inflammation, multiple sclerosis, Guillain-Barré syndrome, visual disorder, tinnitus, vertigo, cardiomyopathies, ischaemic coronary artery disorders, arrhythmias, palpitations, pericarditis, atrioventricular block, hypertension, haemorrhage or bleeding (any site), hypercoagulation, syncope, cerebrovascular accident, arteriosclerosis, Raynaud's phenomenon, asthma, pleural effusion, interstitial lung disease, pneumonitis, ascites, gastrointestinal ulceration and perforation, gastrointestinal tract inflammation, odynophagia, hepatitis (including hepatic enzyme increased), hepatopathy, cholelithiasis, new onset or worsening of psoriasis, bullous conditions, Stevens-Johnson syndrome, erythema multiforme, lichenoid reactions, renal impairment, nephropathy, fistula, coagulation time prolonged. **Consult SPC in relation to other side effects. Pharmaceutical Precautions**: Store in refrigerator (2°-8°C). Do not freeze. Keep the pre-filled syringe and pre-filled pen in the outer carton to protect from light. **Legal Category**: POM. **Marketing Authorisation Number(s):** EU/1/09/544/001, EU/1/09/544/005 and EU/1/09/544/008 **UK NHS Cost:** £715 per pack of 2 pre-filled syringes, pens or cartridges of 200 mg each. **Marketing Authorisation Holder**: UCB Pharma S.A., Allée de la Recherche 60, 1070 Brussels, Belgium. **Further information is available from**: *Northern Ireland:* UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE.Tel: +44 (0) 1753 777100. Fax: +44 (0)1753 536632. Email: UCBCares.UK@ucb.com; *Republic of Ireland:* UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, City West Road, Dublin 24, Ireland Tel: +353 1 4632371 Fax: +353 14637396. Email: UCBCares.IE@ucb.com

Date of Revision: June 2022 (IE-P-CZ-AS-2200042). Cimzia is a registered trademark

Adverse events should be reported. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk** for Northern Ireland and **www.hpra.ie/homepage/about-us/report-an-issue** for Republic of Ireland. Adverse events should also be reported to UCB Pharma Ltd.
Email: **UCBCares.IE@UCB.com**