ORENICA® (abatacept) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing.

PRESENTATION: 250 mg powder for concentrate for solution for IV infusion, 250 mg pre-filled syringe and ClickJet pre-filled pen, for SC injection, each pre-filled syringe and pen contains 25 mg of abatacept in 1 ml.

INDICATIONS: Rheumatoid arthritis (IV infusion and SC pre-filled syringe and pen): Treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a Tumour Necrosis Factor (TNF) α inhibitor. A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate. See SmPC.

Polyarthritis juvenile idiopathic arthritis (pJIA) (IV infusion only): Orencia 250 mg powder for concentrate for solution for infusion is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor.

DOSEAGE AND ADMINISTRATION: Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. Orencia 250 mg powder for concentrate for solution for IV infusion

Adults and elderly Patients: weighing < 70 kg: 100 mg q 4 weeks Patients: weighing ≥ 70 kg: 150 mg q 4 weeks. Paediatric patients: 6 to 17 years of age, weighing less than 75 kg: 1 mg/kg q 4 weeks. Paediatric patients weighing 75 mg or more: should be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orencia should be given at 4 and 8 weeks, then every 4 weeks thereafter. Children Use in children below 6 years of age is not recommended.

Orencia SC is indicated for injection (SC pre-filled syringe and pen) Adults and elderly

Orencia SC may be administered with or without an influenza (IV) loading dose. Orencia SC should be administered weekly at a dose of 125 mg by subcutaneous injection regardless of weight. If a single IV infusion is given to initiate treatment (IV loading dose before SC administration), the first 25 mg abatacept SC should be administered within a day of the IV infusion, followed by the weekly 125 mg abatacept SC injection. Patients transitioning from Orencia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. Children Administration in children below 6 years of age is not recommended. The continuation of treatment with abatacept at the re-assessed if patients do not respond within 6 months.

CONTRAINDICATIONS: Hypersensitivity to the active substance or excipients. Stevens and Jones methanol, and other known or postulated infectious reactions such as sepsis and septic shock. Warnings and precautions: Allergic Reaction: Caution in patients with a history of allergy reactions. Anaphylaxis or anaphylactoid reactions can occur after the first infusion and can be life threatening. Orencia IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactic reaction. Injection: Caution should be exercised when considering use in patients with a history of frequent infections, or underlying conditions which may predispose to infection. Treatment with Orencia should not be initiated in patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orencia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF antagonist to Orencia. Co-administration of Orencia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progression of lymphoproliferative disorders (LPL). Orencia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. Malignancies: The potential role of Orencia in the development of malignancies is unknown. However, periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer, see SmPC. Elderly: Caution should be used when treating elderly patients due to a higher incidence of malignancies is unknown. However, periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer, see SmPC. Elderly: Caution should be used when treating elderly patients due to a higher incidence of malignancies in this patient group. Autimmune processes. Theoretical risk of deterioration in autoimmune disease. Immunisation: Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orencia. See SmPC. DRUG INTERACTIONS: Concomitant therapy of Orencia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orencia in combination with sulfasalazine, hydroxychloroquine or leflunomide. PREGNANCY AND LACTATION: Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast feed during treatment and for up to 4 weeks after last dose treatment. UNDESIRABLE EFFECTS: In adult placebo-controlled trials the following adverse drug reactions were reported. Incidence: ≥ 1/100, ≥ 1/10, ≥ 1/1000, < 1/100. Lower respiratory tract infection including bronchitis, sinusitis, lower respiratory tract infection, Herpes, infections including (herpes simplex, oral herpes and herpes zoster), rhinitis, pneumonia, influenza, leukaemia, headache, dizziness, paracetamol, conjunctivitis, hypertension, flushing, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatis), alopecia, pruritus, pain in extremity, fatigue, asthma, local injection site reactions*, systemic injection reactions* (e.g. pruritus, throat tightness, dyspnea) (Orencia SC), Decrinsion (e.g. alopecia, pruritus, respiratory, cardiovascular, allergic, infections, skin abscess, pyelonephritis, pelvic inflammatory disease, basal cell carcinoma, squamous cell carcinoma, skin papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraines, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, bronchospasm, wheezing, dyspnoea, gastrointestinal infection, lymphoma, lung neoplasm, malignant, throat tightness. See SmPC for information on other undesirable effects.

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER AND BASIC NHS PRICE: Orencia 250 mg concentrate for solution for infusion: EU/1/07/389/019, vial pack: £150.40. Orencia 75 mg solution for injection (pre-filled syringe): EU/1/07/389/010 and ClickJet pre-filled pen: EU/1/07/389/017, 4 pre-filled syringes with needle guard: £42.50. Orencia 125 mg solution for injection (pre-filled syringe): EU/1/07/389/018 and ClickJet pre-filled pen: EU/1/07/389/016, 4 pre-filled pens: £120.90.

MARKETING AUTHORISER: Bristol-Myers Squibb Pharma EID, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Bristol-Myers Squibb Pharmaceuticals Ltd Medical Information on 0800 731 1736 or medicalinformation@bms.com.