UK/NLA/0013/15(2)a – August 2018

Nucala® ▼ (mepolizumab) Prescribing information

(Please consult the full Summary of Product Characteristics (SmPC) before prescribing)

Nucala® (mepolizumab) powder for solution for injection. Each vial contains 100 mg mepolizumab. After reconstitution, each ml of solution contains 100 mg mepolizumab. Indications: Indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older. Dosage and administration: Nucala should be prescribed by physicians experienced in the diagnosis and treatment of severe refractory eosinophilic asthma. Adults and adolescents aged 12 years and over: Recommended dose is 100 mg administered subcutaneously once every 4 weeks. Children aged 6 to 11 years old: Recommended dose is 40 mg administered subcutaneously once every 4 weeks. Treatment is intended long-term and the need for continued therapy should be considered at least on an annual basis. Method of administration is subcutaneous only, administered by a healthcare professional. It may be injected into the upper arm, thigh, or abdomen. The powder should be reconstituted under aseptic conditions and administered within 8 hours, protected from sun light, at <30 degrees Celsius. Each vial of Nucala should be used for a single patient, and any remainder of the vial should be discarded. Contraindications: Hypersensitivity to the active substances or to any of the excipients (sucrose, sodium phosphate dibasic heptahydrate and polysorbate 80). Precautions: Not to be used to treat acute asthma exacerbations. Asthma related adverse events or exacerbations may occur during treatment. Abrupt discontinuation of corticosteroid after initiation of therapy is not recommended. Hypersensitivity and administration-related reactions may occur within hours of administration, but some instances may have a delayed onset. Pre-existing helminth infections should be treated before commencing Nucala. Special populations: No dose adjustment is required for elderly, hepatic impaired and renal impaired patients with a CrCl 50-80ml/min (limited data for patients with CrCl <50ml/min). Interactions with other medicinal products: No interaction studies have been performed. The potential for interactions is considered low. Pregnancy and breast-feeding: Experience limited. Balance risks against benefits. Side effects: Very Common (≥1/10): Headache. Common (≥1/100 to <1/10): Lower respiratory tract infection, urinary tract infection, pharyngitis, hypersensitivity reactions, nasal congestion, abdominal pain upper, eczema, back pain, administration related reactions (rash, flushing, myalgia), local injection site reactions, pyrexia. Rare (≥1/10,000 to <1/1,000): anaphylaxis. Immunogenicity: In trials 15/260 adult and adolescent patients (6%) developed anti-mepolizumab antibodies. Neutralising antibodies were detected in just 1 adult subject. See SmPC for other side effects. Legal category: POM. Presentation and Basic NHS cost: Nucala®. 1 vial - £840.00. Marketing authorisation (MA) numbers [EU/1/15/1043/001]; MA holder: GlaxoSmithKline Trading Services Limited, Currabinny, Carrigaline, County Cork, Ireland. Last date of revision: August 2018. UK/NLA/0013/15(2)a. Nucala® is a registered trademark of the GlaxoSmithKline group of companies.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellowcard in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.