

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to Teva UK Limited on +44 (0) 207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

CINQAERO® (reslizumab) 10mg/ml concentrate for solution for infusion Abbreviated Prescribing Information. **Presentation:** Vial containing either 25mg of reslizumab in 2.5ml or 100mg of reslizumab in 10ml (10 mg/ml). **Indications:** Add-on therapy in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus another medicinal product for maintenance treatment. **Dosage and administration:** CINQAERO should be prescribed by physicians experienced in the diagnosis and treatment of severe eosinophilic asthma. Intravenous infusion only. Should be administered as a 20–50 minute intravenous infusion through a sterile, non-pyrogenic infusion, single-use, low protein binding filter (0.2 µm). Must not be administered as a bolus injection or as undiluted concentrate. CINQAERO is intended for long-term treatment. Review treatment at least annually based on disease severity and exacerbation control. See SmPC for dilution instructions and administration. *Adults and Elderly:* Based on body weight below 35kg or above 199kg; dose is 3mg/kg given once every four weeks. For patients body weight between 35kg and 199kg; refer to dosing in table 1 of SmPC. *Children:* Not recommended in children and adolescents up to 17 years old. *Renal and Hepatic Impairment:* No dose adjustment required. **Contraindications:** Hypersensitivity to active substance or any excipients. **Precautions and warnings:** Not to be used to treat acute asthma exacerbations. Asthma-related symptoms or exacerbations

may occur. The name and batch number of the administered product should be recorded for traceability purposes. Acute systemic reactions, including anaphylactic reactions were observed during or within 20 minutes after infusion. Patients should be monitored during and for an appropriate time following administration. If an anaphylactic reaction occurs, discontinue treatment immediately and permanently. Patients with pre-existing helminth infections should be treated before commencing CINQAERO therapy. If infection occurs during treatment, temporary discontinuation of treatment should be considered. **Interactions:** No formal drug interaction studies have been performed. **Pregnancy:** Not recommended. **Lactation:** Antibodies may be transferred to the newborns through milk. Not recommended during the first few days after birth. See SmPC for further information. **Effects on ability to drive and use machines:** Negligible influence on the ability to drive and use machines. **Adverse reactions:** Anaphylactic reaction, malignancies. *Common:* Blood creatine phosphokinase increased. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** Monitor for signs and symptoms of adverse effects and initiate symptomatic treatment. **Legal category:** POM. **Marketing Authorisation Number:** EU/1/16/1125/001-2. **Marketing Authorisation Holder:** Teva B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands. **Job Code:** MED-IE-00037. **Date of Preparation:** June 2021.