PI-12314; October 2023

Nucala (mepolizumab) Prescribing information Great Britain (GB)

Please refer to the next page for Nucala (mepolizumab) prescribing information for Northern Ireland

(Please consult the full Summary of Product Characteristics for Great Britain (SmPC GB) before prescribing)

Presentation: *Nucala (mepolizumab) solution for injection in pre-filled pen. Each 1 ml pre-filled pen contains 100 mg mepolizumab. Nucala solution for injection in pre-filled syringe. Available as 100 mg solution for injection in a pre-filled syringe. Each 1 ml pre-filled syringe contains 100 mg mepolizumab. Available as 40 mg solution for injection in pre-filled syringe; the 40 mg solution for injection formulation is approved for use in severe eosinophilic asthma only. Each 0.4 mL pre-filled syringe contains 40 mg of mepolizumab. Nucala powder for solution for injection*. Each vial contains 100 mg mepolizumab. After reconstitution, each 1 ml of solution contains 100 mg mepolizumab. **Indication: Severe eosinophilic asthma:** Indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older. **Chronic rhinosinusitis with nasal polyps (CRSwNP):** indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. **Eosinophilic granulomatosis with polyangiitis (EGPA):** indicated as an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis. **Hypereosinophilic syndrome (HES):** indicated as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause. **Posology and method of administration**: **Severe eosinophilic asthma:** Nucala should be prescribed by physicians experienced in the diagnosis and treatment of severe refractory eosinophilic asthma, CRSwNP, EGPA or HES. **For 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. **For CRSwNP the recommended dose in adults is**: 100 mg of mepolizumab administered subcutaneously once every 4 weeks. **For EGPA the recommended dose for adults and adolescents aged 12 years and older** is 300 mg administered subcutaneously once every 4 weeks. Children aged between 6 and 11 years old: Children weighing ≥ 40 kg recommended dose is 200 mg administered subcutaneously once every 4 weeks. Children weighing < 40 kg recommended dose is 100 mg administered subcutaneously once every 4 weeks. **HES recommended dose in adults is** 300 mg administered subcutaneously once every 4 weeks. Treatment is intended long-term and need for continued therapy should be considered at least annually. Administration is by subcutaneous injection only. *Powder for solution for injection:* Should be administered by a healthcare professional. Requires reconstitution. Each vial should be used for a single patient, and any remainder of the vial should be discarded. *Solution for injection in a pre-filled pen and pre-filled syringe (100 mg):* May be self-administered by the patient or administered by a caregiver if their healthcare professional determines it is appropriate, and patient/caregiver are trained in injection techniques. *Pre-filled syringe (40 mg)* - must be administered by a healthcare professional or a caregiver. Please see package leaflet for instructions on administration. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions**: Name and batch number of the administered product should be recorded in patient file. Not to be used to treat acute asthma exacerbations. Asthma-related adverse symptoms or exacerbations may occur during treatment. Abrupt discontinuation of corticosteroids after initiation of therapy is not recommended. Hypersensitivity reactions (e.g. anaphylaxis, urticaria, angioedema, rash, bronchospasm, hypotension) and administration-related reactions have occurred following administration, generally within hours of administration, but in some instances, they may have a delayed onset (i.e. typically within several days). These reactions may occur for the first time after a long duration of treatment. Pre-existing helminth infections should be treated before commencing Nucala. If patients become infected and do not respond to anti-helminth treatment, temporary discontinuation of Nucala should be considered. Nucala has not been studied in patients with organ threatening or life-threatening manifestations of EGPA. Nucala has not been studied in patients with life-threatening manifestations of HES **Special populations:** No dose adjustment is required in elderly patients, patients with hepatic impaired or patients with renal impairment with a CrCl 50-80ml/min. **Interactions with other medicinal products**: No interaction studies have been performed. Potential for interactions is considered low. **Fertility, pregnancy and breast-feeding**: Potential for harm to a human foetus is unknown. Preferable to avoid use during pregnancy. Administration should only be considered if the expected benefit to mother is greater than risk to foetus. No data on excretion of Nucala in human milk or on human fertility. **Side effects**: *Very Common (≥1/10):* Headache. *Common (≥1/100 to <1/10):* Lower respiratory tract infection, urinary tract infection, pharyngitis, hypersensitivity reactions (systemic allergic), nasal congestion, abdominal pain upper, eczema, back pain, administration related reactions (systemic non-allergic; most commonly including rash, flushing, myalgia), local injection site reactions, pyrexia. *Rare (≥1/10,000 to <1/1,000):* anaphylaxis. Please consult SmPC for further information on adverse reactions. **Legal category**: POM. **Presentation and Basic NHS cost:** Nucala 1 vial, 1 pre-filled pen, or 1 pre-filled syringe 100 mg - £840.00, or 1 pre-filled syringe 40 mg - £336.00. **Marketing authorisation (MA) numbers GB- [vial:** PLGB 19494/0285**; pre-filled pen:** PLGB 19494/0290**; prefilled-syringe 100 mg:** PLGB 19494/0291; **pre-filled syringe 40 mg**: PLGB 19494/0303**]; MA holder**: **GB**- GlaxoSmithKline UK Limited 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom **Last date of revision:** October 2023, PI-12314.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ 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.

PI-12314; October 2023

Nucala (mepolizumab) Prescribing information Northern Ireland (NI)

(Please consult the full Summary of Product Characteristics for Northern Ireland (SmPC NI) before prescribing)

Presentation: *Nucala (mepolizumab) solution for injection in pre-filled pen. Each 1 ml pre-filled pen contains 100 mg mepolizumab. Nucala solution for injection in pre-filled syringe. Available as 100 mg solution for injection in a pre-filled syringe. Each 1 ml pre-filled syringe contains 100 mg mepolizumab. Available as 40 mg solution for injection in pre-filled syringe; the 40 mg solution for injection formulation is approved for use in severe eosinophilic asthma only. Each 0.4 mL pre-filled syringe contains 40 mg of mepolizumab. Nucala powder for solution for injection*. Each vial contains 100 mg mepolizumab. After reconstitution, each 1 ml of solution contains 100 mg mepolizumab. **Indication: Severe eosinophilic asthma:** Indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older. **Chronic rhinosinusitis with nasal polyps (CRSwNP):** indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. **Eosinophilic granulomatosis with polyangiitis (EGPA):** indicated as an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis. **Hypereosinophilic syndrome (HES):** indicated as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause. **Posology and method of administration**: **Severe eosinophilic asthma:** Nucala should be prescribed by physicians experienced in the diagnosis and treatment of severe refractory eosinophilic asthma, CRSwNP, EGPA or HES. **For 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. **For CRSwNP the recommended dose in adults is**: 100 mg of mepolizumab administered subcutaneously once every 4 weeks. **For EGPA the recommended dose for adults and adolescents aged 12 years and older** is 300 mg administered subcutaneously once every 4 weeks. Children aged between 6 and 11 years old: Children weighing ≥ 40 kg recommended dose is 200 mg administered subcutaneously once every 4 weeks. Children weighing < 40 kg recommended dose is 100 mg administered subcutaneously once every 4 weeks. **HES recommended dose in adults is** 300 mg administered subcutaneously once every 4 weeks. Treatment is intended long-term and need for continued therapy should be considered at least annually. Administration is by subcutaneous injection only. *Powder for solution for injection:* Should be administered by a healthcare professional. Requires reconstitution. 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Hypersensitivity reactions (e.g. anaphylaxis, urticaria, angioedema, rash, bronchospasm, hypotension) and administration-related reactions have occurred following administration, generally within hours of administration, but in some instances, they may have a delayed onset (i.e. typically within several days). These reactions may occur for the first time after a long duration of treatment. Pre-existing helminth infections should be treated before commencing Nucala. If patients become infected and do not respond to anti-helminth treatment, temporary discontinuation of Nucala should be considered. Nucala has not been studied in patients with organ threatening or life-threatening manifestations of EGPA. Nucala has not been studied in patients with life-threatening manifestations of HES. **Special populations:** No dose adjustment is required in elderly patients, patients with hepatic impaired or patients with renal impairment with a CrCl 50-80ml/min. **Interactions with other medicinal products**: No interaction studies have been performed. Potential for interactions is considered low. **Fertility, pregnancy and breast-feeding**: Potential for harm to a human foetus is unknown. Preferable to avoid use during pregnancy. Administration should only be considered if the expected benefit to mother is greater than risk to foetus. 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Please consult SmPC for further information on adverse reactions. **Legal category**: POM. **Presentation and Basic NHS cost:** Nucala 1 vial, 1 pre-filled pen, or 1 pre-filled syringe 100 mg - £840.00, or 1 pre-filled syringe 40 mg - £336.00. **Marketing authorisation (MA) numbers NI- [vial: E**U/1/15/1043/001**; pre-filled pen:** EU/1/15/1043/003**; prefilled-syringe 100 mg:** EU/1/15/1043/005; **pre-filled syringe 40 mg**: EU/1/15/1043/009**]; MA holder**: **NI**- GlaxoSmithKline Trading Services Limited,12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland **Last date of revision:** October 2023, PI-12314.

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