Mepolizumab (Nucala®)

Reduce direct handling to a minimum and wear appropriate personal protective equipment

Form	100mg powder for solution for injection
Reconstitution	• Reconstitute the contents of the vial with 1.2 mL of sterile water for injection preferably using a 2 to 3 mL syringe and a 21gauge needle. The stream of sterile water should be directed vertically, onto the centre of the lyophilised cake. Allow the vial to sit at room temperature during reconstitution, gently swirling the vial for 10 seconds with circular motion at 15-second intervals until the powder is dissolved. • Note: The reconstituted solution **must not be shaken** • Following reconstitution, Nucala® should be visually inspected for particulate matter and clarity prior to use. The solution should be clear to opalescent, and colourless to pale yellow or pale brown, free of visible particles. Small air bubbles, however, are expected and acceptable. • If particulate matter remains in the solution or if the solution appears cloudy or milky, the solution must not be used.
Compatibility & Stability	This medicinal product must not be mixed with other medicinal products
Administration	**Subcutaneous Injection** • A 1 mL polypropylene syringe fitted with a disposable needle 21 gauge to 27-gauge x 0.5 inch (13 mm) should preferably be used • Administer the 1 mL injection (equivalent to 100mg mepolizumab) subcutaneously into the upper arm, thigh, or abdomen • For EGPA or Eosinophilic driven Arthritis, administration of 300mgs may be necessary (100mgs x 3 injections) every 4 weeks, under the governance of the rheumatology consultants. It is recommended that individual injection sites are separated by at least 5 cm.
Documentation Requirements	Batch and expiry should be recorded in patient's notes.
Monitoring	• Pre and post injection vital signs • Observe for 1-hour post first injection and 30 mins for second and third injections • For rheumatology patients receiving 300mgs the patient must be observed for 1 hour after the first 3 doses, then 15 minutes monthly thereafter until the rheumatology consultant deems them fit to self-administer the medication without observation. • Blood eosinophil count ≥ 300/microliter in previous 12 months prior to commencing treatment • Routine bloods- FBC, Renal, Liver, Bone profile, CRP, CK by GP/phlebotomy at commencement of therapy and thereafter every 3 months • If CK is elevated but patient is asymptomatic it is OK for infusion to proceed. If in any doubt contact Consultant or Registrar • If the patient presents to the unit and meets the criteria in **7.7**, medical review may be required prior to administrating medication
Adverse Drug Reactions	• Acute and delayed systemic reactions, including hypersensitivity reactions (e.g., anaphylaxis, urticaria, angioedema, rash, bronchospasm, hypotension), have occurred following administration of Nucala® These reactions generally occur within hours of administration, but in some instances have a delayed onset (i.e., typically within several days). These reactions may occur for the first time after a long duration of treatment

Additional Information	• Nucala ®should not be used to treat acute asthma exacerbations • Asthma-related adverse events or exacerbations may occur during treatment. Patients should be instructed to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment • Abrupt discontinuation of corticosteroids after initiation of Nucala® therapy is not recommended • Reduction in corticosteroid doses, if required, should be gradual and performed under the supervision of a physician • Nucala has not been studied in patients with organ threatening or life-threatening manifestations of EGPA • Mepolizumab crosses the placental barrier in monkeys. Animal studies do not indicate reproductive toxicity. The potential for harm to a human fetus is unknown. As a precautionary measure, it is preferable to avoid the use of Nucala during pregnancy. Administration of Nucala to pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. • See **PPG-CUH-CUH-243** Policy Procedure and Guidelines for Management of Patients Attending CUH Infusion Unit for Intravenous Therapy CUH for more information

Information provided relates to Nucala® (GlaxoSmithKline)