

Nucala[®] (mepolizumab) – New formulation approval

- On June 6, 2019, [GlaxoSmithKline announced](#) the FDA approval of [Nucala \(mepolizumab\)](#) single-dose prefilled autoinjector and single-dose prefilled syringe, for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype; and treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
 - Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Nucala autoinjector and single-dose prefilled syringe may be administered under the guidance of a healthcare provider. Both formulations allow for self-administration or administration by a patient caregiver after the healthcare provider determines it is appropriate.
 - This is the first interleukin-5 antagonist approved for at-home administration.
- Nucala was previously approved as a lyophilized powder in a single-dose vial for reconstitution.
 - Nucala vials for injection require reconstitution and administration by a healthcare professional.
- Warnings and precautions of Nucala include hypersensitivity reactions, acute asthma symptoms or deteriorating disease, opportunistic infections (ie, herpes zoster), reduction of corticosteroid dosage, and parasitic (helminth) infection.
- The most common adverse reactions ($\geq 5\%$) with Nucala use were headache, injection site reaction, back pain, and fatigue.
- The recommended dosage of Nucala for severe asthma is 100 mg administered once every 4 weeks by subcutaneous (SC) injection into the upper arm, thigh, or abdomen.
- The recommended dosage of Nucala for EGPA is 300 mg administered once every 4 weeks by SC injection as 3 separate 100-mg injections into the upper arm, thigh, or abdomen. It is recommended that the individual 100-mg injections be administered at least 5 cm (approximately 2 inches) apart if more than 1 injection is administered at the same site.
- GlaxoSmithKline plans to launch the prefilled autoinjector and single-dose prefilled syringe formulations of Nucala shortly. Both the autoinjector and prefilled syringe will be available in a 100 mg strength.