

Nucala® (mepolizumab) – New orphan indication

- On December 12, 2017, the <u>FDA announced</u> the approval of <u>GlaxoSmithKline's Nucala</u> (<u>mepolizumab</u>) for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Nucala is also approved for the add-on maintenance treatment of patients with severe asthma aged
 12 years and older, and with an eosinophilic phenotype.
 - Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.
- According to the <u>National Institutes of Health</u>, EGPA (formerly known as Churg-Strauss syndrome) is a condition characterized by asthma, high levels of eosinophils, and inflammation of blood vessels. The inflamed vessels can affect the lungs, gastrointestinal tract, skin, heart and nervous system.
- Approximately 0.11 to 2.66 new cases per 1 million people are diagnosed with EGPA each year, with an overall prevalence of 10.7 to 14 per 1,000,000 adults. In the U.S., there are approximately 5000 patients with EGPA.
- The safety and efficacy of Nucala were based on data from a 52-week clinical trial of 136 patients with EGPA. Patients received Nucala or placebo while continuing oral corticosteroid therapy. The primary efficacy assessments measured Nucala's treatment impact on disease remission.
 - Patients receiving Nucala achieved a significantly greater accrued time in remission vs. placebo (Odds Ratio [OR] = 5.9, 95% CI: 2.7, 13.0).
 - A significantly higher proportion of patients receiving Nucala achieved remission at both weeks 36 and 48 vs. placebo (OR = 16.7, 95% CI: 3.6, 77.6).
 - Significantly more patients who received Nucala achieved remission within the first 24 weeks and remained in remission for the remainder of the 52-week study treatment period vs. placebo (19% vs. 1%, respectively; OR = 19.7; 95% CI: 2.3, 167.9).
- The recommended dosage of Nucala for the treatment of EGPA is 300 mg administered once every 4 weeks by subcutaneous (SC) injection as 3 separate 100 mg injections into the upper arm, thigh or abdomen.
 - Nucala should be reconstituted and administered by a healthcare professional.
 - 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.
 - The recommended dosage of Nucala for the treatment of severe asthma is 100 mg administered once every 4 weeks by SC injection into the upper arm, thigh, or abdomen.



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