Indication

NUCALA is indicated for the add-on maintenance treatment of patients 6 years and older with severe asthma with an eosinophilic phenotype. NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.

Important Safety Information

CONTRAINDICATIONS

NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred with NUCALA. These reactions generally occur within hours of administration but can have a delayed onset (ie, days). If a hypersensitivity reaction occurs, discontinue NUCALA.

Please see additional Important Safety Information throughout. Please see the accompanying full Prescribing Information, including Patient Information, for NUCALA or visit NUCALAHCP.com.

Nucala
(mepolizumab)
Injection 100 mg/mL

The NUCALA Patient

Patients 6 years and older with severe asthma and:

High-dose ICS plus additional controller

2+ exacerbations* in the previous 12 months **and/or daily OCS**

Baseline blood eosinophils ≥150 cells/µL, which is predictive of efficacy for NUCALA

*Exacerbations were defined as the worsening of asthma that required use of oral/systemic corticosteroids and/or hospitalization and/or emergency department visits; for patients on maintenance oral/systemic corticosteroids, exacerbations were defined as requiring at least double the existing maintenance dose for at least 3 days.

ICS=inhaled corticosteroids; OCS=oral corticosteroids.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Acute Asthma Symptoms or Deteriorating Disease
NUCALA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Opportunistic Infections: Herpes Zoster
In controlled clinical trials, 2 serious adverse reactions of herpes zoster occurred with NUCALA compared to none with placebo. Consider vaccination if medically appropriate.

Reduction of Corticosteroid Dosage
Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with NUCALA. Decreases in corticosteroid doses, if appropriate, should be gradual and under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection
Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving NUCALA and do not respond to anti-helminth treatment, discontinue NUCALA until infection resolves.

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At-Home Administration

Autoinjector

The NUCALA Autoinjector and prefilled syringe are only for use in patients aged ≥12 years.

Easy to Use[1]

9 OUT OF 10
patients found the Autoinjector very or extremely easy to use

99%
of patients successfully used the Autoinjector

Study Description: 12-week, open-label study assessed the correct use of the NUCALA Autoinjector in patients aged ≥12 years with severe eosinophilic asthma (SEA) (N=104). NUCALA was administered as one 100-mg subcutaneous injection every 4 weeks by the patient or caregiver after being trained on proper technique with the Autoinjector at baseline. Successful use was determined by investigator observation using a checklist of steps based on Instructions for Use and visually inspecting the Autoinjector following the third dose. Ease of use was measured at study end on a 5-point scale (not at all, a little, moderately, very, and extremely) in the 102 patients with successful use.

At-home administration is for use under healthcare provider guidance. Provide proper training on injection technique, preparation, and administration using Instructions for Use after determining at-home use is appropriate.

In-office administration is also available. Lyophilized powder should be reconstituted and administered by a healthcare provider. In line with clinical practice, monitoring of patients after administration is recommended.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (≥3% and more common than placebo) reported in the first 24 weeks of 2 clinical trials with NUCALA (and placebo) were: headache, 19% (18%); injection site reaction, 8% (3%); back pain, 5% (4%); fatigue, 5% (4%); influenza, 3% (2%); urinary tract infection, 3% (2%); abdominal pain upper, 3% (2%); pruritus, 3% (2%); eczema, 3% (<1%); and muscle spasms, 3% (<1%).

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Nucala
(mepolizumab)
Injection 100 mg/mL

CHOOSE NUCALA FOR **REAL-LIFE RESULTS.**

PROVEN PROTECTION FROM EXACERBATIONS[2]

REAL-WORLD EVIDENCE[3]

LONG-TERM RESULTS[4]

MENSA[2]: 32-week study comparing treatment with NUCALA 100 mg or placebo added to SOC in 576 patients aged ≥12 years with SEA. Exacerbations: 53% reduction with NUCALA vs placebo (0.83/year vs 1.74/year, respectively; *P*<0.001).

REALITI-A[3]: Prespecified interim analysis of an ongoing, 2-year, prospective, multinational, single-arm, observational cohort study assessing real-world effectiveness and use of NUCALA 100 mg in 368 adult patients with SEA.
Study Limitations: May not reflect final results. Real-world studies are designed to evaluate associations among variables and not to definitively establish causality. Limitations important when interpreting results: lack of comparator arm; differences in patient populations and data collection vs randomized controlled trials.

COLUMBA[4]: 4.5-year open-label study assessing the safety, immunogenicity, and efficacy of NUCALA 100 mg added to asthma controller therapy in 347 patients aged ≥12 years with SEA.

SOC (standard of care) = regular treatment with high-dose ICS and at least 1 other controller with or without OCS.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

Systemic Reactions, including Hypersensitivity Reactions: In 3 clinical trials, the percentages of subjects who experienced systemic (allergic and nonallergic) reactions were 3% for NUCALA and 5% for placebo. Manifestations included rash, flushing, pruritus, headache, and myalgia. A majority of the systemic reactions were experienced on the day of dosing.

Injection site reactions (eg, pain, erythema, swelling, itching, burning sensation) occurred in subjects treated with NUCALA.

USE IN SPECIFIC POPULATIONS

A pregnancy exposure registry monitors pregnancy outcomes in women exposed to NUCALA during pregnancy. To enroll call 1-877-311-8972 or visit www.mothertobaby.org/asthma.

The data on pregnancy exposures are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as the pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimesters.

References: 1. Bernstein D, Pavord ID, Chapman KR, et al. Usability of mepolizumab single-use prefilled autoinjector for patient self-administration [published online ahead of print, June 28, 2019]. *J Asthma.* doi:10.1080/02770903.2019.1630641. **2.** Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med.* 371(13):1198-1207. **3.** Data on file, GSK. **4.** Khatri S, Moore W, Gibson PG, et al. Assessment of the long-term safety of mepolizumab and durability of clinical response in patients with severe eosinophilic asthma. *J Allergy Clin Immunol.* 2019;143(5):1742-1751.

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