Nucala

(mepolizumab)

New Product Slideshow

MPR

Introduction

- **Brand name:** Nucala
- **Generic name:** Mepolizumab
- **Pharmacological class:** Interleukin-5 antagonist
- **Strength and Formulation:** 100mg per vial; lyophilized powder for SC injection after reconstitution; preservative-free
- **Manufacturer:** GlaxoSmithKline
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

NUCALA


NDC 0173-0881-01
Rx Only
Nucala®
(mepolizumab)
for Injection
100 mg/vial
For subcutaneous injection after reconstitution.
Single-use vial. Discard unused portion.
CONTENTS: Each vial delivers mepolizumab 100 mg, polysorbate 80 (0.67 mg), sodium phosphate dibasic heptahydrate (7.14 mg), and sucrose (160 mg). After reconstitution with 1.2 mL of Sterile Water for Injection, USP, the reconstituted solution concentration is 100 mg/mL and delivers 1 mL.
No preservative.
No U.S. standard of potency.
1 vial

Indications

- As add-on maintenance treatment of severe asthma in patients ≥12 years old, and with an eosinophilic phenotype
- **Limitations of use:** not for treating other eosinophilic conditions. Not for relief of acute bronchospasm or status asthmaticus

Dosage & Administration

- Give by SC injection into upper arm, thigh, or abdomen
- 100mg once every 4 weeks

Considerations for Special Populations

- **Pregnancy:** Monitor closely
- **Nursing mothers:** Consider benefits and potential adverse effects
- **Pediatric:** <12 years: not established
- **Geriatric:** Insufficient number of patients studied

Warnings/Precautions

- **Not for treating** acute asthma symptoms or exacerbations
- **Discontinue** if hypersensitivity reactions occur
- Opportunistic infections (eg, herpes zoster); consider varicella vaccination if appropriate prior to starting therapy

Warnings/Precautions

- Treat pre-existing helminth infections before initiating therapy; **discontinue** Nucala if treatment-resistant infection occurs while on therapy until resolves
- Avoid abrupt discontinuation of systemic or inhaled corticosteroids; reduce dose gradually upon Nucala initiation
- Reduction may unmask previously suppressed allergic conditions

Adverse Reactions

- Headache
- Injection site reactions
- Back pain
- Fatigue
- Infections
- Hypersensitivity reactions
- Possible antibody formation

Mechanism of Action

- Mepolizumab binds to interleukin-5 (IL-5) with a dissociation constant of 100 pM, inhibiting the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface
- By inhibiting IL-5 signaling, it reduces the production and survival of eosinophils; however, the mechanism of mepolizumab action in asthma has not been definitively established

Clinical Trials

- Nucala was studied in 3 double-blind, randomized, placebo-controlled trials
- **Trial 1** was a 52-week dose-ranging and exacerbation-reduction trial in asthma patients with a history of ≥2 exacerbations in the previous year despite use of high-dose inhaled corticosteroids plus additional controller(s) with or without oral steroids
- In this trial, mepolizumab IV (75mg, 250mg, and 750mg) given once every 4 weeks were evaluated vs. placebo

Clinical Trials

- **Trial 2** was a confirmatory trial in asthma patients with the same exacerbation history as Trial 1
  - Patients received either mepolizumab 75mg IV, Nucala 100mg SC, or placebo once every 4 weeks for 32 weeks
- **Trial 3** was a second confirmatory trial in asthma patients who required daily oral corticosteroids in addition to high-dose inhaled corticosteroids plus additional controller(s)
  - Patients received either Nucala 100mg SC or placebo once every 4 weeks for 24 weeks

Clinical Trials

- The primary endpoint for Trials 1 and 2 was the frequency of exacerbations defined as worsening of asthma requiring oral/systemic corticosteroids and/or hospitalization and/or ER visits
- In **Trial 1**, patients receiving mepolizumab 75mg IV experienced significantly fewer exacerbations (0.52, [95% CI: 0.39, 0.69]) and exacerbations requiring hospitalization/ER visits (0.40, [95% CI: 0.19, 0.81]) vs. placebo
- Results of this study supported evaluation of mepolizumab 75mg IV and 100mg SC in the subsequent trials (Nucala is not indicated for IV use and should only be administered by the SC route)

Clinical Trials

- In **Trial 2**, patients treated with mepolizumab 75mg IV or Nucala 100mg SC also experienced fewer exacerbations (0.53, [95% CI: 0.40, 0.72]; 0.47, [95% CI: 0.35, 0.64], respectively) and exacerbations requiring hospitalization/ER visits (0.68, [95% CI: 0.33, 1.41]; 0.39, [95% CI: 0.18, 0.83], respectively) vs. placebo

Clinical Trials

- The primary endpoint of **Trial 3** was the percent reduction of oral corticosteroid dose during Weeks 20–24 vs. baseline dose, while maintaining asthma control
- Patients receiving Nucala achieved greater reductions in daily maintenance oral corticosteroid dose vs. placebo
- A 90–100% reduction was seen in 23% of patients in the Nucala group vs. 11% in the placebo group

Clinical Trials

- In addition, 54% of Nucala-treated patients achieved ≥50% reduction in the daily prednisone dose vs. 33% in placebo (95% CI for difference: 4%, 37%)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the complete product monograph available at:

  http://www.empr.com/nucala/drugproduct/400/