Fasenra (benralizumab)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Fasenra
- **Generic name:** Benralizumab
- **Pharmacological class:** Interleukin-5 antagonist
- **Strength and Formulation:** 30mg/mL; solution for SC injection; preservative-free
- **Manufacturer:** AstraZeneca
- **How supplied:** Single-dose prefilled syringe—1
- **Legal Classification:** Rx

Fasenra


Fasenra™
(benralizumab)
Injection
30 mg/mL
Rx only
NDC 0310-1730-30
1 single-dose prefilled syringe
Discard unused portion.
AstraZeneca
For Subcutaneous Injection Only
Store the prefilled syringe refrigerated at 2°C - 8°C
(36°F - 46°F) in original carton to protect from light.
Do not shake or freeze the syringe.

Indications

- As add-on maintenance treatment of **severe asthma** in patients ≥12yrs 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 inj into upper arm, thigh, or abdomen
- 30mg once every 4 weeks for the first 3 doses, then once every 8 weeks thereafter

Considerations for Special Populations

- **Pediatric:** Not established
- **Pregnancy:** Insufficient human data to establish drug-associated risk
- **Nursing mothers:** Consider mother's need and potential adverse effects on child
- **Elderly:** No overall differences in safety or effectiveness observed

Warnings/Precautions

- **Not** for treating acute asthma symptoms or exacerbations
- **Discontinue** if hypersensitivity reactions occur
- Treat pre-existing helminth infections before initiating therapy; discontinue Fasenra if treatment-resistant infection occurs while on therapy until resolves

Warnings/Precautions

- **Avoid** abrupt discontinuation of systemic or inhaled corticosteroids; reduce dose gradually upon Fasenra initiation, if appropriate
- Reduction may be associated with systemic withdrawal symptoms and/or unmask previously suppressed conditions

Adverse Reactions

- Headache
- Pharyngitis
- Pyrexia
- Hypersensitivity reactions

Mechanism of Action

- Benralizumab directly binds to the alpha subunit of the human interleukin-5 receptor, which is expressed on the surface of eosinophils and basophils
- The absence of fucose in the Fc domain of benralizumab facilitates binding to receptors on immune effectors cells, such as natural killer cells, leading to apoptosis of eosinophils and basophils through antibody-dependent cell-mediated cytotoxicity

Clinical Studies

- Fasenra was evaluated in a 52-week dose-ranging exacerbation trial, 3 confirmatory trials, and a 12-week lung function trial

Clinical Studies

- **Trial 1** (N=1,204) and **Trial 2** (N=1,306) were randomized, double-blind, parallel-group, placebo-controlled exacerbation trials in patients aged ≥12 years and 48 and 56 weeks in duration, respectively
- Fasenra was given once every 4 weeks for the first 3 doses, and then every 4 or 8 weeks thereafter as add-on to background treatment, and was compared to placebo

Clinical Studies

- **Trial 3** (N=220) was a randomized, double-blind, parallel-group, oral corticosteroid (OCS) reduction trial
- Baseline median OCS dose was 10mg for all the treatment groups: placebo, Fasenra every 4 weeks, or Fasenra every 4 weeks for the first 3 doses, then once every 8 weeks

Clinical Studies

- The **primary endpoint** for Trials 1 and 2 was the rate of asthma exacerbations in patients with baseline blood eosinophil counts of ≥300 cells/μL who were taking high-dose inhaled corticosteroid (ICS) and long-acting beta agonist (LABA)

Clinical Studies

- In **Trial 1**, 35% of patients receiving Fasenra experienced an asthma exacerbation vs 51% on placebo
- In **Trial 2**, 40% of patients receiving Fasenra experienced an asthma exacerbation vs. 51% on placebo
- The time to first exacerbation was longer for patients in the Fasenra group vs placebo in both Trials 1 and 2

Clinical Studies

- **Trial 3** studied the effect of Fasenra on reducing the use of maintenance OCS
- The **primary endpoint** was percent reduction from baseline of the final OCS dose during Weeks 24−28, while maintaining asthma control

Clinical Studies

- Patients receiving Fasenra achieved greater reductions in daily maintenance OCS dose, while maintaining asthma control
- The median percent reduction in daily OCS dose from baseline was **75%** in patients receiving Fasenra vs **25%** in patients receiving placebo
- Reductions of ≥50% in the OCS dose were seen in **66%** of patients receiving Fasenra vs **37%** of patients receiving placebo

Clinical Studies

- Fasenra also consistently improved mean change from baseline in FEV_1 over time for Trials 1, 2, and 3
- In a 12-week lung function trial in patients with mild-to-moderate asthma (N=211), treatment with benralizumab also improved change from baseline in FEV_1 at Week 12 vs placebo
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/fasenra/drug/34769/