Fasenra®
(benralizumab) Subcutaneous Injection 30 mg

>120,000 patients have been treated with FASENRA® worldwide[1]

CHOOSE FASENRA® FOR ITS DEMONSTRATED EFFICACY IN SEVERE EOSINOPHILIC ASTHMA

FASENRA® is indicated as an add-on maintenance treatment of adult patients with severe eosinophilic asthma.[2]

FASENRA® significantly reduced the rate of clinically significant exacerbations by 51% compared to placebo at week 48 in patients with blood eosinophil count ≥300 cells/µL taking high-dose ICS + LABA (SIROCCO; 1° endpoint; 0.74 and 1.52, respectively; RR: 0.49 [95% CI: 0.37, 0.64]; $p<0.001$).[2*]

Interested in useful resources for you and your patients? Visit fasenra.ca or scan the QR code

Clinically significant exacerbation = Worsening of asthma leading to use of oral/systemic corticosteroids for ≥3 days, ER visit requiring oral/systemic corticosteroids, or hospitalization. For patients on maintenance OCS, a clinically significant exacerbation requiring OCS was defined as a temporary increase in stable oral/systemic corticosteroids for ≥3 days or a single depo-injectable dose.[2]

* SIROCCO: 48-week, phase 3, randomized, double-blind study in patients with severe, uncontrolled asthma taking high-dose ICS + LABA. In the intent-to-treat (ITT) population, patients received benralizumab 30 mg every 8 weeks (first 3 doses Q4W; n=267) or placebo (n=267) Q4W. The primary efficacy (ITT) population had blood eosinophil count ≥300 cells/µL.[2]

CI: confidence interval; ER: emergency room; ICS: inhaled corticosteroids; LABA: long-acting beta$_2$-agonist; OCS: oral corticosteroids; Q4W: every 4 weeks; RR: rate ratio.

Meet Faith

Faith

Teacher | Age 32

Choose FASENRA® for patients like Faith

History:

- Diagnosed with severe asthma 3 years ago.
- Experienced a second exacerbation in the last 12 months requiring OCS.

Examination:[2,3]

- Pre-bronchodilator FEV_1: 1.9 L (64%)
- Blood eosinophils: 300 cells/µL
- ACQ-6 score: 2.8

Current treatments:

- High-dose ICS + LABA

Fictitious patient. May not be representative of all cases.
ACQ-6: Asthma Control Questionnaire, six-question version; FEV_1: forced expiratory volume in 1 second; ICS: inhaled corticosteroid; LABA: long-acting $beta_2$-agonist; OCS: oral corticosteroid.

Meet Eric

Eric

Accountant | Age 44

Choose FASENRA® for patients like Eric

History:[2,3]

- Recently diagnosed with severe asthma.
- Recently had a second exacerbation resulting in an ER visit.

Examination:[2,3]

- Pre-bronchodilator FEV_1: 1.9 L (64%)
- Blood eosinophils: 320 cells/µL
- Total IgE: 340 IU/mL
- Skin prick test: Positive for perennial aeroallergens
- ACQ-6 score: 2.8

Current treatments:

- High-dose ICS + LABA

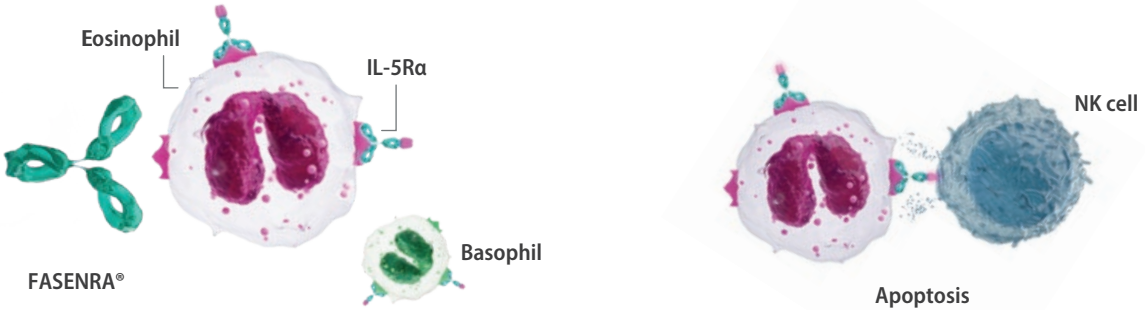
Fictitious patient. May not be representative of all cases.
ACQ-6: Asthma Control Questionnaire, six-question version; ER: emergency room; FEV_1: forced expiratory volume in 1 second; ICS: inhaled corticosteroid; IgE: immunoglobulin E; LABA: long-acting $beta_2$-agonist.

FASENRA® has a targeted mechanism of action[2*]

- Airway inflammation is an important component in the pathogenesis of asthma.[2]
- Eosinophils and other cell types are involved in inflammation in asthma.[2]

Discover the targeted mechanism of action of FASENRA®*

FASENRA®, an anti-eosinophil monoclonal antibody — **selectively binds to the IL-5Rα, expressed on the surface of eosinophils and basophils** — **...and induces apoptosis of eosinophils and basophils in vitro through enhanced antibody-dependent cell-mediated cytotoxicity (ADCC)**

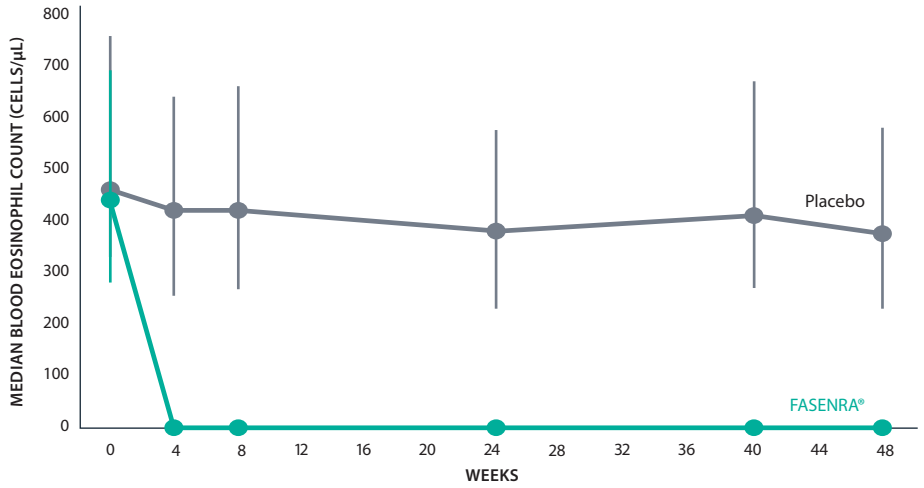


FASENRA® reduces eosinophilic inflammation through enhanced ADCC; however, the exact mechanism of action has not been definitively established.[2]

* Comparative clinical significance unknown.
IL-5Rα: interleukin-5 receptor alpha subunit; NK cell: natural killer T cell.

FASENRA® demonstrated reductions in blood eosinophils vs. placebo after the first 4 weeks[2]*

SIROCCO pharmacodynamic endpoint: Median blood eosinophil count[2,3†]



99.6%
REDUCTION
([95% CI: -113.6, -85.6];
6.9% vs. -92.7% LS mean change
for placebo vs. FASENRA®
respectively; $p<0.0001$)

Adapted from FASENRA® Product Monograph and Data on File.

Near complete blood eosinophil depletion was seen at the first observed time point (week 4) and sustained throughout the treatment period.[2]*

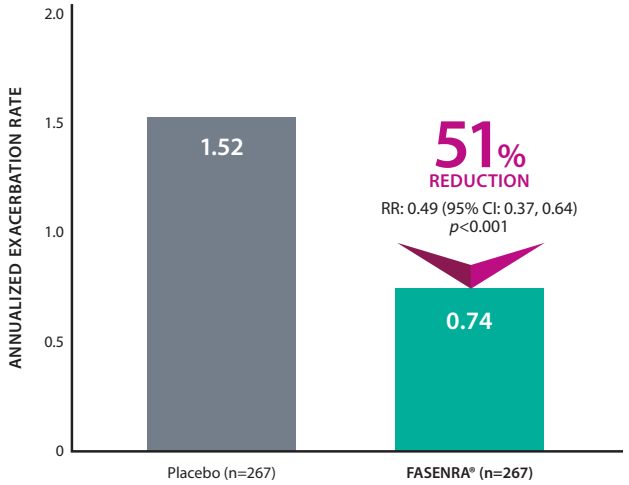
Maintenance of near complete eosinophil depletion was observed throughout a 56-week extension study (BORA).[2*‡]

* Clinical significance unknown.
† SIROCCO: 48-week, phase 3, randomized, double-blind study in patients with severe, uncontrolled asthma taking high-dose ICS + LABA. The primary efficacy (ITT) population had blood eosinophil count ≥300 cells/µL.[2]
‡ BORA: 56-week, phase 3, uncontrolled, single-blind extension study of 440 patients with severe eosinophilic asthma who were tolerant to FASENRA®.[2]
CI: confidence interval; ICS: inhaled corticosteroids; ITT: intent-to-treat; LABA: long-acting beta$_2$-agonist; LS: least squares.

FASENRA® provided significant reductions in the rate of exacerbations vs. placebo

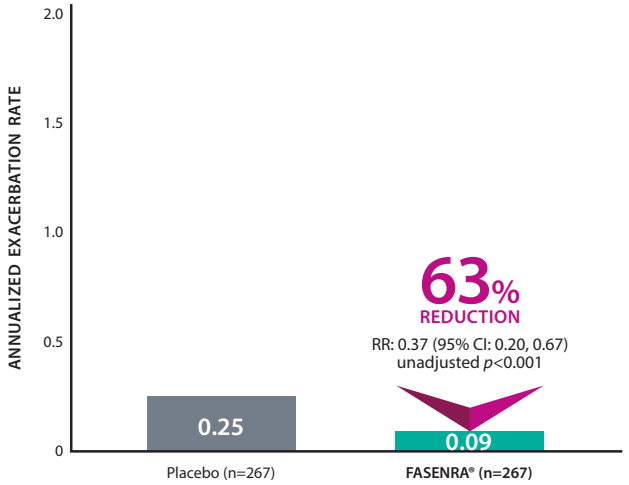
In patients with blood eosinophil count ≥300 cells/µL taking high-dose ICS + LABA...[2,3]

SIROCCO primary endpoint: Rate of clinically significant exacerbations at week 48



NNT=2 to prevent one exacerbation

SIROCCO secondary endpoint: Rate of exacerbations requiring hospitalization/ER visit at week 48



NNT=7 to prevent one exacerbation requiring hospitalization

Adapted from FASENRA® Product Monograph.

Clinically significant exacerbation = Worsening of asthma leading to use of oral/systemic corticosteroids for ≥3 days, ER visit requiring oral/systemic corticosteroids, or hospitalization. For patients on maintenance OCS, a clinically significant exacerbation requiring OCS was defined as a temporary increase in stable oral/systemic corticosteroids for ≥3 days or a single depo-injectable dose.[2]

* SIROCCO: 48-week, phase 3, randomized, double-blind study in patients with severe, uncontrolled asthma taking high-dose ICS + LABA. The primary efficacy (ITT) population had blood eosinophil count ≥300 cells/µL.[2]

CI: confidence interval; ER: emergency room; ICS: inhaled corticosteroids; ITT: intent-to-treat; LABA: long-acting beta$_2$-agonist; NNT: number-needed-to-treat; OCS: oral corticosteroids; RR: rate ratio.

FASENRA® has a proven safety profile

FASENRA® was generally well tolerated, with a low incidence of adverse events[2]

Adverse events with ≥1% incidence with FASENRA® and ≥1% more common with FASENRA® than placebo

Adverse Event	FASENRA® (n=822)	Placebo (n=847)	Adverse Event	FASENRA® (n=822)	Placebo (n=847)
Headache	8%	6%	Cough	3%	2%
Arthralgia	4%	2%	Pyrexia	3%	2%
Pharyngitis	4%	2%	Myalgia	2%	1%

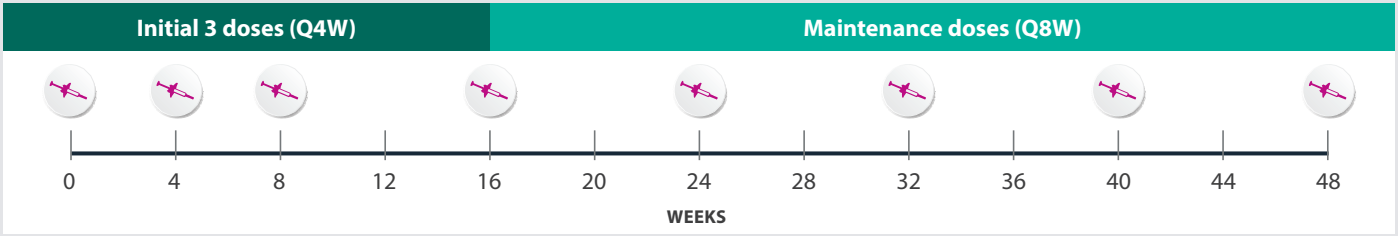
Safety extension trials

In a select subset of patients who were tolerant to FASENRA® and entered the 56-week, single-blind, uncontrolled, extension trial (n=440), the safety profile of FASENRA® was consistent with that observed in placebo-controlled studies.[2]

Patients (n=226) transitioned to another extension study, MELTEMI, and were treated with FASENRA® Q8W for up to 43 months.[4]

Q8W: every 8 weeks.

FASENRA® offers a convenient dosing schedule[2]



Flexible administration options for you and your patients[2]

AT-HOME ADMINISTRATION

A patient may self-inject, or the patient's caregiver may administer FASENRA® after the healthcare professional determines it is appropriate.[2]

The Connect360° Program can provide training for patients and caregivers injecting FASENRA®.

IN-CLINIC ADMINISTRATION

FASENRA® can be administered at any Connect360° Program clinic or your office.

Talk to your patients about which administration option is most convenient for them

FASENRA® is available both as a pen and as a prefilled syringe.

FASENRA PEN™

FASENRA® prefilled syringe

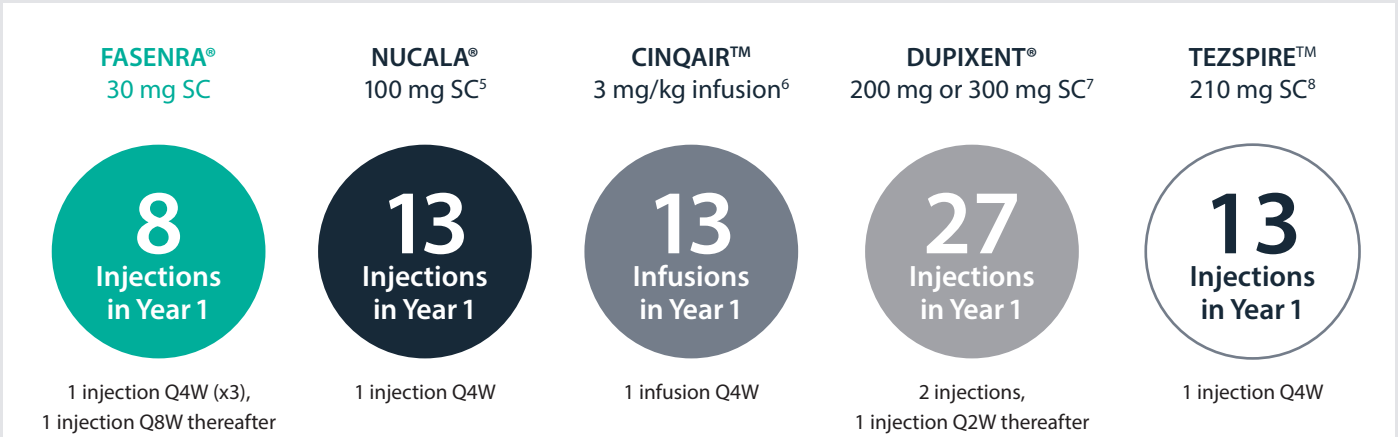
(not actual size)

FASENRA® should be initiated by a qualified healthcare professional experienced in diagnosing and treating severe asthma, with medical follow-up as necessary. Administration by patients or caregivers should only be considered after proper injection training, demonstrated proficiency, and education on signs and symptoms of hypersensitivity reactions.[2]

Refer to Product Monograph for complete dosing and administration information.

Q4W: every 4 weeks; Q8W: every 8 weeks.

Comparison of dosing frequency for severe eosinophilic asthma treatments[2,5-8]



Adapted from individual Product Monographs. See respective Product Monographs for complete dosing and administration information. Comparative clinical significance unknown.

FASENRA® offers a dosing schedule with the fewest injections per year.*

All trademarks are the property of their respective owners.
* Comparative clinical significance unknown.
Q2W: every other week; Q4W: every 4 weeks; Q8W: every 8 weeks; SC: subcutaneous.

Important Safety Information[2]

Clinical use:

FASENRA® is not indicated for other eosinophilic conditions or for relief of acute bronchospasm or status asthmaticus.

FASENRA® is not indicated in the pediatric population, as the efficacy and safety of FASENRA® has not been established in patients less than 18 years of age.

There is limited experience with FASENRA® in patients 65 years of age and older. No overall differences in efficacy or safety of FASENRA® were observed between geriatric and adult patients treated with FASENRA® in clinical trials. Sensitivity of some older individuals, however, cannot be excluded.

Relevant warnings and precautions:

- FASENRA® should not be used to treat acute asthma symptoms or exacerbations
- Corticosteroid reductions
- Helminth infection
- Hypersensitivity reactions
- Pregnant and nursing women

For more information:

Please consult the Product Monograph at **fasenra-en.azpm.ca** for important information regarding adverse reactions, drug interactions, and dosing instructions which have not been discussed in the piece. The Product Monograph is also available by calling **1-800-668-6000**.

Consider FASENRA® as an add-on maintenance treatment for your patients with severe eosinophilic asthma

FASENRA® demonstrated reduction in blood eosinophils[2]*

- In a pharmacodynamic study, a reduction was observed 24 hours after the first dose.

Demonstrated efficacy and safety profile[2]

- Reduced exacerbation rates vs. placebo.
- Generally well tolerated.

Convenient dosing schedule[2]

- 1 SC injection Q4W for the first 3 visits, then 1 SC injection Q8W thereafter.
- Administered with FASENRA PEN™ or FASENRA® prefilled syringe.

Consider FASENRA® for your next move

* Clinical significance unknown.
Q4W: every 4 weeks; Q8W: every 8 weeks; SC: subcutaneous.

References:
1. Data on File. AstraZeneca Canada Inc. Signed October 12, 2023.
2. FASENRA® Product Monograph, AstraZeneca Canada Inc.
3. Bleecker ER, FitzGerald JM, Chanez P, *et al.* Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β_2-agonists (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. *Lancet*. 2016;388(10056):2115–2127 (incl. supplement).
4. Korn S, Bourdin A, Chupp G, *et al.* Integrated safety and efficacy among patients receiving benralizumab for up to 5 years. *Allergy Clin Immunol Pract*. 2021;9(12):4381–4392.
5. NUCALA Product Monograph, GlaxoSmithKline Inc.
6. CINQAIR Product Monograph, Teva Canada Ltd.
7. DUPIXENT Product Monograph, Sanofi Genzyme.
8. TEZSPIRE Product Monograph, AstraZeneca Canada Inc.

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AstraZeneca

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REVIEWED BY PAAB

Fasenra® (benralizumab) Subcutaneous Injection 30 mg