

Patient Information
FASENRA® (fas-en-rah)
(benralizumab)
injection, for subcutaneous use

What is FASENRA?

FASENRA is a prescription medicine used with other asthma medicines for the maintenance treatment of asthma in people 12 years and older whose asthma is not controlled with their current asthma medicines. FASENRA helps prevent severe asthma attacks (exacerbations) and may improve your breathing. Medicines such as FASENRA reduce blood eosinophils. Eosinophils are a type of white blood cell that may contribute to your asthma.

- FASENRA is not used to treat other problems caused by eosinophils.
- FASENRA is not used to treat sudden breathing problems. Tell your healthcare provider if your asthma does not get better or if it gets worse after you start treatment with FASENRA.

It is not known if FASENRA is safe and effective in children under 12 years of age.

Do not use FASENRA if you are allergic to benralizumab or any of the ingredients in FASENRA. See the end of this leaflet for a complete list of ingredients in FASENRA.

Before using FASENRA, tell your healthcare provider about all of your medical conditions, including if you:

- are taking oral or inhaled corticosteroid medicines. **Do not** stop taking your corticosteroid medicines unless instructed by your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine to come back.
- have a parasitic (helminth) infection.
- are pregnant or plan to become pregnant. It is not known if FASENRA will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with FASENRA.
 - **Pregnancy Registry.** There is a pregnancy registry for women who use FASENRA while pregnant. The purpose of the registry is to collect information about the health of you and your baby. You can talk to your healthcare provider about how to take part in this registry or you can get more information and register by calling 1-877-311-8972 or go to mothertobaby.org/Fasenra.
- are breastfeeding or plan to breastfeed. It is not known if FASENRA passes into your breast milk. You and your healthcare provider should decide if you will use FASENRA and breastfeed. Talk to your healthcare provider about the best way to feed your baby if you use FASENRA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Do not stop taking your other asthma medicines unless your healthcare provider tells you to.

How will I use FASENRA?

- FASENRA is injected under your skin (subcutaneously) one time every 4 weeks for the first 3 doses, and then every 8 weeks.
- FASENRA comes in a single dose prefilled syringe and in a single dose autoinjector.
- A healthcare provider will inject FASENRA using the single-dose prefilled syringe.
- If your healthcare provider decides that you or a caregiver can give the injection of FASENRA, you or your caregiver should receive training on the right way to prepare and give the injection using the FASENRA PEN.
- **Do not** try to inject FASENRA until you have been shown the right way by your healthcare provider. **See the detailed “Instructions for Use” that comes with FASENRA PEN for information on how to prepare and inject FASENRA.**
- If you miss a dose of FASENRA, call your healthcare provider.

What are the possible side effects of FASENRA?**FASENRA may cause serious side effects, including:**

- **allergic (hypersensitivity) reactions, including anaphylaxis.** Serious allergic reactions can happen after you get your FASENRA injection. Allergic reactions can sometimes happen hours or days after you get your injection. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of an allergic reaction:
 - swelling of your face, mouth and tongue
 - breathing problems
 - fainting, dizziness, feeling lightheaded (low blood pressure)
 - rash
 - hives

The most common side effects of FASENRA include headache and sore throat.

These are not all the possible side effects of FASENRA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FASENRA?

- Store FASENRA in the refrigerator between 36°F to 46°F (2°C to 8°C).
- FASENRA may be stored at room temperature between 68°F to 77°F (20°C to 25°C) **for up to 14 days.**
- Once removed from the refrigerator and brought to room temperature FASENRA must be used within 14 days or thrown away.
- Store FASENRA in the original carton until you are ready to use it to protect it from light.
- Do not freeze FASENRA. Do not use FASENRA that has been frozen.
- Do not expose FASENRA to heat.
- Do not use FASENRA past the expiration date.
- **Keep FASENRA and all medicines out of the reach of children.**

General information about the safe and effective use of FASENRA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use FASENRA for a condition for which it was not prescribed. Do not give FASENRA to other people, even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for information about FASENRA that is written for health providers.

What are the ingredients in FASENRA?

Active ingredient: benralizumab

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 20, α,α -trehalose dihydrate, and Water for Injection

Manufactured by: AstraZeneca AB, Södertälje, Sweden SE-15185

U.S. License Number 2059

Distributed by: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

FASENRA is a trademark of the AstraZeneca group of companies.

©AstraZeneca 2019

For more information, go to <https://www.FASENRA.com> or call 1-800-236-9933.