

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 severe asthma in adults and children 6 years of age and older whose asthma is not controlled with their current asthma medicines. FASENRA helps prevent severe asthma attacks (exacerbations) and may improve your breathing.
 - 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.
 - to treat adults with eosinophilic granulomatosis with polyangiitis (EGPA).
 - to treat adults and children 12 years of age and older with hypereosinophilic syndrome (HES). FASENRA helps reduce symptoms and prevent flares.
- FASENRA reduces blood eosinophils. Eosinophils are a type of white blood cell that may contribute to your condition.

It is not known if FASENRA is safe and effective in:

- children with asthma younger than 6 years of age.
- children with EGPA younger than 18 years of age.
- children with HES younger than 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.
- 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 medicines for your condition 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, for asthma.
 - one time every 4 weeks for EGPA and HES.
- 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 single-dose autoinjector FASENRA PEN.
- In children with asthma aged 6 to 11 years, FASENRA should only be given by a caregiver or healthcare provider.
- **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.
- If you use or give too much FASENRA, call the Poison Help Line at 1-800-222-1222.

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 get 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 in:

- **adults and children with asthma include** headache and sore throat.
- **adults with EGPA include** headache.
- **adults and children with HES include** headache, allergic reactions, and flu-like symptoms.

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).
- Store FASENRA in the original carton to protect from light.
- FASENRA may be stored at room temperature up to 77°F (25°C) **for up to 14 days.**
- After FASENRA is removed from the refrigerator and brought to room temperature, it must be used within 14 days or thrown away (disposed of).
- **Do not** freeze. **Do not** shake. **Do not** expose to heat.
- Do not use FASENRA past the expiration (EXP) 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 that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about FASENRA that is written for healthcare 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

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