

Package leaflet: Information for the patient

Fasenra® 30 mg solution for injection in pre-filled syringe benralizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fasenra is and what it is used for
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1. What Fasenra is and what it is used for

What Fasenra is

Fasenra is a medicine containing the active substance benralizumab, which is a monoclonal antibody, a type of protein that recognises and attaches to a specific target substance in the body. The target of benralizumab is a protein called interleukin-5 receptor, which is found particularly on a type of white blood cell called an eosinophil.

What Fasenra is used for

Fasenra is used to treat **severe eosinophilic asthma** in adults. Eosinophilic asthma is a type of asthma where patients have too many eosinophils in the blood or lungs.

Fasenra is used together with other medicines to treat asthma (high doses of ‘corticosteroid inhalers’ plus other asthma medicines) when the disease is not well controlled by those other medicines alone.

How Fasenra works

Eosinophils are white blood cells involved in asthma inflammation. By attaching to the eosinophils, Fasenra helps to reduce their numbers.

What are the benefits of using Fasenra

Fasenra may reduce the number of asthma attacks you are experiencing, help you breathe better and decrease your asthma symptoms. If you are taking medicines called ‘oral corticosteroids’, using Fasenra may also allow you to reduce the daily dose or stop the oral corticosteroids you need to control your asthma.

2. What you need to know before you use Fasenra

Do not use Fasenra:

- If you are **allergic** to benralizumab or any of the other ingredients of this medicine (listed in section 6). **Check with your doctor, nurse or pharmacist** if you think this applies to you.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before you are given Fasenra:

- if you have a **parasitic infection** or if you live in an area where parasitic infections are common or you are travelling to such a region. This medicine may weaken your ability to fight certain types of parasitic infections,
- if you have had an **allergic reaction to an injection or medicine in the past** (see section 4 for symptoms of an allergic reaction).

Also, talk to your doctor, nurse or pharmacist when you are given Fasenra:

- if your **asthma remains uncontrolled or worsens** during treatment with this medicine.
- if you have any symptoms of an **allergic reaction** (see section 4). Allergic reactions have occurred in patients receiving this medicine.

Look out for signs of serious allergic reactions

Fasenra can potentially cause serious allergic reactions. You must look out for signs of these reactions (such as hives, rash, breathing problems, fainting, dizziness, feeling lightheaded and/or swelling of your face, tongue or mouth) while you are taking Fasenra.

It is important that you talk to your doctor about how to recognise early symptoms of serious allergic reactions and how to manage these reactions if they occur.

Other medicines for asthma

Do not suddenly stop taking your preventer medicines for your asthma once you have started Fasenra.

If your response to the treatment allows it, your doctor may try to reduce the dose of some of these medicines, especially ones called ‘corticosteroids’. This should be done gradually, under the direct supervision of your doctor.

Other medicines and Fasenra

Tell your doctor if you are taking, have recently taken or might take any other medicines before using Fasenra.

Children and adolescents

The safety and benefits of this medicine are not known in children below the age of 18.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, **ask your doctor for advice** before using this medicine.

Do not use Fasenra if you are pregnant unless your doctor tells you otherwise. It is not known whether Fasenra could harm your unborn baby.

It is not known whether the ingredients of Fasenra can pass into breast milk. **If you are breast-feeding or plan to breast-feed, talk to your doctor.**

Driving and using machines

It is unlikely that Fasenra will affect your ability to drive and use machines.

3. How to use Fasenra

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Fasenra is given as an injection just under the skin (subcutaneously). You and your doctor or nurse should decide if you should inject Fasenra yourself. You should not inject Fasenra yourself if you have not received Fasenra previously and if you had previous allergic reaction with Fasenra.

You or your caregiver should receive training on the right way to prepare and inject Fasenra. Read the 'Instructions for Use' for the pre-filled syringe carefully before using Fasenra.

The recommended dose is an injection of 30 mg. The first 3 injections are every 4 weeks. After this, injections are 30 mg every 8 weeks.

If a dose of Fasenra is missed

If you have forgotten to inject a dose of Fasenra, talk to your doctor, pharmacist or nurse as soon as possible.

Stopping treatment with Fasenra

Do not stop treatment with Fasenra unless your doctor advises you to. Interrupting or stopping the treatment with Fasenra may cause your asthma symptoms and attacks to come back.

If your asthma symptoms get worse while receiving injections of Fasenra, **call your doctor**.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious allergic reactions

Seek medical attention immediately if you think you may be having an allergic reaction. Such reactions may happen within hours or days after the injection.

Not known (the frequency cannot be determined from the available data):

- anaphylaxis
symptoms usually include:
 - swelling of your face, tongue, or mouth
 - breathing problems
 - fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)

Common (these may affect **up to 1 in 10 people**):

- hives
- rash

Other side effects:

Common (these may affect **up to 1 in 10 people**)

- headache
- pharyngitis (sore throat)
- fever (high temperature)
- injection site reaction (for example pain, redness, itching, swelling near where the injection was given)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme

website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fasentra

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store in the original package to protect from light.

Store in a refrigerator (2°C to 8°C).

The syringe may be kept at room temperature up to 25°C for a maximum of 14 days. After removal from the refrigerator, Fasentra must be used within 14 days or discarded.

Do not shake, freeze or expose to heat.

Fasentra is for single use only. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fasentra contains

The active substance is benralizumab. One pre-filled syringe of 1 mL solution contains 30 mg benralizumab.

The other ingredients are histidine, histidine hydrochloride monohydrate, trehalose dihydrate, polysorbate 20 and water for injections.

What Fasentra looks like and contents of the pack

Fasentra is a solution in a clear glass syringe. Its colour may vary from colourless to yellow. It may contain particles.

Fasentra is available in a pack containing 1 pre-filled syringe.

Marketing Authorisation Holder

AstraZeneca UK Limited,
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Manufacturer

MedImmune UK Ltd
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Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name

Fasenra 30 mg solution for injection
in pre-filled syringe

Reference number

17901/0322

This is a service provided by the Royal National Institute of the Blind.