Package leaflet: Information for the patient

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

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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

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1. What Fasenra is and what it is used for

What Fasenra is
Fasenra contains 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
Asthma
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 condition is not well controlled by those other medicines alone.

Eosinophilic granulomatosis with polyangiitis (EGPA)
Fasenra is used to treat EGPA in adults. EGPA is a condition where people have too many eosinophils in the blood and tissues and also have a form of vasculitis. This means there is inflammation of the blood vessels. This condition most commonly affects the lungs and sinuses but often affects other organs such as the skin, heart and kidneys.

Hypereosinophilic syndrome (HES)
Fasenra is used to treat HES in adults and adolescents 12 years and older weighing at least 35 kg. Patients with HES have a high number of eosinophils in the blood. These cells can damage organs in the body, particularly heart, lungs, nerves and skin.

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

What are the benefits of using Fasenra

Asthma
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.

EGPA
Fasenra can reduce symptoms and prevent flare-ups of EGPA. This medicine may also allow you to reduce the daily dose of oral corticosteroids you need to control your symptoms.

HES
Fasenra helps reduce your symptoms and prevent flares of HES.

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 use 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 use 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.

Fasenra is **not a rescue medicine.** Do not use it to treat a sudden asthma attack.

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.

In order to improve the traceability of biological medicinal products, record the name and the lot number, included on the outer carton and the label of the pre-filled pen, every time you get a new package of Fasenra and provide this information when reporting any side effects.

Other medicines for asthma, EGPA and HES
Do not suddenly stop taking or change the dose of your other medicines for your condition 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 and under the direct supervision of your doctor.

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

Children and adolescents
Do not give this medicine to children with asthma and EGPA below the age of 18 because the safety and benefits of this medicine are not known in this population.

Do not give this medicine to children with HES below the age of 12 or adolescents 12 years of age and older weighing less than 35 kg. The safety and benefits of this medicine are not known in this population.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, 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.

Fasenra contains Polysorbate 20
This medicine contains 0.06 mg of polysorbate 20 (plant-derived) in each 30 mg pre-filled pen. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Fasenra Pen

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

Asthma
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.

EGPA
The recommended dose is an injection of 30 mg every 4 weeks.

HES
The recommended dose is an injection of 30 mg every 4 weeks.

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 inject Fasenra. Read the 'Instructions for Use' for the Fasenra Pen carefully before using Fasenra.

If you forget to use Fasenra
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 estimated 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**):
- hypersensitivity reactions (hives, rash)

Other side effects

Common (these may affect **up to 1 in 10 people**)
- headache (in patients with EGPA or HES: **very common** [may affect **more than 1 in 10 people**])
- 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 Fasenra Pen

Keep this medicine out of the sight and reach of children.
Fasenra Pen is for single-use only.
Do not use this medicine after the expiry date which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month.
Store in the original package in order to protect from light.
Store in a refrigerator (2 °C to 8 °C).

The Fasenra Pen may be kept at room temperature up to 25 °C for a maximum of 14 days. After removal from the refrigerator, Fasenra must be used within 14 days or discarded, and the discard date should be written on the carton.
Do not shake, freeze or expose to heat.

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

The other ingredients are histidine, histidine hydrochloride monohydrate, trehalose dihydrate, polysorbate 20 (E 432) and water for injections.

What Fasenra looks like and contents of the pack
Fasenra is a clear solution which is colourless to yellow. It may contain particles.

Fasenra is available in a pack containing 1 pre-filled pen.

Marketing Authorisation Holder

AstraZeneca UK Limited,
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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	**Reference number**
Fasenra 30 mg solution for injection in pre-filled pen	17901/0350

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