

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
2. What you need to know before you use Fasenra
3. How to use Fasenra
4. Possible side effects
5. How to store Fasenra
6. Contents of the pack and other information

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 national reporting system** listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fasenra

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, Fasenra must be used within 14 days or discarded.

Do not shake, freeze or expose to heat.

Fasenra 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 Fasenra 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 Fasenra looks like and contents of the pack

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

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

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Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

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Instructions for use

Fasenra 30mg

Solution for Injection in Pre-filled Syringe

Benralizumab

For Subcutaneous Injection

Single-use Pre-filled Syringe

Before using your Fasenra pre-filled syringe, your healthcare provider should show you or your caregiver how to use it correctly.

Read this 'Instructions for Use' before you start using your Fasenra pre-filled syringe and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

If you or your caregiver have any questions, talk to your healthcare provider.

Important information

Store Fasenra in a refrigerator between 2°C to 8°C in its carton until you are ready to use it.

Fasenra 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.

Do not use your Fasenra pre-filled syringe if:

- it has been frozen
- it has been dropped or damaged
- the security seal on the carton has been broken
- the expiry date (EXP) has passed

Do not:

- shake your pre-filled syringe
- share or re-use your pre-filled syringe

If any of the above happens, throw away the syringe in a puncture-resistant sharps container and use a new pre-filled syringe.

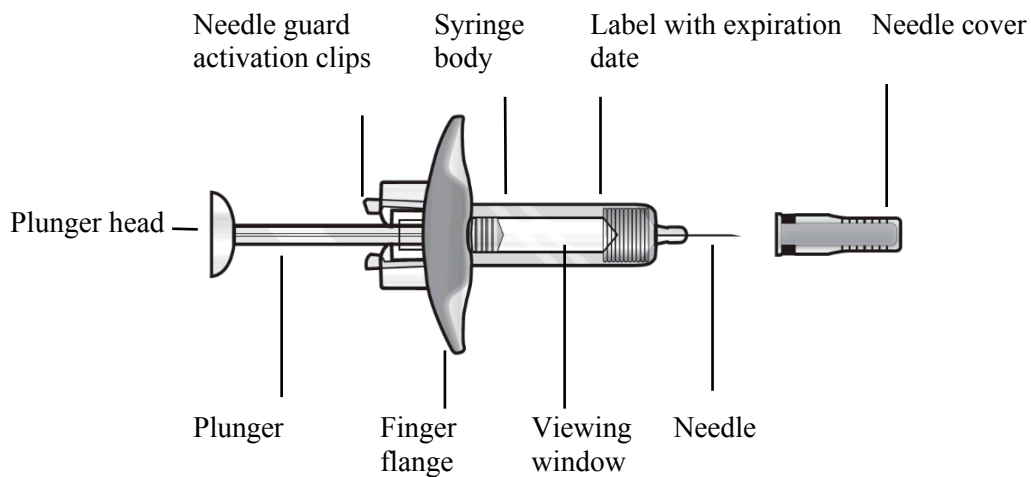
Each Fasenra pre-filled syringe contains 1 dose of Fasenra that is for one-time use only.

Keep Fasenra and all medicines out of the sight and reach of children.

Your Fasenra pre-filled syringe

Do not remove the needle cover until you have reached Step 6 of these instructions and are ready to inject Fasenra.

Do not touch the needle guard activation clips to keep from activating the safety device (needle guard) too soon.



Step 1 - Gather Supplies

- 1 Fasenra pre-filled syringe from the refrigerator
 - 1 alcohol wipe
 - 1 cotton ball or gauze
 - 1 puncture-resistant sharps container.
- (See Step 9 - Dispose the used pre-filled syringe)



Pre-filled syringe



Alcohol wipe



Cotton ball or gauze



Sharps container

Step 2 - Prepare to use your pre-filled syringe

Check the expiry (EXP) date. Do not use if the expiry date has passed.
Let Fasenra warm up at room temperature 20°C to 25°C for about 30 minutes before giving the injection.

Do not warm the pre-filled syringe in any other way. For example, do not warm it in a microwave or hot water, or put it near other heat sources.
 Use Fasenra within 14 days of removing from the refrigerator.



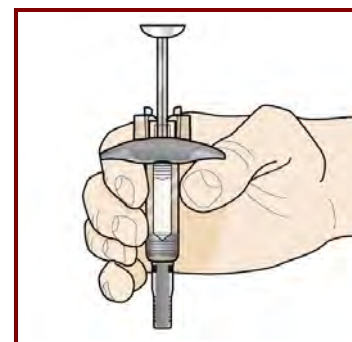
Step 3 - Check the liquid

Open the carton. Peel off the entire lid from the plastic tray.

Grasp the syringe body (not the plunger) to remove the pre-filled syringe from its tray.

Look at the liquid through the viewing window. The liquid should be clear and colourless to yellow. It may contain small white particles.
Do not inject Fasenra if the liquid is cloudy, discoloured, or contains large particles.

You may see a small air bubble in the liquid. This is normal. You do not need to do anything about it.



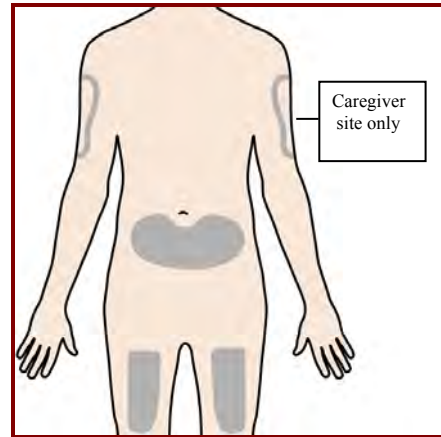
Step 4 - Choose the injection site

The recommended injection site is the front of your thigh. You may also use the lower part of your abdomen.

Do not inject:

- into the 5 cm area around your belly-button
- where the skin is tender, bruised, scaly or hard
- into scars or damaged skin
- through clothing

A caregiver may inject you in the upper-arm, thigh, or abdomen. **Do not** try to inject yourself in the arm. For each injection, choose a different site that is at least 3 cm away from where you last injected.

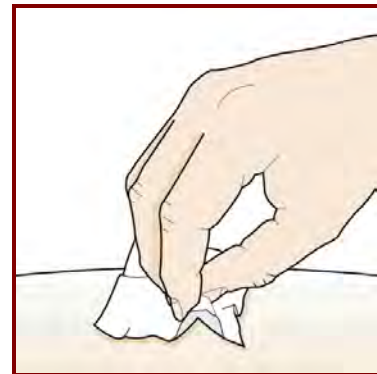


Step 5 - Clean the injection site

Wash your hands well with soap and water. Clean the injection site with an alcohol wipe in a circular motion. Let it air dry.

Do not touch the cleaned area before injecting.

Do not fan or blow on the cleaned area.



Step 6 - Pull off the needle cover

Hold the syringe body with 1 hand, and carefully pull the needle cover straight off with your other hand.

Do not hold the plunger or plunger head while removing the needle cover.

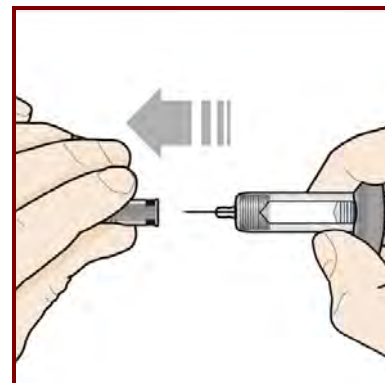
Put the needle cover aside to throw away later.

You may see a drop of liquid at the end of the needle. This is normal.

Do not use the syringe if it is dropped without the needle cover in place or if the needle is damaged or dirty.

Do not touch the needle, or let it touch any surface.

Go straight on to the next steps, without delay.



Step 7 - Inject Fasenra

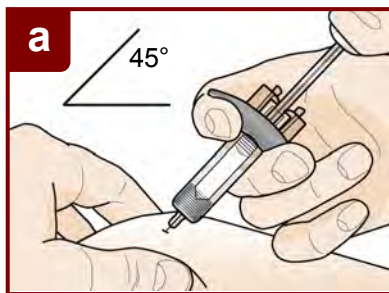
Hold the pre-filled syringe in 1 hand as shown.

Use your other hand to gently pinch and hold the area of skin where you want to inject. This creates a firmer surface.

Do not press down on the plunger until the needle is completely inserted into the skin.

Do not pull back on the plunger at any time.

Inject Fasenra by following the steps in figures a, b and c.



Use a quick, dart-like motion to insert the needle into the pinched skin. Insert the needle at an angle of 45 degrees.



Use your thumb to push down on the plunger head. Keep pushing until it is down as far as it will go. This is to make sure you inject all of the medication.



Keep your thumb pressed down on the plunger head as you take the needle out of the skin. Slowly ease up on the plunger until the needle guard covers the needle.

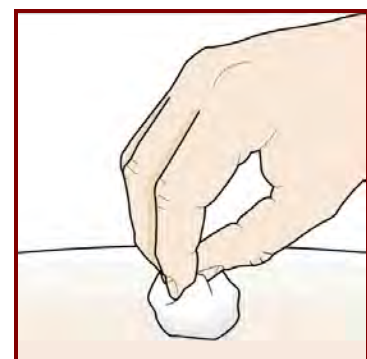
Step 8 - Check the injection site

There may be a small amount of blood or liquid where you injected. This is normal.

Gently hold pressure over your skin with a cotton ball or gauze until the bleeding stops.

Do not rub the injection site.

If needed, cover the injection site with a small bandage.



Step 9 - Dispose the used pre-filled syringe

- Each pre-filled syringe contains a single dose of Fasenra and **cannot be re-used**.
- Put your used pre-filled syringe in a puncture-resistant **sharps container** right away after use.

Do not throw away the pre-filled syringe in your household waste.

Do not re-cap the pre-filled syringe.

Throw away the cap and other used supplies in your household waste.



Disposal guidelines

Dispose of the full container as instructed by your healthcare provider or pharmacist.

Do not recycle your used sharps container.