FASENRA® Prefilled Syringe

Benralizumab, 30 mg/mL solution for injection

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Fasenra** prefilled syringe (called **Fasenra** in this document). It does not contain all the information that is known about **Fasenra**. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Fasenra** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Fasenra is used for

Fasenra contains the active ingredient benralizumab, a monoclonal antibody (a type of protein). Benralizumab works by binding to a specific receptor on eosinophils called the interleukin-5 (IL-5) receptor. By binding to this receptor **Fasenra** reduces blood eosinophils. Eosinophils are a type of white blood cell involved in inflammation of asthma and eosinophilic granulomatosis with polyangiitis (EGPA).

Asthma

Fasenra is used in adults and adolescents (12 years of age and older) to treat a type of asthma - eosinophilic asthma - which is where patients have too many eosinophils in the blood and lungs. **Fasenra** is used together with other medicines you take regularly to treat your asthma (inhaled corticosteroids plus other asthma medicines - for example a daily "preventer" puffer/inhaler).

If you are already using other asthma medicines (such as your daily "preventer" puffer/inhaler) but your asthma is not well controlled by these medicines, then **Fasenra** may help to reduce the number of asthma attacks (exacerbations) and may also make it easier for you to breathe normally. If you are taking medicines called oral corticosteroids (eg prednisolone) **Fasenra** may also help reduce the oral corticosteroid dosage you need to take each day to control your asthma.

You must not stop taking or reduce the dose of your other asthma medicines unless your doctor advises you to. Fasenra does not treat acute asthma symptoms such as a sudden asthma attack. You will still need your "reliever" puffer/inhaler.

Eosinophilic granulomatosis with polyangiitis (EGPA)

Fasenra is used to treat EGPA in adults (18 years of age and older). EGPA is a condition where people have too many eosinophils in the blood and tissues and also have a form of vasculitis (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.

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

Your doctor may have prescribed **Fasenra** for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.
It is available only with a doctor's prescription.
This medicine is not expected to affect your ability to drive a car or operate machinery.
There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you have Fasenra

When you must not use it

Do not have Fasenra if you have an allergy to benralizumab or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)

You should not have this medicine after the expiry date printed on the pack, if the packaging is torn or shows signs of tampering or there are visible signs of deterioration of the product.

If your injection is given by a doctor, nurse or pharmacist they will usually check that the expiry date printed on the pack has not passed and that the packaging is not torn or showing signs of tampering. However, if you are given **Fasenra** by a pharmacist and it has expired or is damaged, return it to your pharmacist for disposal.

There is not enough information to recommend the use of **Fasenra** for children with asthma under the age of 12 years.

There is not enough information to recommend the use of **Fasenra** for children and adolescents with EGPA under the age of 18 years.

If you are not sure whether you should have this medicine, talk to your doctor, nurse or pharmacist.

Before you start on it

Ask your doctor, nurse or pharmacist if you have any questions about your personal Asthma Action Plan.

Your doctor or nurse should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to use regularly to control your asthma (eg "preventer" puffers/inhalers, as well as **Fasenra**), as well as what "reliever" medicines to use when you have sudden asthma attacks.

Tell your doctor if you have any allergies including allergies to other medicines, foods, preservatives or dyes, animals or plants.

Tell your doctor if you have or have had any of the following medical conditions:

- an allergic reaction to benralizumab
- an infection caused by parasites (eg parasitic worms) or if you live in/are travelling to an area where parasitic infections are common as this medicine may weaken your ability to fight certain types of parasitic infections. The parasitic infection should be treated before you are given **Fasenra**.
- have any other medical conditions
- take any medicines for any other condition

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. It is not known whether the ingredients of **Fasenra** can pass into breast milk. The effects of **Fasenra** in pregnant women or their unborn babies are not known. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you have Fasenra.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. This includes all the medicines that you use for your conditions. It is possible that some medicines and **Fasenra** may interfere with each other. Your doctor and pharmacist can advise you.

Fasenra has been used together with other commonly used medicines for asthma and EGPA.

Do not suddenly stop taking your other medicines once you have started Fasenra. Some medicines (especially corticosteroids) must be stopped gradually, under the supervision of your doctor and based on your response to **Fasenra**.

How Fasenra is given

Fasenra is given as an injection into the fat layer just under the skin (subcutaneous). The injections are usually given in your upper arm, thigh or abdomen.

If your doctor or nurse have recommended that you/your caregiver can give your injection, make sure you/your caregiver reads the 'Instructions for Use' carefully before using **Fasenra** (see 'How it is given' section below).

Follow all directions given to you/your caregiver by your doctor or nurse carefully.

How much is given and how long to take it

Asthma

The recommended dose for adults and children who are 12 years and over is 30 mg (one injection). You will need one injection every 4 weeks for the first 3 doses, then one injection every 8 weeks after that.

EGPA

The recommended dose for adults (18 years and over) is 30 mg (one injection) every 4 weeks.

Continue Fasenra for as long as your doctor tells you. Fasenra helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

How it is given

Each pack of **Fasenra** prefilled syringes has an Instructions for Use booklet included. Read the Instructions for Use booklet carefully before you start using **Fasenra**.

The injections are usually given in your thigh or abdomen, however when given by someone else (for example a caregiver or your doctor, nurse or pharmacist), it may also be given in the upper arm.

Do not try to inject yourself in the arm.

If you miss a dose

If you have missed a dose of Fasenra contact your doctor, nurse, or pharmacist as soon as possible. They will tell you what you need to do. You may need to reschedule your appointment if your injection is given to you by a doctor or nurse. If you/your caregiver give the injection, do not take your missed dose unless your doctor, nurse or pharmacist tell you to.

If you are not sure what to do, ask your doctor, nurse or pharmacist.

If you have trouble remembering your appointments or when to inject yourself, ask your doctor, nurse or pharmacist for some hints.

If you are given too much (overdose)

If **Fasenra** is given under the close supervision of a doctor, nurse or pharmacist it is unlikely that you will be given too much.

If you are concerned that you have been given too much Fasenra, tell your doctor, nurse or pharmacist immediately. Otherwise telephone the National Poisons Centre (Ph: 0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have taken too much Fasenra. Do this even if there are no signs of discomfort or poisoning.

While you are having Fasenra

Things you must do

If you have an Asthma Action Plan follow it closely at all times. If your asthma is uncontrolled or worsening tell your doctor.

If you are about to be started on any new medicine, remind your doctor, nurse and pharmacist that you are having Fasenra.

Tell any other healthcare professionals including doctors, dentists, nurses and pharmacists who treat you that you are having this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are having this medicine. It may affect other medicines used during surgery.

If you become pregnant while having this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are having this medicine. It may interfere with the results of some tests.

Keep all of your doctor's and/or hospital's appointments so that you don't miss any doses and your progress can be checked.

Things you must not do

Do not have Fasenra to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop having Fasenra unless your doctor advises you to. Interrupting or stopping **Fasenra** treatment may cause your symptoms and flare-ups to come back or become more frequent.

Do not stop using or reduce the dose of your other medicines unless your doctor advises you to. Some medicines (especially corticosteroids) must be stopped gradually, under the supervision of your doctor and on your response to **Fasenra**.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are having Fasenra. This medicine helps most people with eosinophilic asthma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- headache
- sore throat
- fever/high temperature
- injection site reactions (eg pain, redness, itching, swelling near where the injection was given).

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If you think you are having an allergic reaction to Fasenra tell you doctor or nurse immediately or go to Accident and Emergency at your nearest hospital.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)

Allergic reactions may occur within minutes or hours after an injection, or may even occur several days after an injection. You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Fasenra.**

After having Fasenra

Storage

Keep **Fasenra** in the refrigerator at 2°C to 8°C. Do not freeze, shake or expose to heat. The single use prefilled syringe should be kept sealed in the original package to protect it from light.

Fasenra may be kept at room temperature up to 25°C for no more than 14 days. This is important whether travelling by car, bus, train, plane or any other form of transport. **Fasenra** must be used within 14 days or discarded.

Keep it where children cannot reach it.

Disposal

After injecting **Fasenra**, immediately throw away the used prefilled syringe in a special 'sharps' disposal container as instructed by your doctor, nurse or pharmacist.

If your doctor tells you to stop using **Fasenra** or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Fasenra prefilled syringe contains 1 mL of solution in a clear glass type I prefilled syringe. Its colour may vary from colourless to yellow, and it may contain white particles.

The glass prefilled syringe includes a stainless steel needle, with a FluoroTec (non-latex) coated plunger stopper and a needle safety guard.

Fasenra prefilled syringe is available in a pack containing 1 prefilled syringe (a single dose).

Ingredients

Fasenra prefilled syringe contains 30 mg of benralizumab as the active ingredient.

Other ingredients include:

- histidine
- histidine hydrochloride monohydrate
- trehalose
- polysorbate 20
- water for injections

This medicine does not contain latex, lactose, sucrose, gluten, tartrazine or any other azo dyes.

Marketed by:

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