▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Fasenra®

benralizumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions people ask about Fasenra. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

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

If you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Read this leaflet carefully before you have Fasenra. Keep it in a safe place as you may need to read it again.

What Fasenra is used for

Fasenra is used 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).

Fasenra contains the substance benralizumab, a humanised monoclonal antibody. Benralizumab works by binding to a specific receptor on the eosinophil called the interleukin-5 (IL-5) receptor. By binding to this receptor Fasenra reduces the number of eosinophils in your blood and lungs. Eosinophils are a type of white blood cell that may make your asthma worse by causing inflammation in the lungs.

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed Fasenra for another reason.

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 have Fasenra

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

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.

The doctor, nurse or hospital pharmacist 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 to take to your doctor/nurse and it has expired or is damaged, return it to your pharmacist for disposal.

Fasenra is not recommended for children aged under 12 years, as the safety and effectiveness are not known in this population.

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 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 allergies to any other medicines, foods, preservatives or dyes.

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.

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 asthma including "preventer" and "reliever" medicines.

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 asthma medicines.

Do not suddenly stop taking your asthma 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 to you by a healthcare professional, such as a doctor or a nurse, as an injection into the fat layer just under the skin (subcutaneous). The injections are usually given in your upper arm, thigh or abdomen.

It is not to be self-administered.

How much is given

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

Continue Fasenra for as long as your doctor tells you.

Fasenra helps to control your asthma, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you miss a dose

If you have missed a dose of Fasenra contact your doctor, nurse, clinic or hospital as soon as possible to reschedule your appointment.

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

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

If you are given too much (overdose)

As Fasenra is given under the close supervision of a healthcare physician 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 Poisons Information Centre (telephone 13 11 26) 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 asthma symptoms and asthma attacks to come back or become more frequent.

Do not stop using or reduce the dose of your other asthma 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

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.

After having Fasenra

Storage

It is unlikely that you will need to store Fasenra at home. It will usually be kept at the hospital, pharmacy, doctor's surgery or other health care professional location before your appointment.

If you need to store Fasenra keep it in the refrigerator at 2°C to 8°C until it is time to take it to your appointment. It must not be frozen. The single use prefilled syringe should be kept sealed in the original package to protect it from light. Do not shake it.

Keep it where children cannot reach it.

Disposal

After injecting Fasenra, your healthcare professional should immediately throw away the used prefilled syringe in a special 'sharps' container.

If you have stored Fasenra at home and your doctor tells you to stop having this medicine 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 contains 1 mL of solution in a clear glass type I prefilled syringe. Its colour may vary from colourless to slightly 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 is available in a pack containing 1 prefilled syringe (a single dose).

Ingredients

Fasenra 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.

Supplier

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