

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

FASENRA (30 mg solution for injection in pre-filled syringe)

FASENRA (30 mg solution for injection in pre-filled pen)

(*Benralizumab)

Read all of this leaflet carefully before you start taking FASENRA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- FASENRA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. What FASENRA is and what it is used for
2. What you need to know before you take 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 hypersensitive (allergic) to benralizumab or any of the other ingredients of FASENRA (listed in section 6). Check with your doctor, nurse or pharmacist if you think this applies to you.

Warnings and precautions

Tell your doctor or health care provider before being 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.

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

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Children and adolescents

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not use FASENRA if you are pregnant.

It is not known whether FASENRA could harm your unborn baby.

For women of childbearing potential: Talk to you doctor about using an adequate and effective contraceptive while you are on FASENRA as it is not known whether FASENRA can affect a woman’s fertility.

It is not known whether the ingredients of FASENRA can pass into breast milk. If you are breastfeeding or plan to breastfeed, talk to your doctor about discontinuing FASENRA.

Driving and using machines

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

3. How to use FASENRA

Do not share medicines prescribed for you with any other person.

Always use FASENRA exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with FASENRA will last. If you have the impression that the effect of FASENRA is too strong or too weak, tell your doctor or pharmacist.

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 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.

If you stop using 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

FASENRA can cause side effects.

Not all side effects reported for FASENRA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FASENRA, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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.

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

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s

publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects you can help provide more information on the safety of FASENRA.

5. How to store FASENRA

Store all medicines out of 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 between 2 °C – 8 °C (in a refrigerator).

The syringe may be kept at room temperature at or below 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.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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 transparent glass syringe with a gray rubber stopper. The solution colour may vary from colourless to yellow. It may contain particles.

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

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

Holder of certificate of registration

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West, Bryanston

Johannesburg, 2191

This leaflet was last revised in

10 July 2025

Registration/application Number

54/30.1/0765