FASENRA PEN™

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using FASENRA?

FASENRA PEN contains the active ingredient benralizumab. FASENRA PEN is used to treat a type of asthma - eosinophilic asthma – in adults and children aged 12 years and over, or eosinophilic granulomatosis with polyangiitis (EGPA) in adults aged 18 years and over.
For more information, see Section 1. Why am I using FASENRA PEN? in the full CMI.

2. What should I know before I use FASENRA PEN?

Do not use if you have ever had an allergic reaction to FASENRA PEN or any of the ingredients listed at the end of the CMI.
Do not use to treat acute asthma symptoms such as a sudden asthma attack. You will still need your reliever puffer/inhaler.
Tell your doctor if you have, or have had, an infection caused by parasites (eg parasitic worms) or if you live in/are travelling to an area where parasitic infections are common.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use FASENRA PEN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FASENRA PEN and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How FASENRA PEN is given?

Your doctor or nurse may have recommended that you/your caregiver can give your subcutaneous (under the skin) injection, or it may be given to you by a healthcare professional.
The recommended dose for asthma is 30 mg (one injection of FASENRA PEN) every 4 weeks for the first 3 doses, then one injection every 8 weeks after that.
The recommended dose for EGPA is 30 mg (one injection of FASENRA PEN) every 4 weeks.
Continue FASENRA PEN for as long as your doctor tells you.
More instructions can be found in Section 4. How FASENRA PEN is given? in the full CMI.

5. What should I know while using FASENRA PEN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using FASENRA PEN. • If you have an Asthma Action Plan follow it closely at all times. If your asthma is uncontrolled or worsening tell your doctor.
Things you should not do	• Do not stop using FASENRA PEN unless your doctor advises you to. It is important to keep using FASENRA PEN even if you feel well. • Do not stop using/reduce the dose of your other medicines unless your doctor advises you to
Looking after your medicine	• Keep FASENRA PEN in the refrigerator (2°C to 8°C). Do not freeze, shake or expose to heat. Protect from light. • FASENRA PEN may be kept at room temperature up to 25°C for no more than 14 days.

For more information, see Section 5. What should I know while using FASENRA PEN? in the full CMI.

6. Are there any side effects?

Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you have symptoms of an allergic reaction. Allergic reactions may occur within minutes or hours after an injection or may even occur several days after an injection.

Less serious side effects include headache, sore throat, fever/high temperature and injection site reactions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

FASENRA PEN™

Active ingredient: *benralizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FASENRA PEN prefilled pen. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using FASENRA PEN.**

Where to find information in this leaflet:

1. Why am I using FASENRA PEN?

FASENRA PEN 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 PEN reduces blood eosinophils. Eosinophils are a type of white blood cell involved in inflammation of asthma and eosinophilic granulomatosis with polyangiitis (EGPA).

Asthma

FASENRA PEN 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 PEN is used together with other asthma 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 PEN 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 PEN 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.

Eosinophilic granulomatosis with polyangiitis (EGPA)

FASENRA PEN 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 PEN 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.

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

2. What should I know before I use FASENRA PEN?

Warnings

Do not use FASENRA PEN:

- If you are allergic to benralizumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- To treat acute asthma symptoms such as a sudden asthma attack. You will still need your reliever puffer/inhaler.

Check with your doctor, nurse of pharmacist if you:

- have, or have had, an allergic reaction to benralizumab
- have, or have had, 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 PEN
- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

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 PEN), as well as what reliever medicines to use when you have sudden asthma attacks.

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

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether the ingredients of FASENRA PEN can pass into breast milk. The effects of FASENRA PEN in pregnant women or their unborn babies are not known. Your doctor can discuss with you the risks and benefits involved.

Children

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

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. This includes all the medicines that you use for your conditions.

Some medicines may interfere with FASENRA PEN and affect how it works.

FASENRA PEN 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 PEN.** Some medicines (especially corticosteroids) must be stopped gradually, under the supervision of your doctor and based on your response to FASENRA PEN.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FASENRA PEN.

4. How FASENRA PEN is given?

How much is given and how long to take it

Asthma

Adults and adolescents (12 years and over)

30 mg (one injection of FASENRA PEN)

- every 4 weeks for the first 3 doses,
- then one injection every 8 weeks after that

EGPA

Adults (18 years and over)

30 mg (one injection of FASENRA PEN) every 4 weeks

Continue FASENRA PEN for as long as your doctor tells you.

FASENRA PEN helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

How to give FASENRA PEN

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* leaflet included in each pack of FASENRA PEN carefully before using FASENRA PEN. **Follow all directions given to you/your caregiver by your doctor or nurse carefully.**

FASENRA PEN is given as an injection into the fat layer just under the skin (subcutaneous).

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.

After injecting FASENRA PEN immediately throw away the used prefilled pen (autoinjector) in a special 'sharps' disposal container as instructed by your doctor, nurse or pharmacist.

If you forget to take FASENRA PEN

If you have missed a dose of FASENRA PEN 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 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 FASENRA PEN

If FASENRA PEN 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 PEN, tell your doctor, nurse or pharmacist immediately as you may need urgent medical attention.

If you think that you or anyone else may have taken too much FASENRA PEN you should immediately:

- contact your doctor, or
- phone the Poisons Information Centre in Australia (**by calling 13 11 26**) or the National Poisons Centre in New Zealand (**by calling 0800 POISON or 0800 764 766**), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using FASENRA PEN?

Things you should do

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

Remind any doctor, dentist, nurse, pharmacist or other health professional you visit that you are using FASENRA PEN. If you are going to have surgery, tell the surgeon or anaesthetist that you are using FASENRA PEN. It may affect other medicines used during surgery.

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 should not do

- Do not have FASENRA PEN 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 PEN unless your doctor advises you to. Interrupting or stopping FASENRA PEN 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 PEN.

Driving or using machines

FASENRA PEN is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

Keep FASENRA PEN in the refrigerator at 2°C to 8°C. Do not freeze, shake or expose to heat. FASENRA PEN should be kept sealed in the original package to protect it from light.

FASENRA PEN 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 PEN must be used within 14 days or discarded.

There is a space on the carton to write the date it is removed from the refrigerator.

Follow the instructions in the carton and Instructions for use leaflet on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• headache • sore throat • fever/high temperature • injection site reactions (eg pain, redness, itching, swelling near where the injection was given).	**Speak to your doctor, nurse of pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reaction - 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.	**Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital.** You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or to Medsafe online at https://pophealth.my.site.com/carmreportnz/s/ in New Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FASENRA PEN contains

Active ingredient (main ingredient)	Benralizumab, 30 mg

Other ingredients (inactive ingredients)	• histidine • histidine hydrochloride monohydrate • trehalose • polysorbate 20 • water for injections

Do not take this medicine if you are allergic to any of these ingredients.

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

What FASENRA PEN looks like

FASENRA PEN (AUST R 313902) contains 1 mL of solution in a clear glass type I prefilled syringe inside a pen (autoinjector). Its colour may vary from colourless to yellow, and it may contain white particles.

The pen includes a stainless-steel needle, with a FluoroTec (non-latex) coated plunger stopper and a needle safety guard inside the pen (autoinjector).

FASENRA PEN is available in packs containing 1 FASENRA PEN (a single dose).

Who distributes FASENRA PEN

Australia

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

New Zealand

AstraZeneca Limited
PO Box 87453, Meadowbank
Auckland 1742.

Telephone:- 0800 684 432

This leaflet was prepared in June 2025.

The Australian Product Information document prepared for use by healthcare providers can be found on the Therapeutic Goods Administration (TGA) website – www.ebs.tga.gov.au/. The New Zealand Data Sheet is available at www.medsafe.govt.nz

FASENRA PEN is a trade mark of the AstraZeneca group of companies.

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