PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Fasenra®

Solution for injection in pre-filled pen

For subcutaneous injection

Composition:

Each pre-filled pen (1 ml) contains:

Benralizumab 30 mg

For inactive ingredients, refer to section 6 – further information.

Read this leaflet carefully in its entirety before you start taking this medication.

Keep this leaflet. You may need it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment/medical condition is similar.

1. WHAT FASENRA IS AND WHAT THE MEDICINE IS INTENDED FOR?

Fasenra is indicated as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids and long-acting β-agonists.

Therapeutic group:

Anti-interleukin-5 receptor α monoclonal antibody.

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 site in the body. The target site of benralizumab is a protein called interleukin-5 receptor, which is found particularly on a type of white blood cell called an eosinophil.

How Fasenra works

Eosinophils are white blood cells involved in asthma inflammation in eosinophilic asthma. By attaching to the eosinophils, Fasenra helps to reduce their numbers. Eosinophilic asthma is a type of asthma where patients have high levels of white blood cells in the blood or lungs of the type eosinophils

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. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- you are sensitive to benralizumab or to any components of the medicine (detailed in section 6). If you think this may be relevant to you, check with the doctor, nurse or pharmacist.

Special warnings regarding use of Fasenra

Before treatment with the medicine tell your doctor if you have:

- 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, during treatment with the medicine tell your doctor if:

- your asthma remains uncontrolled or worsens during treatment with this medicine.
- you have any symptoms of an allergic reaction (see section 4). Allergic reactions has 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 the 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.

Children and adolescent

Fasenra is not intended for use in children. There is no data regarding efficacy and safety of this preparation in children below the age of 18.

! If you are taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including non-prescription medicines and food supplements.

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'. Discontinue use of this medicines (especially corticosteroids), should be done gradually, under the direct supervision of your doctor.

! 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. Fasenra should be avoided in pregnancy unless your doctor tells you otherwise. It is not known if Fasenra may harm your fetus.

It is not known if the ingredients of the medicine passes into breast milk. If you are breastfeeding or planning to breastfeed, consult your doctor.

! Driving and using machines

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use Fasenra 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 under the skin (subcutaneously) only. 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' (appear at the end of this leaflet) fully before using Fasenra.

The recommended dose is an injection of 30 mg. The first 3 injections are given every 4 weeks. After this, you will be given 1 injection of 30 mg every 8 weeks.

If you miss a Fasenra dose

If you miss a Fasenra dose contact your healthcare professional as soon as possible.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

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 Fasenra injections, **contact your doctor.**

If you have any further questions on the use of Fasenra, ask your doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Fasenra may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of 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.

Frequency not known (the frequency cannot be determined from the available data):

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

Common side effects (they can 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 at the injection site)

If a side effect appers, if any of the side effects worsens, or if you experience side effects not mentioned in the leaflet, consult the doctor.

Report side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il /

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning.
- Store between 2°C to 8°C (in a refrigerator). If needed, the pen 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.

- Keep Fasenra in the original package in order to protect from light.
- Do not shake, freeze or expose to heat.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. In any case of doubt, consult the pharmacist who dispended the medicine to you.
- Do not store different medications in the same pack.

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.

6. FURTHER INFORMATION

In addition to the active ingredient this medicine also contains:

Water for injection, α,α-trehalose dihydrate, L-histidine hydrochloride monohydrate, L-histidine and polysorbate 20.

What the medicine looks like?

Fasenra is a clear to yellowish solution. The solution may contain particles.
Fasenra is available in a pack containing 1 pre-filled pen.

Manufacturer:

Catalent Indiana LLC, 1300 South Patterson Drive, Bloomington, IN 47403, USA.

License Holder and Importer:

AstraZeneca (Israel) Ltd.,
P.O.B. 1455, Hod Hasharon 4524075.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 160-82-35371-00

This leaflet format was determined by the Ministry of Health and was checked and approved by the Ministry of Health in October 2018, and was updated according to Ministry of Health guidelines in April 2020.