

**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.**

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  $\beta$ -agonists.

**Therapeutic group:**

Anti-interleukin-5 receptor  $\alpha$  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 characterized by high levels of eosinophils-type white blood cells in the blood or lungs.

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

**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 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.
- 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.

Fasenra is **not a rescue medicine**. Do not use it to treat a sudden asthma attack.

### **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**

Do not give Fasenra to children below the age of 18 because the safety and benefits of this medicine are not known in this population.

### **Drug interactions**

**If you are taking or have recently taken any other medicines including non-prescription medicines and food supplements, tell your doctor or pharmacist.**

**Do not suddenly stop taking or change the dose of your preventer medicines for your asthma** once you have started Fasentra. 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 and under the direct supervision of your doctor.

### **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Fasentra should be avoided in pregnancy unless your doctor tells you otherwise. It is not known if Fasentra 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 Fasentra will affect your ability to drive and use machines.

## **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use Fasentra according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined only by your doctor.

**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.

Fasentra is given as an injection under the skin (subcutaneously) only. You and your doctor or nurse should decide if you should inject Fasentra yourself. You should not inject Fasentra yourself if you have not received Fasentra previously and if you had previous allergic reaction with Fasentra.

You or your caregiver should receive training on the right way to inject Fasentra. Read the 'Instructions for Use' fully before using Fasentra.

**Do not exceed the recommended dose.**

**If you forget to use Fasentra**

**If you have forgotten to inject a dose of Fasentra, 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.

Adhere to the treatment as recommended by your doctor.

### **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.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding use of this medicine, consult a doctor or pharmacist.**

## **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):**

- hypersensitivity reactions (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 appears, 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](http://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. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Fasenra is for single use only.
- Store between 2°C to 8°C (in a refrigerator). If needed, Fasenra 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. The date of removal from the refrigerator must be indicated on the packaging.
- 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 dispensed the medicine to you.
- Do not store different medications in the same pack.

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,  $\alpha,\alpha$ -trehalose dihydrate, L-histidine hydrochloride monohydrate, L-histidine and polysorbate 20.

### **What does the medicine look like and what is the contents of the package?**

Fasenra is a colourless to yellow 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.,

1 Atirei Yeda St., Kfar Saba 4464301.

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

Revised in January 2023 according to MoH guidelines.

## Instructions for use for self administration

### **Fasenra®**

#### **Solution for injection in pre-filled pen**

Each pre-filled pen (1 ml) contains:

Benralizumab 30 mg

#### **For subcutaneous injection**

#### **Single-use Pre-filled Pen**

Before using your Fasenra pre-filled pen, your healthcare provider should show you or your caregiver how to use it correctly.

Read this 'Instructions for Use' before you start using your Fasenra pre-filled pen and before each use. There may be new information. This information does not take the place of talking to your attending doctor about your medical condition or your treatment. If you or your caregiver have any questions, talk to the attending doctor.

#### **Important information**

Store Fasenra in a refrigerator between 2°C to 8°C in its original carton until you are ready to use it. If required, Fasenra may be kept at room temperature (of up to 25°C) for a maximum of 14 days.

After removal from the refrigerator, Fasenra must be used within 14 days or discarded.

**Do not** use your Fasenra pre-filled pen if:

- the pen has been frozen or the liquid in the pen has been frozen
- the pen has been dropped or damaged
- the security seal has been broken
- the expiry date has passed.

**Do not** shake your pre-filled pen.

**Do not** share or re-use the pre-filled pen.

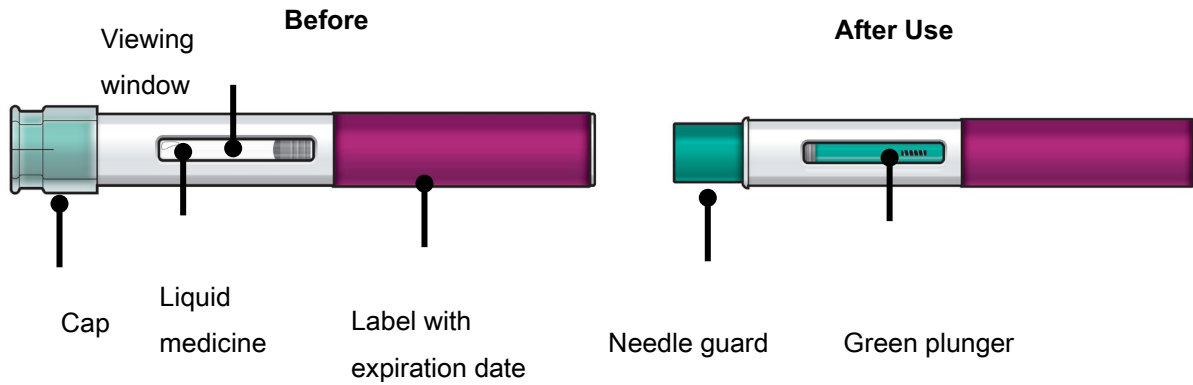
If any of the above happens, throw away the pen in a puncture-resistant sharps container and use a new pre-filled pen.

Each Fasenra pre-filled pen contains 1 dose of Fasenra that is for one-time use only.

Fasenra and any other medicine must be kept out of the reach and sight of children.

## Your Fasenra pre-filled pen

**Do not** remove the cap until you have reached Step 6 of these instructions and are ready to inject Fasenra.



### Step 1 - Gather Supplies

- 1 pre-filled pen from the refrigerator
- 1 alcohol wipe
- 1 cotton ball or gauze
- 1 puncture-resistant sharps container (please see Step 10 - Dispose the used pen safely)



Fasenra pen



Alcohol wipe



Cotton ball or gauze

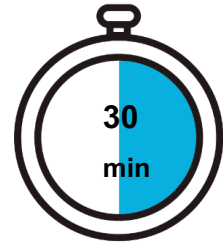


Sharps container



## Step 2 - Prepare to use the Fasenra pre-filled pen

Check the expiry (EXP) date. Do not use if the expiry date has passed.



**Prior to administration, allow the pre-filled pen to reach room temperature (between 20°C to 25°C) by leaving the carton out of the refrigerator for about 30 minutes.**

**Do not warm** the pen in any other way. For example, do not warm it in a microwave or hot water, or put it near other heat sources.

Use Fasenra pen within 14 days of removing from the refrigerator.

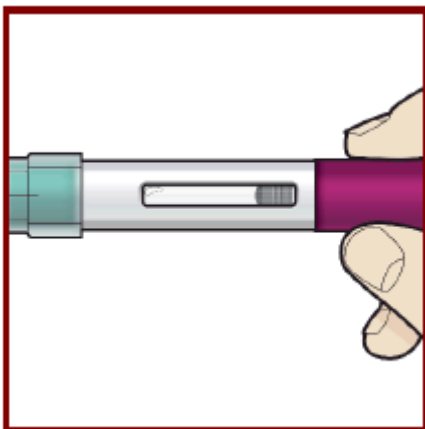
**Do not** remove the cap until you have reached Step 6.

## Step 3 - Check the liquid in the pre-filled pen

**Look at the liquid in the pen through the viewing window.** The liquid should be clear and colourless to yellow. It may contain small white particles.

**Do not** use Fasenra pre-filled pen if the liquid in the pen is cloudy, discoloured, or contains large particles.

You may see a small air bubble in the liquid. This is normal. You do not need to do anything about it.

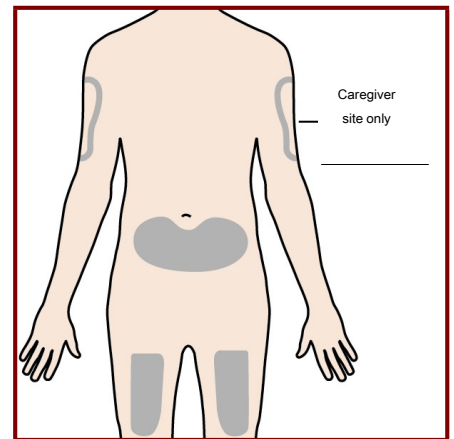


#### **Step 4 - Choose the injection site**

The recommended injection site is the front of your thigh.

You may also use the lower part of your abdomen.

- **Do not inject** into the 5 cm area around your belly-button.
- **Do not inject** where the skin is tender, bruised, scaly or hard.
- **Do not inject** into scars or damaged skin.
- **Do not inject** through clothing.



If a caregiver is given the injection, he may inject you in the upper-arm, thigh, or abdomen. **Do not try to inject yourself in the arm.** For each injection, choose a different site that is at least 3 cm away from where you last injected.

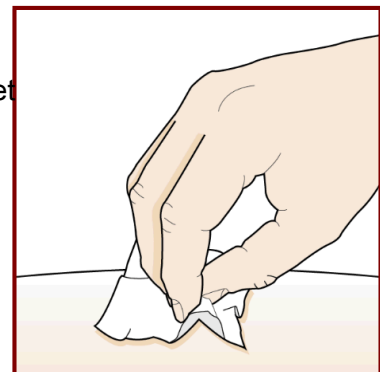
#### **Step 5 - Clean the injection site**

Wash your hands well with soap and water.

Clean the injection site with an alcohol wipe in a circular motion. Let it air dry.

**Do not** touch the cleaned area before injecting.

**Do not** fan or blow on the cleaned area.



#### **Step 6 - Pull off the cap**

Hold the pen body with 1 hand, and carefully pull the cap straight off with your other hand.

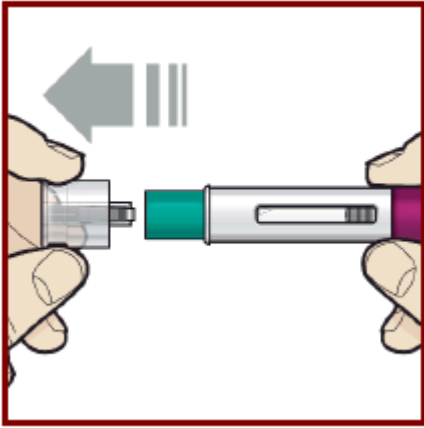
Put the cap aside to throw away later.

The green needle guard is now exposed. It is there to prevent you from touching the needle.

**Do not** try to touch the needle or push on the needle guard with your finger.

Do not try to put the cap back on the Fasenra Pen. You could cause the injection to happen too soon or damage the needle.

Complete the following steps right away after removing the cap.



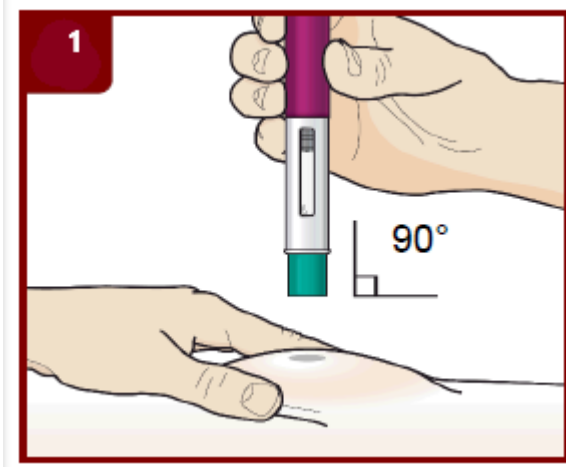
### **Step 7 - Inject Fasenra**

Follow your healthcare provider's instructions on how to inject. You can either gently pinch the skin at the injection site or give the injection without pinching the skin.

Follow the instructions detailed in figures 1, 2, 3 and 4 to inject Fasenra.

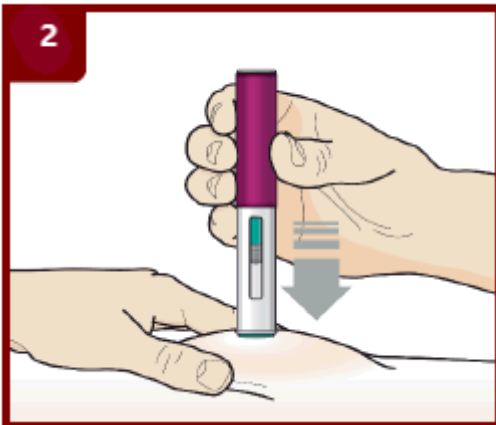
Hold the Fasenra Pen in place for the entire injection.

**Do not** change the position of the Fasenra Pen after the injection has started.

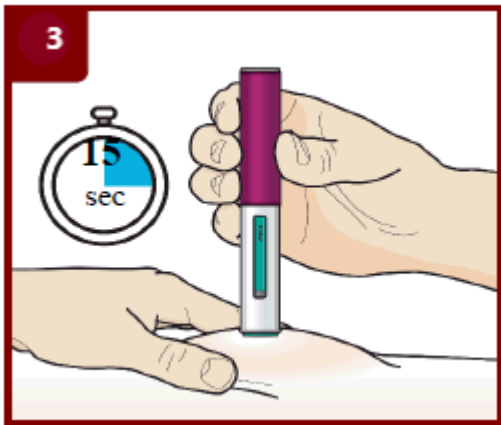


### **Position the Fasenra Pen at the injection site.**

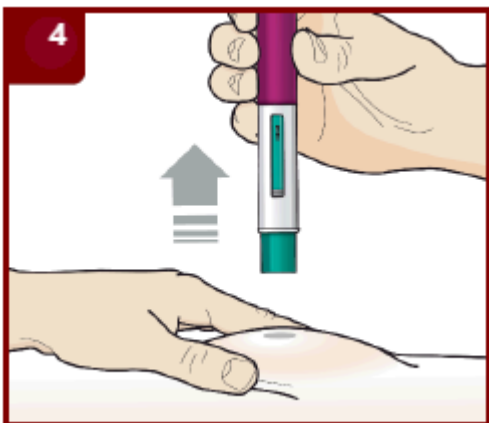
1. Place the needle guard of the Fasenra Pen flat against your skin (90-degree angle). Make sure you can see the viewing window.



2. **Press down firmly.** You will hear a click. A **'click'** tells you the injection has started. The green plunger will move down in the viewing window during the injection.

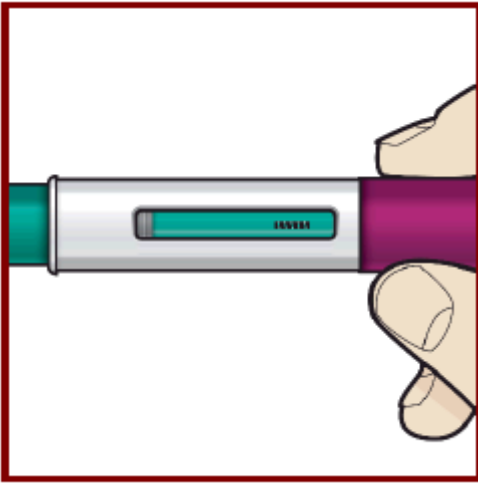


3. **Hold down firmly for 15 seconds.** You will hear a second **'click'**. The second click tells you the injection has finished. The green plunger will fill the viewing window.



4. **Lift the Fasentra Pen straight up.** The needle guard will slide down and lock into place over the needle.

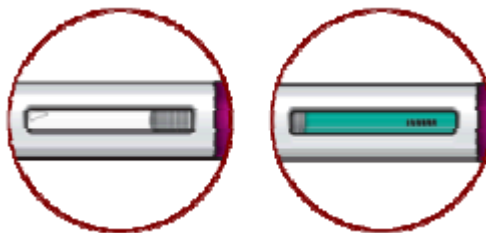
### Step 8 - Check the viewing window



Check the viewing window to make sure all the liquid has been injected.

If the green plunger does not fill the viewing window, you may not have received the full dose. If this happens or if you have any other questions, call the attending doctor.

Before injection



After injection

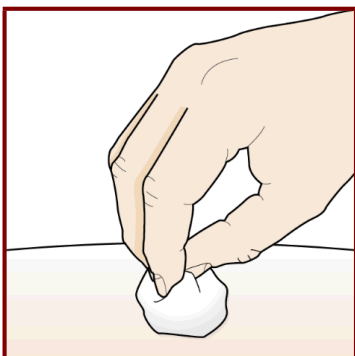
### Step 9 - Check the injection site

There may be a small amount of blood or liquid where you injected. This is normal.

Gently hold pressure over your skin with a cotton ball or gauze until the bleeding stops.

**Do not** rub the injection site.

If needed, cover the injection site with a small bandage.



**Step 10 - Dispose the used pen safely**

- Each pre-filled pen contains a single dose of Fasenra and **cannot be re-used**.
- Put your used pen in a **puncture-resistant sharps container** right away after use.

**Do not** throw away the pre-filled pen in your household waste.

Throw away the cap and other used supplies in your household waste.



Dispose the puncture-resistant sharps container as instructed by your healthcare provider or pharmacist.

**Do not** recycle your used sharps container.