PATIENT MEDICATION INFORMATION

Pr FASENRA®
benralizumab injection

Read this carefully before you start taking **FASENRA** and each time you get an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FASENRA**.

What is FASENRA used for?
FASENRA is a prescription medicine used in addition to other asthma medicines for maintenance treatment of adult patients with severe eosinophilic asthma, whose asthma is not controlled with their current asthma medicines. Severe eosinophilic asthma is a type of asthma where patients have increased eosinophils in the blood or lungs. Eosinophils are a type of white blood cell that are associated with inflammation of the airways that can cause your asthma to get worse or can increase the number of asthma attacks.

FASENRA helps reduce the number of asthma attacks that you experience.

FASENRA is not used to treat other problems caused by eosinophils. FASENRA is not used to treat sudden breathing problems.

How does FASENRA work?
FASENRA contains the active substance, benralizumab, a monoclonal antibody that works by affecting white blood cells called eosinophils. Eosinophils are a type of white blood cell that may contribute to your asthma by causing inflammation in the lungs. By attaching to the eosinophils, FASENRA reduces the number of eosinophils in the blood and lungs.

What are the ingredients in FASENRA?
Medicinal ingredient: benralizumab
Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrate, polysorbate 20 and water.

FASENRA comes in the following dosage form:
Solution for injection.

Each single-use prefilled syringe contains 30 mg of benralizumab in 1 mL of solution.

Do not use FASENRA if:
You are allergic to benralizumab or any of the other ingredients of this medicine. Talk to your doctor about whether this may apply to you.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FASENRA. Talk about any health conditions or problems you may have, including if you:
- have any symptoms of an allergic reaction, including to other medicines of this type (monoclonal antibodies) as they can cause severe allergic reactions when injected into the body (see **What are possible side effects from using FASENRA?**). Serious allergic

reactions have occurred in patients receiving FASENRA.
- have a parasitic infection or if you live in an area where parasitic infections are common or if you are travelling to such a region. FASENRA may weaken your ability to fight certain types of parasitic infections. Parasitic infections should be treated prior to starting treatment with FASENRA.
- feel that your asthma symptoms get worse when being treated with FASENRA.

Other warnings you should know about:

Effects when treatment with FASENRA is stopped
Do not stop receiving injections of FASENRA unless advised by your doctor. Interrupting or stopping the treatment with FASENRA may cause your asthma symptoms to become worse or cause an asthma attack.

Other medicines for asthma
Do not suddenly stop taking your other asthma medications once you have started FASENRA. These medicines (especially *corticosteroids*) must be stopped gradually, under the direct supervision of your doctor.

Pregnancy and breastfeeding
- If you are pregnant, think you may be pregnant, or are planning to become pregnant, tell your doctor before using this medicine. It is preferable to avoid the use of FASENRA during pregnancy. It is not known if FASENRA may harm your unborn baby. There is a pregnancy registry for women who are treated with FASENRA while pregnant. The purpose of the registry is to collect information about the health of you and your baby. You can talk to your healthcare provider about how to take part in this registry or you can get more information and register by calling 1-877-311-8972 or by visiting http://mothertobaby.org.
- If you become pregnant while being treated with FASENRA or within 4 months of stopping treatment with FASENRA, tell your doctor right away.
- It is not known whether the ingredients of FASENRA can pass into breast milk. If you are breastfeeding or plan to breastfeed, you must tell your doctor before being treated with FASENRA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

How to take FASENRA:
FASENRA is given to you as an injection just under the skin (subcutaneously) by a healthcare professional who is experienced in the monitoring and treatment of signs and symptoms of allergic reactions.

Usual dose:
The recommended dose is 30 mg every 4 weeks for the first 3 injections, and then every 8 weeks thereafter.

Overdose:

If you think you have taken too much FASENRA, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If a dose of FASENRA is missed, contact your healthcare professional as soon as possible to re-schedule your appointment.

What are possible side effects from using FASENRA?

FASENRA can cause side effects, although not everybody will get them.

These are not all the possible side effects that you may experience when taking FASENRA. If you experience any side effects not listed here, tell your healthcare professional.

Common side effects (may affect up to 1 in 10 people):

Allergic Reactions
Allergic reactions (e.g., hives, rash) have occurred in patients receiving FASENRA. These reactions often happen within minutes to hours after an injection, but sometimes symptoms can start several days later. Tell your healthcare professional and get immediate emergency medical attention if you have any of the following symptoms of an allergic reaction:

- swelling of your face, eyelids, lips, tongue, or mouth
- difficulty breathing, very wheezy, cough, chest tightness
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)
- hives
- rash

Other common side effects that can occur with FASENRA include:

- headache
- sore throat
- fever
- injection site reactions (e.g., pain, redness, itching, swelling near where the injection was given)

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date that is stated on the label. The expiry date refers to the last day of the stated month.
- Store in the original package to protect from light.
- Store in a refrigerator (2°C to 8°C). Discard unused drug if left out of the refrigerator more than 24 hours.
- Do not shake or freeze.

If you want more information about FASENRA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website www.astrazeneca.ca, or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

This leaflet was prepared by AstraZeneca Canada Inc.

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