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Fasenra (*benralizumab*)

An overview of Fasenra and why it is authorised in the EU

What is Fasenra and what is it used for?

Fasenra is an asthma medicine used to treat adults with a particular type of asthma called eosinophilic asthma.

It is used as an additional treatment in adults with severe asthma that is not adequately controlled by a combination of high-dose inhaled corticosteroids plus medicines called long-acting beta-agonists.

Fasenra contains the active substance benralizumab.

How is Fasenra used?

Fasenra is available as a solution for injection in pre-filled syringes and pre-filled pens. It can only be obtained with a prescription and treatment should be started by doctors with experience in the diagnosis and treatment of severe asthma.

The recommended dose is 30 mg injected under the skin of the thighs or belly every 4 weeks for the first 3 doses, and every 8 weeks afterwards. If the injection is given by a doctor or carer, it can also be given under the skin of the upper arm. If agreed with the treating doctor, patients already using Fasenra and with no history of severe allergic reactions, or their carers, can inject Fasenra themselves after proper training, including on how to watch out for signs and symptoms of allergic reactions. Fasenra should be given for as long as the patient benefits from it, and doctors should re-assess at least once a year whether treatment should be continued.

For more information about using Fasenra, see the package leaflet or contact your doctor or pharmacist.

How does Fasenra work?

In eosinophilic asthma, symptoms are associated with having too many of a type of white blood cell called eosinophils in the blood and in phlegm in the lungs. The active substance in Fasenra, benralizumab, is a monoclonal antibody (a type of protein) designed to attach to receptors (targets) called interleukin-5 receptors on the surface of eosinophils. By attaching to interleukin-5 receptors,

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Fasenra activates the immune system (the body's natural defences) to kill the eosinophils in the blood and lungs. This helps to reduce inflammation, resulting in a reduction in asthma attacks and improvement of symptoms.

What benefits of Fasenra have been shown in studies?

Fasenra was shown to reduce the number of exacerbations (flare-ups) of asthma during treatment in 2 main studies involving a total of 2,511 patients with eosinophilic asthma that was not adequately controlled by a combination of high-dose inhaled corticosteroids and long-acting beta-agonists. Among patients with the highest number of blood eosinophils before treatment, the number of severe flare-ups per year was 0.66 in patients treated with Fasenra (given every 4 weeks for the first 3 doses and every 8 weeks afterwards), compared with 1.14 in patients given placebo (a dummy treatment).

A third study involving 220 patients showed that more patients given Fasenra had their condition improved to the extent that they could reduce their dose of corticosteroids by an average of 75% compared with 25% of those given placebo.

What are the risks associated with Fasenra?

The most common side effects with Fasenra (which may affect up to 1 in 10 people) include headache and pharyngitis (sore throat). For the full list of side effects and restrictions of Fasenra, see the package leaflet.

Why is Fasenra authorised in the EU?

Fasenra has been shown to be more effective than placebo at reducing the number of asthma flare-ups and the need for corticosteroid treatment. The medicine is well tolerated with few side effects. The European Medicines Agency therefore decided that Fasenra's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Fasenra?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Fasenra have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Fasenra are continuously monitored. Side effects reported with Fasenra are carefully evaluated and any necessary action taken to protect patients.

Other information about Fasenra

Fasenra received a marketing authorisation valid throughout the EU on 8 January 2018.

Further information on Fasenra can be found on the Agency's website: ema.europa.eu/medicines/Human/EPAR/fasenra.

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