

# Benralizumab for severe asthma

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Whiston Hospital  
Warrington Road,  
Prescot, Merseyside, L35 5DR  
Telephone: 0151 426 1600

St Helens Hospital  
Marshalls Cross Road,  
St Helens, Merseyside, WA9 3DA  
Telephone: 01744 26633

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Benralizumab is and what it is used for?
2. What you need to know before you use Benralizumab
3. How to use a Benralizumab pen
4. Possible side effects
5. How to store a Benralizumab pen
6. Contents of the pack and other information.

## 1. What Benralizumab is and what it is used for?

### What Benralizumab is

Benralizumab is a medicine containing a type of protein that recognises and attaches to a specific target substance in the body. The target of Benralizumab is a protein called interleukin-5 receptor, which is found particularly on a type of white blood cell called an eosinophil. You may also see it referred to as Fasenra, which is the brand name.

### What Benralizumab is used for

Benralizumab is used to treat severe eosinophilic asthma in adults. Eosinophilic asthma is a type of asthma, where patients have too many eosinophils in the blood or lungs.

Benralizumab is used together with other medicines to treat asthma (high doses of 'corticosteroid inhalers' plus other asthma medicines), when the disease is not well controlled by those other medicines alone.

### How Benralizumab works

Eosinophils are white blood cells involved in asthma inflammation. By attaching to the eosinophils, Benralizumab helps to reduce their numbers.

### The benefits of using Benralizumab

Benralizumab 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 Benralizumab may also allow you to reduce the daily dose or stop the oral corticosteroids you need to control your asthma.

## 2. What you need to know before you use Benralizumab

### Do not use Benralizumab if:

- You are allergic to Benralizumab or any of the other ingredients of this medicine (listed in section 6). Check with your doctor, nurse or pharmacist if you think this applies to you.

### Warnings and precautions

Talk to your doctor, nurse or pharmacist before you are given Benralizumab 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. As 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, talk to your doctor, nurse or pharmacist when you are given Benralizumab if:

- Your asthma remains uncontrolled or worsens during treatment with this medicine.
- You have any symptoms of an allergic reaction (see section 4) while taking Benralizumab. Allergic reactions have occurred in patients receiving this medicine (such as breathing problems, fainting, dizziness, feeling lightheaded and/or swelling of your face, tongue or mouth).

## 6. Contents of the pack and other information

### What Benralizumab pen contains

The active substance is Benralizumab. One pre-filled pen of 1 mL solution contains 30mg Benralizumab.

The other ingredients are histidine, histidine hydrochloride monohydrate, trehalose dihydrate, polysorbate 20 and water for injections.

### What Benralizumab looks like and contents of the pack

Benralizumab is a solution which is colourless to yellow. It may contain particles.

Benralizumab is available in a pack containing 1 pre-filled pen.

## Other side effects

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

- Headache
- Pharyngitis (sore throat)
- Fever (high temperature)
- Injection site reaction (for example pain, redness, itching, swelling near where the injection was given)

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

## 5. How to store a Benralizumab pen

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Store in the original package to protect from light.

Store in a refrigerator (2°C to 8°C). The Benralizumab pen may be kept at room temperature up to 25°C for a maximum of 14 days. After removal from the refrigerator, Benralizumab must be used within 14 days or discarded. Do not shake, freeze or expose to heat.

Benralizumab pen 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. These measures will help protect the environment.

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.

## Look out for signs of serious allergic reactions

Benralizumab 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 your face, tongue or mouth) while you are taking Benralizumab. 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.

## Other medicines for asthma

Do not suddenly stop taking your preventer medicines for your asthma once you have started Benralizumab.

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'. This should be done gradually, under the direct supervision of your doctor.

## Other medicines and Benralizumab

Tell your doctor if you are taking, have recently taken or might take any other medicines before using Benralizumab.

## Children and adolescents

The safety and benefits of this medicine are not known in children below the age of 18.

## Pregnancy and breastfeeding

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.

Do not use Benralizumab if you are pregnant, unless your doctor tells you otherwise. It is not known whether Benralizumab could harm your unborn baby. It is not known whether the ingredients of Benralizumab can pass into breast milk. If you are breastfeeding or plan to breastfeed, talk to your doctor.

## Driving and using machines

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

## 3. How to use a Benralizumab pen

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

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

You or your caregiver should receive training on the right way to prepare and inject Benralizumab. Read the 'instructions for use' for the Benralizumab pen carefully before using Benralizumab.

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

### If a dose of Benralizumab is missed

If you have forgotten to inject a dose of Benralizumab, talk to your doctor, pharmacist or nurse as soon as possible.

### Stopping Benralizumab treatment

Do not stop treatment with Benralizumab unless your doctor advises you to. Interrupting or stopping the treatment with Benralizumab, may cause your asthma symptoms and attacks to come back.

If your asthma symptoms get worse while receiving injections of Benralizumab, contact your doctor.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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.

**Not known** (the frequency cannot be determined from the available data):

- Swelling of your face, tongue, or mouth
- Breathing problems
- Fainting, dizziness, feeling lightheaded (due to a drop in blood pressure).

**Common** (these may affect up to 1 in 10 people):

- Hives
- Rash.