



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Cinqaero

## reslizumab

This is a summary of the European public assessment report (EPAR) for Cinqaero. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Cinqaero.

For practical information about using Cinqaero, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Cinqaero and what is it used for?

Cinqaero is an asthma medicine that is 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 properly controlled by a combination of high-dose corticosteroids taken by inhalation plus another medicine used for the prevention of asthma. The medicine contains the active substance reslizumab.

### How is Cinqaero used?

Cinqaero can only be obtained with a prescription and should be prescribed by doctors with experience in the treatment of eosinophilic asthma. It is available as a concentrate for making a solution for infusion (drip) into a vein. The recommended dose is 3 mg for each kg of bodyweight. The infusion should be given once every four weeks, for as long as the patient is considered to benefit, and doctors should re-assess at least once a year whether treatment should be continued. For further information, see the package leaflet.

### How does Cinqaero 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 Cinqaero, reslizumab, is a monoclonal antibody designed to attach to a substance called interleukin-5, which



stimulates the growth and activity of eosinophils. By attaching to interleukin-5 and blocking its activity, Cinquaero reduces the number of 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 Cinquaero have been shown in studies?**

The benefits of Cinquaero have been shown in two main studies involving 953 patients with eosinophilic asthma that was not well controlled by inhaled corticosteroids and other asthma medication used for the prevention of the disease. Cinquaero was compared with placebo (a dummy infusion), both given every 4 weeks for a year. The main measure of effectiveness was based on the number of flare-ups (exacerbations) of asthma during treatment. Flare-ups were seen in 32% of patients (151 out of 477) given Cinquaero compared with 50% (237 out of 476) of those given placebo. Additionally there was evidence of an improvement in lung function and asthma symptoms, and a decrease in number of eosinophils in the blood in patients given Cinquaero. Supportive data suggested that the benefit was maintained for up to two years.

### **What are the risks associated with Cinquaero?**

The most common side effect with Cinquaero (which may affect about 2 people in 100) is an increase in levels of the enzyme creatine phosphokinase in the blood (a measure of possible damage to muscles). Anaphylactic (severe allergic) reactions may affect less than 1 person in 100.

For the full list of all side effects and restrictions with Cinquaero, see the package leaflet.

### **Why is Cinquaero approved?**

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Cinquaero's benefits are greater than its risks and recommended that it be approved for use in the EU. The reduction in flare-ups and improvement in lung function seen with Cinquaero were considered clinically relevant, particularly for patients who cannot be adequately controlled with high doses of inhaled corticosteroids and another medicine used for the prevention of asthma. Overall the medicine was well tolerated, and appropriate measures to monitor and manage risks have been put in place.

### **What measures are being taken to ensure the safe and effective use of Cinquaero?**

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

### **Other information about Cinquaero**

The European Commission granted a marketing authorisation valid throughout the European Union for Cinquaero on 16 August 2016.

The full EPAR for Cinquaero can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Cinquaero, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2016.