



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Respreeza

## human alpha<sub>1</sub>-proteinase inhibitor

This is a summary of the European public assessment report (EPAR) for Respreeza. 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 Respreeza.

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

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

Respreeza is a medicine used in adults with alpha<sub>1</sub>-proteinase inhibitor deficiency, an inherited disorder that can cause lung problems such as increasing shortness of breath and which may also affect the liver. Respreeza is used to slow down damage to the lungs in patients with severe disease.

Respreeza contains the active substance human alpha<sub>1</sub>-proteinase inhibitor.

### How is Respreeza used?

Respreeza is available as a powder and solvent to be made into a solution for infusion (drip) into a vein. The first infusion should be given under the supervision of a healthcare professional experienced in the treatment of alpha<sub>1</sub>-proteinase inhibitor deficiency. Subsequent infusions can be given by a caregiver or by the patient.

The recommended dose of Respreeza is 60 mg per kilogram body weight, given once a week. The infusion should last around 15 minutes.

The medicine can only be obtained with a prescription. For further information, see the package leaflet.



## **How does Respreeza work?**

The active substance in Respreeza, human alpha<sub>1</sub>-proteinase inhibitor, is a natural protein in the blood which protects lung tissue from damage. It is obtained from human blood and works by replacing the protein that is lacking in patients with alpha<sub>1</sub>-proteinase inhibitor deficiency.

## **What benefits of Respreeza have been shown in studies?**

Respreeza has been shown to slow down lung damage in one main study involving 180 patients with lung damage due to alpha<sub>1</sub>-proteinase inhibitor deficiency. In the study, Respreeza was compared with placebo (a dummy treatment) and the main measure of effectiveness was the decrease in lung density. Lung density is an indicator of the extent of lung damage: the bigger the decrease in lung density, the greater is the damage to the lung. The decrease in lung density after 24 months was around 2.6 g/l in patients who received Respreeza, compared with a decrease of around 4.2 g/l in patients receiving placebo.

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

The most common side effects with Respreeza (which may affect up to 1 in 10 people) are dizziness, headache, dyspnoea (shortness of breath) and nausea. Allergic reactions have been observed during treatment, some of which were severe.

Because of the risk of severe allergic reactions, Respreeza must not be used in patients who are lacking IgA, a protein in the blood, and who have developed antibodies against it because these patients are more prone to allergic reactions. For the full list of all side effects and restrictions with Respreeza, see the package leaflet.

## **Why is Respreeza approved?**

The main study with Respreeza showed that the medicine is effective at slowing down the damage to the lungs in patients with alpha<sub>1</sub>-proteinase inhibitor deficiency, and this effect is considered relevant for patients with severe disease. Allergic reactions were the main safety concern with Respreeza, but advice on how to manage this risk has been included in the product information. No other major concerns have been identified about the safety of the medicine.

Therefore, the Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Respreeza'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 Respreeza?**

The company that markets Respreeza will carry out a further study to assess whether an increased dose of 120 mg/kg may lead to improved effects compared with the currently recommended dose.

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

## **Other information about Respreeza**

The European Commission granted a marketing authorisation valid throughout the European Union for Respreeza on 20 August 2015.

The full EPAR for Respreeza 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%20medicines/European%20public%20assessment%20reports). For more information about treatment with Respreeza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2016.