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EPAR summary for the public

Cinryze

C1 inhibitor (human)

This is a summary of the European public assessment report (EPAR) for Cinryze. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Cinryze.

What is Cinryze and what is it used for?

Cinryze is a medicine used to treat angioedema (swelling) attacks in adults, adolescents and children over 2 years with hereditary angioedema. It is also used to prevent angioedema attacks that can be triggered by medical, dental or surgical procedures. Patients with hereditary angioedema have attacks of swelling that can occur anywhere in the body, such as in the face or limbs, or around the gut, causing discomfort and pain.

Cinryze is also used for routine prevention in adults, adolescents and children from 6 years of age who have severe and frequent angioedema attacks for which prevention with oral medicines is not adequate or in patients whose attacks are not adequately treated.

Cinryze contains the active substance C1 inhibitor (human).

How is Cinryze used?

Cinryze can only be obtained with a prescription. Treatment should be started under the supervision of a doctor experienced in treating hereditary angioedema.

Cinryze is available as a powder and solvent that are made up into a solution for injection into a vein.

For treatment of angioedema attacks in adults, adolescents and children over 2 years and weighing more than 25 kg, the patient is given 1,000 Units at the first sign of an angioedema attack. A second dose of 1,000 Units may be given if the patient has not responded adequately after one hour, or sooner for attacks in the larynx (voice box) or if the start of the treatment had been delayed. The dose is reduced to 500 Units in children aged 2 to 11 years weighing 10 to 25 kg.

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For prevention before a medical, dental or surgical procedure in adults, adolescents and children over 2 years and weighing more than 25 kg, Cinryze is given as 1,000 Units within the 24 hours before the procedure. The dose is reduced to 500 Units in children aged 2 to 11 years weighing 10 to 25 kg.

For routine prevention in adults and adolescents, Cinryze is given as 1,000 Units every 3 or 4 days. In children from 6 to 11 years of age the dose is reduced to 500 Units. The doctor should review the need for routine prevention on a regular basis and can adjust the frequency of the injections or the dose according to how the patient is responding.

The doctor may decide that the caregivers and patients can carry out the injection provided that they have been adequately trained.

How does Cinryze work?

The active substance in Cinryze, human C1 inhibitor, is a protein extracted from human blood.

The C1 inhibitor protein is required to control the 'complement' and 'contact' systems, collections of proteins in the blood that fight against infection and cause inflammation. Patients with low levels of this protein have excessive activity of these two systems, which leads to the symptoms of angioedema. Cinryze is used to replace the missing C1 inhibitor, correcting the deficiency and helping to prevent or treat angioedema attacks.

What benefits of Cinryze have been shown in studies?

Cinryze was more effective than placebo in treating and preventing attacks of angioedema in two main studies involving patients with hereditary angioedema, most of whom were adults. In the first study, Cinryze or placebo (a dummy treatment) were used to treat angioedema attacks in 71 patients. The main measure of effectiveness in this study was how long it took for the symptoms to start improving. Over 50% of patients receiving Cinryze had started having improvements 2 hours into treatment, compared with 33% of patients given placebo.

The second study, involving 24 patients from the first study, looked at the number of attacks over 12-week periods when patients were given Cinryze or placebo as prevention. The patients chosen for the second study were those with frequent attacks, at least two attacks per month on average. The average number of attacks experienced in patients treated with Cinryze was 6.1 over the 12-week period compared with 12.7 for patients on placebo.

The company provided data on the use of Cinryze in 91 adults and children with hereditary angioedema to prevent attacks when undergoing a medical, surgical or dental procedure. Cinryze was effective in preventing attacks triggered by these procedures, with 98% of procedures not triggering an attack within 72 hours.

Two main studies involving children aged 6 to 11 years were also carried out. In the first study, Cinryze was used to treat angioedema attacks in 9 children with hereditary angioedema. The main measure of effectiveness in this study was how long it took for the symptoms to start improving. All the patients were given Cinryze and started having improvements 4 hours into treatment.

In the second study, Cinryze was given as prevention to 6 children with hereditary angioedema. The average number of attacks during 12 weeks of treatment with Cinryze was reduced compared with the period before Cinryze and the attacks were less severe, did not last as long and required less treatment.

Supportive data on the effectiveness of Cinryze in children aged 2 to 5 years were also provided.

What are the risks associated with Cinryze?

The only common side effect seen in studies with Cinryze (seen in between 1 and 10 patients in 100) is rash, which is not serious and typically involves the arms, chest, abdomen or the injection site. For the full list of all side effects and restrictions with Cinryze, see the package leaflet.

Why has Cinryze been approved?

Based on the evidence from the studies, the CHMP concluded that Cinryze'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 Cinryze?

The company that makes Cinryze will ensure that healthcare professionals in all Member States who are expected to prescribe Cinryze are provided with an educational pack instructing them to ensure that caregivers and patients who will give the medicine at home are properly trained. There will also be a training leaflet for patients that should be kept at home.

In addition, the company will maintain a patient registry to provide further data on long-term safety and the way the medicine is used in practice.

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

Other information about Cinryze

The European Commission granted a marketing authorisation valid throughout the European Union for Cinryze on 15 June 2011.

The full EPAR for Cinryze can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Cinryze, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2017.