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EPAR summary for the public

Firazyr

icatibant

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

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

What is Firazyr and what is it used for?

Firazyr is a medicine used to treat the symptoms of attacks of hereditary angioedema in adults, adolescents and children aged over 2 years. Patients with 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. Attacks of hereditary angioedema can be life threatening when they involve the throat. Firazyr is used in patients whose angioedema is linked to naturally low levels of a protein called 'C1 esterase inhibitor'.

Firazyr contains the active substance icatibant.

Because the number of patients with angioedema is low, the disease is considered 'rare', and Firazyr was designated an 'orphan medicine' (a medicine used in rare diseases) on 17 February 2003.

How is Firazyr used?

Each pre-filled syringe of Firazyr contains 30 mg icatibant in 3 ml. The medicine is given by injecting it slowly under the skin, preferably in the abdomen (belly). The recommended dose of Firazyr in adults is one injection (3 ml). If symptoms continue or come back, a second injection can be given after 6 hours. If needed, treatment can be repeated for a third time after an additional 6 hours. No more than three injections should be given in any 24-hour period.

The dose for adolescents and children depends on their body weight.

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The doctor may decide that the patient or their caregiver can inject the medicine themselves, after they have been properly trained by a healthcare professional.

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

How does Firazyr work?

Patients with hereditary angioedema have high levels of a substance called 'bradykinin', which is involved in causing inflammation and swelling. The active substance in Firazyr, icatibant, blocks the receptors that bradykinin normally attaches to. This blocks the activity of bradykinin, helping to relieve the symptoms of the disease.

What benefits of Firazyr have been shown in studies?

Firazyr was found effective in two main studies in adults with hereditary angioedema involving the skin or the abdomen. The main measure of effectiveness was how long it took for the patient's symptoms to be relieved. In both studies, the time it took for symptoms to improve was shorter for patients taking Firazyr than the comparator medicine.

The first study compared Firazyr with tranexamic acid (another medicine for hereditary angioedema) in 74 patients, and the second study compared Firazyr with placebo (a dummy treatment) in 56 patients. Patients' symptoms were relieved on average 2 to 2.5 hours after receiving Firazyr, compared with 12 hours for tranexamic acid in one study and 4.6 hours for placebo in the other study. Firazyr was also found effective among patients included in the two studies who had attacks of angioedema that affected the throat.

In another study involving 22 adolescents and children aged over 2 years with hereditary angioedema, symptoms improved on average 1 hour after the patients received Firazyr.

What are the risks associated with Firazyr?

The most common side effects with Firazyr (seen in more than 1 patient in 10) are injection site reactions including erythema (redness), swelling, burning, itching and pain at injection sites.

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

Why is Firazyr approved?

The European Medicines Agency decided that Firazyr's benefits are greater than its risks and recommended that it be given marketing authorisation.

Firazyr was found to relieve swelling in the skin and abdomen, as well as swelling of the throat. It works in a different way to other authorised treatments.

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

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

Other information about Firazyr

The European Commission granted a marketing authorisation valid throughout the European Union for Firazyr on 11 July 2008.

The full EPAR for Firazyr 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 Firazyr, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Firazyr can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designations.

This summary was last updated in 10-2017.