

**EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)****FIRAZYR****EPAR summary for the public**

*This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.*

*If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*

**What is Firazyr?**

Firazyr is a solution for injection that contains the active substance icatibant.

**What is Firazyr used for?**

Firazyr is used to treat the symptoms of attacks of hereditary angioedema in adults. 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. 'Hereditary' means that the disease is caused by the patient's genes. Firazyr is used in patients whose angioedema is linked to naturally low levels of a protein called 'C1 esterase inhibitor'.

Because the number of patients who have hereditary 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.

The medicine can only be obtained with a prescription.

**How is Firazyr used?**

Firazyr is given as a slow injection under the skin by a doctor or nurse, preferably in the abdomen (tummy). The recommended dose of Firazyr is one injection. If symptoms continue or come back, a second injection can be given after six hours. If needed, treatment can be repeated for a third time after an additional six hours. No more than three injections should be given in any 24-hour period. Firazyr has not been tested in children.

**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 itself to. This blocks the activity of bradykinin, helping to relieve the symptoms of the disease.

**How has Firazyr been studied?**

The effects of Firazyr were first tested in experimental models before being studied in humans. Firazyr has been studied in two main studies in patients with angioedema of the skin or the abdomen. The first study compared Firazyr with tranexamic acid (another medicine used for this disease) in 74

patients, and the second study compared Firazyr with placebo (a dummy treatment) in 56 patients. The main measure of effectiveness was how long it took until the patient's symptoms were relieved.

**What benefit has Firazyr shown during the studies?**

Firazyr was more effective than tranexamic acid and placebo in controlling the symptoms of the disease. In both studies, the time it took for the patient's symptoms to improve was shorter for patients taking Firazyr than for those taking tranexamic acid or placebo. Patients experienced relief an average of 2.0 to 2.5 hours after receiving Firazyr, compared with 12.0 hours after receiving tranexamic acid and 4.6 hours after receiving placebo.

**What is the risk associated with Firazyr?**

The most common side effects with Firazyr (seen in more than 1 patient in 10) are erythema (redness), swelling, a warm sensation, burning, itching and pain. For the full list of all side effects reported with Firazyr, see the Package Leaflet.

Firazyr should not be used in people who may be hypersensitive (allergic) to icatibant or to any of the other ingredients.

**Why has Firazyr been approved?**

The Committee for Medicinal Products for Human Use (CHMP) decided that Firazyr's benefits are greater than its risks for the symptomatic treatment of acute attacks of hereditary angioedema in adults. The Committee recommended that Firazyr be given marketing authorisation.

**Other information about Firazyr:**

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

The summary of opinion of the Committee for Orphan Medicinal Products for Firazyr is available [here](#).

The full EPAR for Firazyr can be found [here](#).

**This summary was last updated in 05-2008.**