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Icatibant Accord (*icatibant*)

An overview of Icatibant Accord and why it is authorised in the EU

What is Icatibant Accord and what is it used for?

Icatibant Accord is a medicine used to treat the symptoms of hereditary angioedema in patients aged 2 years and over.

Patients with angioedema have rapid 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 the swelling around the throat presses against the airway. Icatibant Accord is used in patients whose angioedema is linked to naturally low levels of a protein called 'C1 esterase inhibitor'.

Icatibant Accord contains the active substance icatibant and is a 'generic medicine'. This means that Icatibant Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Firazyr. For more information on generic medicines, see the question-and-answer document here.

How is Icatibant Accord used?

Treatment with Icatibant Accord should be started under the supervision of a healthcare professional. Icatibant Accord is available as a solution in a pre-filled syringe to be injected slowly under the skin, preferably in the abdomen (belly). The doctor may decide that the patient or their caregiver can inject the medicine themselves, after they have been trained by a healthcare professional.

The recommended dose of Icatibant Accord in adults is one single injection. 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.

The medicine can only be obtained with a prescription.

For more information about using Icatibant Accord, see the package leaflet or contact your doctor or pharmacist.

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How does Icatibant Accord 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 Icatibant Accord, icatibant, blocks the receptors that bradykinin normally attaches to. This blocks the activity of bradykinin, helping to relieve the symptoms of the disease.

How has Icatibant Accord been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Firazyr, and do not need to be repeated for Icatibant Accord.

As for every medicine, the company provided data on the quality of Icatibant Accord. There was no need for 'bioequivalence' studies to investigate whether Icatibant Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Icatibant Accord is very similar to the reference medicine and when given by injection under the skin, the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Icatibant Accord?

Because Icatibant Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Icatibant Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Icatibant Accord has been shown to be comparable to Firazyr. Therefore, the Agency's view was that, as for Firazyr, the benefits of Icatibant Accord outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Icatibant Accord are continuously monitored. Suspected side effects reported with Icatibant Accord are carefully evaluated and any necessary action taken to protect patients.

Other information about Icatibant Accord

Icatibant Accord received a marketing authorisation valid throughout the EU on 16 July 2021.

Further information on Icatibant Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/icatibant-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 07-2021.