LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Icatibant Teva
(icatibant acetate)

SE/H/2064/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Icatibant Teva
icatibant acetate

Solution for injection in pre-filled syringe, 30 mg

This is a summary of the public assessment report (PAR) for Icatibant Teva. It explains how Icatibant Teva was assessed, and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Icatibant Teva.

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

What is Icatibant Teva and what is it used for?
Icatibant Teva is a 'generic medicine'. This means that Icatibant Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Firazyr. Icatibant Teva is used for treating the symptoms of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older.

In HAE levels of a substance in your bloodstream called bradykinin are increased and this leads to symptoms like swelling, pain, nausea, and diarrhoea. Icatibant Teva blocks the activity of bradykinin and therefore ends the further progression of the symptoms.

How does Icatibant Teva work?
In HAE levels of a substance in your bloodstream called bradykinin are increased and this leads to symptoms like swelling, pain, nausea, and diarrhoea. Icatibant Teva blocks the activity of bradykinin and therefore ends the further progression of the symptoms.

How is Icatibant Teva used?
The pharmaceutical form of Icatibant Teva is solution for injection in pre-filled syringe.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Icatibant Teva have been shown in studies?
No additional studies were needed as Icatibant Teva is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Firazyr.

What are the possible side effects of Icatibant Teva?
Because Icatibant Teva is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Icatibant Teva approved?
It was concluded that, in accordance with EU requirements, Icatibant Teva has been shown to have comparable quality and to be similar to the reference medicine Firazyr. Therefore, the

Medical Products Agency in Sweden decided that, as for Firazyr, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Icatibant Teva?
A risk management plan has been developed to ensure that Icatibant Teva is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Icatibant Teva, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Icatibant Teva
The full PAR for Icatibant Teva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Icatibant Teva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-09.