LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Tivacoma
(icatibant acetate)

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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

Tivacoma
icatibant acetate

Solution for injection in pre-filled syringe, 30 mg

This is a summary of the public assessment report (PAR) for Tivacoma. It explains how Tivacoma 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 Tivacoma.

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

What is Tivacoma and what is it used for?
Tivacoma is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Firazyr.

Tivacoma is used for treating the symptoms of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older.

How does Tivacoma work?

In hereditary angioedema (HAE) levels of a substance in your bloodstream called bradykinin are increased and this leads to symptoms like swelling, pain, nausea, and diarrhoea.
The active substance in Tivacoma, icatibant, blocks the activity of bradykinin and therefore ends the further progression of the symptoms.

How is Tivacoma used?

The pharmaceutical form of Tivacoma is solution for injection in pre-filled syringe, for subcutaneous injection (under the skin).

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 Tivacoma have been shown in studies?

No additional studies were needed as Tivacoma is a generic medicine considered to be bioequivalent to the reference medicine, Firazyr.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body. Since both Tivacoma and the reference medicine, Firazyr, is given by subcutaneous injection and contains the same active substance they are considered to produce the same levels of the active substance in the blood and no additional studies were needed.

What are the possible side effects from Tivacoma?

Because Tivacoma 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 side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Tivacoma approved?

It was concluded that, in accordance with EU requirements, Tivacoma has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Firazyr. Therefore, the Swedish Medical Products Agency 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 Tivacoma?

A risk management plan has been developed to ensure that Tivacoma 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 Tivacoma, 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 Tivacoma

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

This summary was last updated in 2022-01.