LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Novastan
(argatroban monohydrate)

SE/H/483/04/DC

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Novastan

(argatroban monohydrate)

Solution for infusion, 1 mg/ml

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

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

What is Novastan and what is it used for?

Novastan can be used by patients who are suffering from a disorder known as heparin-induced thrombocytopenia type II (HIT type II). Patients with HIT type II are at risk of developing blood clots in their blood circulation that can cause heart attacks, stroke, breathing problems and problems with the blood supply to their limbs. Novastan can prevent these problems or prevent them from becoming worse.

How does Novastan work?

Novastan is an anticoagulant (a drug that helps to prevent blood clots from forming in the blood circulation). It works by blocking the action of thrombin, a substance in the blood that is important in blood clotting.

How is Novastan used?

The pharmaceutical form of Novastan is solution for infusion.

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.

What benefits of Novastan have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Novastan is effective in treating anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy.

What are the possible side effects of Novastan?

For the full list of all side effects reported with Novastan, see section 4 of the package leaflet.

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

Why is Novastan approved?

The effect of Novastan in the treatment of anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy was shown by the company. Therefore, the Medical Products Agency in Sweden decided that Novastan's benefits are greater than its risks and recommended that it be approved for use.

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

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

The marketing authorisation for Novastan was granted on 2016-05-19 in Sweden.

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

This summary was last updated in 2016-06.