LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pilexam
(tranexamic acid)

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(tranexamic acid)

Solution for injection

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

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

What is Pilexam and what is it used for?

Pilexam is a 'generic medicine'. This means that Pilexam is similar to a 'reference medicine' already authorised in the European Union (EU) called Cyklokapron.

Pilexam is used in adults and children above one year of age for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis.
Specific indications include:

- Heavy periods in women
- Gastrointestinal bleeding
- Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract
- Ear, nose, or throat surgery
- Heart, abdominal, or gynecological surgery
- Bleeding after you have been treated with another medicine to break down blood clots.

How does Pilexam work?

Pilexam contains tranexamic acid which belongs to a group of medicines called antihaemorragics; antifibrinolitics, aminoacids.

Tranexamic acid exerts an anti-haemorrhagic activity by inhibiting the fibrinolytic properties of plasmin.

How is Pilexam used?

The pharmaceutical form of Pilexam is solution for injection for intravenous injection.

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 Pilexam have been shown in studies?

No additional studies were needed as Pilexam is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Cyklokapron.

What are the possible side effects of Pilexam?

Because Pilexam 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 Pilexam approved?

It was concluded that, in accordance with EU requirements, Pilexam has been shown to have comparable quality and to be similar to the reference medicine Cyklokapron. Therefore, the Medical Products Agency in Sweden decided that, as for Cyklokapron, 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 Pilexam?

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

The marketing authorisation for Pilexam was granted on 2013-11-21 in Sweden.

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

This summary was last updated in 2013-11.