LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Trasylol
# (aprotinin)

# SE/H/1671/01/MR

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# Summary Public Assessment Report

Trasylol
(aprotinin)

Solution for injection/infusion, 10000 KIU/ml

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

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

**What is Trasylol and what is it used for?**

Trasylol belongs to a group of medicines called anti-fibrinolytics, i.e. medicines to prevent blood loss.

**How does Trasylol work?**

Trasylol can help to reduce the amount of blood loss you have during and after heart surgery. It is also used to reduce the need for a blood transfusion during and after heart surgery.

**How is Trasylol used?**

The pharmaceutical form of Trasylol is solution for injection/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 Trasylol have been shown in studies?**

The company provided its own data on efficacy and safety studies. These studies have shown that Trasylol is effective in reducing the amount of blood loss you have during and after heart surgery. It is also used to reduce the need for a blood transfusion during and after heart surgery.

**What are the possible side effects of Trasylol?**

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

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

**Why is Trasylol approved?**

It was noted that the effect of Trasylol in reducing the amount of blood loss you have during and after heart surgery and the need for a blood transfusion during and after heart surgery was

significantly better than treatment with placebo. Therefore, the Medical Products Agency in Sweden decided that Trasylol'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 Trasylol?**

A risk management plan has been developed to ensure that Trasylol 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 Trasylol, 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 Trasylol**

The marketing authorisation for Trasylol was granted on 1967-12-13 in Sweden.

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

This summary was last updated in 2018-02