Package leaflet: Information for the patient

Trasylol 10,000 KIU/ml solution for injection or infusion

Aprotinin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor/surgeon giving you Trasylol
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

1. What Trasylol is and what it is used for

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

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. Your doctor/surgeon has decided that you would benefit from Trasylol treatment because you are at increased risk of major blood loss since you will undergo a heart bypass operation using a circulation outside your body (heart-lung machine).

Your doctor will administer Trasylol after careful consideration of the benefits and risks, and the availability of alternative treatments.

2. What you need to know before you are given Trasylol

You must not be given Trasylol

- if you are **allergic to aprotinin** or any of the other ingredients of this medicine (listed in section 6).
- if a **positive aprotinin-specific IgG antibody** test is available, showing an increased risk of an allergic reaction to Trasylol

- if no aprotinin specific IgG antibody test is possible prior to treatment and you have received or you suspect that you have received aprotinin-containing medicinal products in the last 12 months.

Warnings and precautions

Talk to your doctor before receiving Trasylol.

Tell your doctor if any of these apply to you, to help him or her decide if Trasylol is suitable for you:

- **Your kidneys do not work properly.** If you have kidney problems Trasylol should only be used if your doctor/surgeon feels it will be of benefit.
- **You have or suspect you have received aprotinin or aprotinin containing fibrin sealants in the last 12 months.**

If any of these apply to you, your doctor will decide whether Trasylol is suitable for you or not.

Trasylol will only be given if your doctor has done **blood tests before** to check you are suitable (e.g. an appropriate aprotinin-specific IgG antibody test), otherwise other medicines may be a better option for you.

You will be monitored carefully for any allergic reaction to the medicine and your doctor/surgeon will treat any symptoms you may experience. Standard emergency treatment for severe allergic reactions should be readily available during treatment with Trasylol

Children and adolescents
The safety and efficacy of Trasylol in children below the age of 18 years have not been established.

Other medicines and Trasylol
Tell your doctor if you are taking, have recently taken or might take any other medicines.

You should specifically tell your doctor if you take:
- medicines used to dissolve blood clots, such as streptokinase, urokinase, alteplase (r-tPA)
- aminoglycosides (antibiotics, medicines used to treat infections)

It is recommended that your doctor/surgeon should, in addition to Trasylol administer heparin (a medicine used to prevent blood clots) before and during the operation. Your doctor will evaluate the dose of heparin based from the results from tests of your blood.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine. If you are pregnant or breast-feeding Trasylol should only be used if your doctor/surgeon finds it will be of benefit. Your doctor will discuss with you the risks and benefits of using this medicine.

3. How to use Trasylol

For adult patients the following dose regimen is recommended:

You will receive a small amount of Trasylol (1 ml) before the operation begins, to test if you are allergic to the Trasylol . Medicines used to prevent the symptoms of allergy (H_1-antagonist and a H_2-antagonist) may be administered 15 minutes prior to the test dose of Trasylol.

If there are no signs of allergy, you will be given 100-200 ml Trasylol over 20 to 30 minutes, followed by 25 - 50 ml per hour (max. 5 - 10 ml/min) until the end of the operation.
In general, you will not be given more than 700 ml of Trasylol at any one time.

There is no special dose recommendation for elderly patients or patients with poor kidney function.

Trasylol will usually be given to you lying down by slow injection or infusion (through 'a drip') through a catheter into a larger vein in your body.

If you are given more Trasylol than the recommended dose
There is no specific substance to counteract the effects of Trasylol.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Although allergic reactions are rare in patients receiving an aprotinin-containing medicinal product for the first time, patients who are given Trasylol more than once may have an increased chance of an allergic reaction. The symptoms of an allergic reaction may include:
- **breathing difficulties**
- **reduced blood pressure**
- **itching, rash and hives**
- **feeling sick**

If any of these occur during administration of Trasylol your doctor/surgeon will stop treatment with the drug.

Other side effects are:

Common: may affect up to 1 in 10 patients

- abnormal kidney function test (blood creatinine increased)

Uncommon: may affect up to 1 in 100 patients
- chest pain (*myocardial ischaemia, coronary occlusion / thrombosis*), heart attack (*myocardial infarction*)
- leakage of heart fluid into the surrounding body cavity (*pericardial effusion*)
- blood clot (*thrombosis*)
    - reduced or interrupted blood supply to the brain (stroke)
- kidney disease (*acute kidney injury, renal tubular necrosis*)

- passing less urine than is normal
- severe allergic reaction (anaphylactic / anaphylactoid reaction)

Rare: may affect up to 1 in 1,000 patients

- blood clot in blood vessels (*arteries*)blood clot in the lungs (pulmonary embolism)

Very rare: may affect up to 1 in 10,000 patients
- swelling on or around the location of the injected skin (injection and infusion site reactions, infusion site (*thrombo- phlebitis*)
- severe blood clotting disorder that results in tissue damage and bleeding (*disseminated intravascular coagulation*)
- inability of the blood to clot or coagulate normally (*coagulopathy*)
- severe allergic shock (*anaphylactic shock*), which is potentially life threatening

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Trasylol

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the outer carton after Expiry date/"EXP". The last day of the month is the expiry date.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trasylol contains
The active ingredient is aprotinin 10,000 KIU/ml
The other excipients are sodium chloride and water for injection

What Trasylol looks like and contents of the pack
Solution for injection/infusion
The solution is clear and colourless

Packsize
Glass vial containing 50 ml

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Nordic Group B.V.
Siriusdreef 41
2132 WT Hoofddorp
the Netherlands

Manufacturer
Fresenius Kabi Austria GmbH
Hafnerstrasse 36
A-8055 Graz
Austria.

Manufacturer:
Apotek Produktion & Laboratorier AB (APL)
Formvägen 5B
906 21 Umeå
Sweden

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
Nordic Pharma Limited
4045 Kingswood Road
Citywest Business Park
Co. Dublin
D24 V06K
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden : Trasylol 10000 KIE/ml injektions-/infusionsvätska, lösning
Ireland : Trasylol 10,000 KIU/ml, solution for injection/infusion

This leaflet was last revised in December 2023

INFORMATION FOR HEALTHCARE PROFESSIONALS

The following information is intended for healthcare professionals only:

Aprotinin should be prescribed by specialists with experience in cardiopulmonary bypass graft surgery.

Parenteral drugs should be inspected visually for particulate matter and colour change prior to administration. Remaining solution should not be stored for later use.

Trasylol is compatible with glucose 20% solution, hydroxyethyl starch solution or Ringer lactate solution. Chemical and physical stability has been demonstrated for diluted solution for up to 6 hours at 25 °C. From a microbiological point of view, the product should be used immediately unless the preparation has been carried out under controlled and validated aseptic conditions. If the product is not used immediately, storage during use and condition prior to use is the responsibility of the user.

Any unused product or waste material should be disposed of in accordance with local requirements.