

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 <Invented name>
- 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 <Invented name> is and what it is used for
2. What you need to know before you are given <Invented name>
3. How to use <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> belongs to a group of medicines called anti-fibrinolytics, i.e. medicines to prevent blood loss.

<Invented name> 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 <Invented name> 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 <Invented name> after careful consideration of the benefits and risks, and the availability of alternative treatments.

2. What you need to know before you are given <Invented name>

You must not be given <Invented name>

- 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 <Invented name>

- 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 <Invented name>.

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

- **Your kidneys do not work properly.** If you have kidney problems <Invented name> 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 <Invented name> is suitable for you or not.

<Invented name> 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 <Invented name>

Children and adolescents

The safety and efficacy of <Invented name> in children below the age of 18 years have not been established.

Other medicines and <Invented name>

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 <Invented name> 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 <Invented name> 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 <Invented name>

For adult patients the following dose regimen is recommended:

You will receive a small amount of <Invented name> (1 ml) before the operation begins, to test if you are allergic to the <Invented name>. Medicines used to prevent the symptoms of allergy (H₁-antagonist and a H₂-antagonist) may be administered 15 minutes prior to the test dose of <Invented name>.

If there are no signs of allergy, you will be given 100-200 ml <Invented name> 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 <Invented name> at any one time.

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

<Invented name> 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 <Invented name> than the recommended dose

There is no specific substance to counteract the effects of <Invented name>.

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 <Invented name> 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 <Invented name> your doctor/surgeon will stop treatment with the drug.

Other side effects are:

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*)
- kidney disease (*acute renal failure, renal tubular necrosis*)
- passing less urine than is normal

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

- blood clot in blood vessels (*arteries*)

- severe allergic reaction (*anaphylactic / anaphylactoid reaction*)
- 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*)
 - blood clot in the lungs (*pulmonary embolism*)
 - 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 [the national reporting system listed in Appendix V](#).

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

5. How to store <Invented name>

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 <Invented name> contains

The active ingredient is aprotinin 10,000 KIU/ml

The other excipients are sodium chloride and water for injection

What <Invented name> 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 22
2132 WT Hoofddorp
the Netherlands

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

<To be completed nationally>

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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

Sweden : Trasylol
Ireland : Trasylol

This leaflet was last revised in 6 February 2018

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.

<Invented name> 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.