SCHEDULING STATUS

S4

TRASYLOL® 10 000 KIU/mL solution for injection and infusion

Aprotinin

Sugar free

Read all of this leaflet carefully before you are given TRASYLOL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.

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 which prevent blood loss.

TRASYLOL (aprotinin) is a highly purified and concentrated form of a naturally occurring enzyme inhibitor prepared from bovine lung tissue.

TRASYLOL is used to reduce the amount of blood loss and the need for a blood transfusion in adults undergoing coronary artery bypass graft surgery requiring the use of a heart-lung machine and are at high risk of major blood loss.

Your doctor will carefully consider if TRASYLOL will be appropriate for you.

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2. What you need to know before you use TRASYLOL

TRASYLOL should not be administered to you:

- If you are allergic to aprotinin or any of the other ingredients listed in section 6.
- If you have tested positive to aprotinin-specific IgG antibody test. There is an increased risk of anaphylactic reaction when treated with TRASYLOL.
- If no aprotinin-specific IgG antibody test is possible prior to treatment and you have received or you suspect that you have received TRASYLOL or other medicines containing aprotinin in the last 12 months.
- If you suffer from pancreatitis.

Warnings and precautions

Special care should be taken with TRASYLOL:

- **If you are undergoing coronary artery bypass graft surgery combined with another cardiovascular procedure you should not receive TRASYLOL; the safety and efficacy of TRASYLOL has not been established in other cardiovascular procedures.**
- Before and during treatment with TRASYLOL you may also be treated with heparin (a medicine used to prevent blood clots); your doctor will determine the dose of heparin based on your blood test results.
- Grafts (your living tissue used during the operation) should not be preserved with blood drawn from your TRASYLOL central infusion line.
- If you have received TRASYLOL or medicines containing aprotinin in the past, particularly in the in last 12 months, you may be at risk of having a serious allergic reaction; your doctor will administer a test dose of TRASYLOL to assess the potential for an allergic reaction.
- If you have never received TRASYLOL your doctor will also administer a test dose of TRASYLOL to assess the potential for an allergic reaction.
- If you have kidney problems or are taking medicines such as antibiotics called aminoglycosides (e.g., gentamicin, streptomycin, kanamycin, amikacin, etc.) which could impair kidney function; TRASYLOL may worsen kidney problems which could lead to kidney failure and death.

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Other medicines and TRASYLOL

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary and traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Thrombolytic agents (medicines used to dissolve blood clots, e.g., streptokinase, urokinase, alteplase (r-tPA)); TRASYLOL may weaken the effect of these medicines.
- Antibiotics called aminoglycosides (e.g., gentamicin, streptomycin, kanamycin, amikacin, etc.) may impair kidney function which could be worsened by TRASYLOL.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before using TRASYLOL.

Safety during pregnancy and lactation has not been established.

3. How to use TRASYLOL

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself TRASYLOL. It will be given to you by a person who is qualified to do so.

Your doctor should administer TRASYLOL to you through a central intravenous line.

An appropriate aprotinin-specific IgG antibody test should be performed in all patients before administration of TRASYLOL.

The following dose regimen is recommended for adult patients:

Owing to the risk of allergic/anaphylactic reactions, a 1 mL (10 000 KIU) test dose should be administered to you at least 10 minutes prior to the remainder of the dose. After the uneventful administration of the 1 mL test dose, the therapeutic dose may be given. Medicines used to prevent the symptoms of allergy (H_1-antagonist and a H_2-antagonist) may be administered to you 15 minutes prior to the test dose of TRASYLOL. Standard emergency

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treatments for anaphylactic and allergic reactions should be readily available.

In general, the total amount of TRASYLOL administered per treatment course should not exceed 7 million KIU.

Your doctor will determine the dosage.

The attending doctor will decide on the length of your treatment with TRASYLOL.

If you receive more TRASYLOL than you should

Since a healthcare provider will administer TRASYLOL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use TRASYLOL

Since a healthcare provider will administer TRASYLOL, it is unlikely that the dose will be missed.

If you stop using TRASYLOL

Your doctor will decide when to stop or interrupt your treatment with TRASYLOL.

4. Possible side effects

TRASYLOL can have side effects.

Not all side effects reported for TRASYLOL are included in this leaflet. Should your general health worsen while using TRASYLOL, please consult your doctor, pharmacist, or other healthcare provider for advice.

Although allergic reactions occur less frequently in patients receiving an aprotinin-containing medicine such as TRASYLOL 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 or anaphylactic reaction may include:

- breathing difficulties
- reduced blood pressure
- itching, rash, and hives

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- feeling sick.

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

If any of the following happens tell your doctor immediately, these are all serious side effects, and you will need urgent medical attention:

Less frequent side effects:

- reduced blood flow to your heart muscle and heart attack (e.g., chest pain or discomfort, pain in your arms, neck, jaw, shoulder or back, nausea, vomiting, fatigue, shortness of breath, sweating, dizziness, coughing)
- accumulation of fluid in the space around your heart (e.g., chest pain, pressure, discomfort, light-headedness, fainting, rapid or irregular heartbeat, coughing, difficulty breathing, hoarseness, anxiety, confusion, hiccoughs)
- blood clots in the arms and legs (e.g., pain, swelling, tenderness, warm and red skin in the affected area of the arm or leg)
- blood clots in vital organs such as the brain, lungs, and kidneys (e.g., sudden numbness or weakness of the face arm or leg especially on one side of the body, confusion, trouble speaking, blurred vision, loss of balance, dizziness, chest or upper back pain, sudden shortness of breath, coughing, fainting, abdominal pain, sudden decrease in urine output, blood in urine, sudden high blood pressure, headache)
- kidney problems (e.g., abnormally small amounts of urine, swelling of the legs, ankles or feet, drowsiness, shortness of breath, fatigue, confusion, nausea, seizures, or coma).

Less frequent side effects experienced post-marketing:

- blood clots in blood vessels throughout the body (e.g., pain, swelling, tenderness, warm and red skin in the affected area of the arms or legs)
- internal bleeding (e.g., blood in the urine or stool, double vision, severe head or neck pain, repeated vomiting, difficulty walking, seizures, joint swelling, and stiffness)
- blood clots in the lungs (e.g., chest or upper back pain, sudden shortness of breath, rapid heart rate, rapid breathing, sweating, anxiety, coughing up blood or pink foamy mucus, fainting).

Tell your doctor if you notice any of the following:

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Less frequent side effects:

- reaction at the injection/infusion site (e.g., pain, tenderness, redness and bulging of the vein).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TRASYLOL.

5. How to store TRASYLOL

Store all medicines out of reach of children.

TRASYLOL vials are stable at room temperature (below 25 °C). TRASYLOL should be inspected visually for particulate matter and colour change prior to administration. If the contents of the vial are cloudy, the product must not be used. Do not use the contents of the vials after the expiry date shown on the label. Any residual solution should not be kept for later use.

Store at or below 25 °C. Protect from light.

Do not remove from the original packaging until administered.

6. Contents of the pack and other information

What TRASYLOL contains

The active substance is aprotinin. Each vial of 50 mL contains aprotinin solution corresponding to 500 000 Kallikrein Inactivator Units, KIU (= 277,8 European Pharmacopoeia Units, E.P. units) aprotinin in sterile 0,9 % sodium chloride solution.

The other ingredients are water for injections and sodium chloride.

What TRASYLOL looks like and contents of the pack

Clear, colourless solution.

TRASYLOL is supplied as a 50 mL vial.

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Holder of Certificate of Registration

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This leaflet was last revised in

14 August 2023

Registration number

H/32/2912

2023.08.18