

# TRASYLOL®

Aprotinin

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## Consumer Medicine Information

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### WHAT IS IN THIS LEAFLET

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This leaflet answers some common questions about TRASYLOL. It does not contain all available information.

It does **NOT** take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving TRASYLOL against the benefits they expect it will have for you.

Please read this leaflet carefully. If you have any concerns about being given this medicine, ask your doctor or your pharmacist.

#### Contents of this leaflet

- WHAT TRASYLOL IS USED FOR
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### WHAT TRASYLOL IS USED FOR

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TRASYLOL is used to prevent and treat abnormal bleeding conditions during Coronary Artery Bypass Graft (CABG) surgery.

TRASYLOL is a sterile intravenous medication. It contains the drug **aprotinin** which is a protein obtained and purified from cow's lungs. Aprotinin is similar to a protein that naturally occurs in humans. Being given TRASYLOL helps to supplement natural processes controlling bleeding while you are undergoing surgery. TRASYLOL is only used in hospitals.

Your doctor may have prescribed TRASYLOL for another reason. Ask your doctor if you have any questions about why TRASYLOL is being prescribed.

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### BEFORE YOU ARE GIVEN TRASYLOL

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#### When you must not have TRASYLOL

You must not have TRASYLOL if:

- you are allergic to aprotinin

- you have been treated with aprotinin in the last 12 months
- you are sitting or standing up. You must be lying down when you are given the drug

You must not be given TRASYLOL that has passed the expiry date. This date appears after the words "EXP" or "EXPIRY" printed on the pack.

Do not use a vial of TRASYLOL if it is cloudy or has little specks in it.

#### Before you are given TRASYLOL

Tell your doctor if:

- you have received TRASYLOL (or another medicine containing aprotinin) on a previous occasion.
- you are allergic to any of the substances mentioned in the **PRODUCT DESCRIPTION** for TRASYLOL, or to other medicines or substances.
- you are pregnant.
- you are breastfeeding.
- you have kidney problems.
- you are taking an aminoglycoside medicine (a group of antibiotics) for example amikacin, gentamicin, neomycin, streptomycin or tobramycin.

#### Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may affect the action of TRASYLOL, or may affect how well TRASYLOL works.

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### HOW TRASYLOL IS GIVEN

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A doctor or a nurse will give you TRASYLOL into a vein, usually as a drip. To make sure you are not allergic to it, you will be tested with a small dose (1 mL) after you have been anaesthetised but before the surgery begins which is injected into a vein at least 10 minutes before the drip is started.

In Open Heart Surgery, TRASYLOL is given during surgery and is discontinued at the end of the operation. In these circumstances, you may not recall being given TRASYLOL. Your doctor/surgeon will be able to tell you how much TRASYLOL you are likely to receive under your own particular circumstances.

TRASYLOL is incompatible with most other drugs, so it shouldn't be put in a drip with

anything other than 20% glucose solution, Ringer lactate solution or hydroxyethyl starch solution.

#### **If you are given too much (overdose)**

The symptoms of overdose with TRASYLOL are not known.

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### **WHILE YOU ARE RECEIVING TRASYLOL**

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#### **Things you must do**

Tell your doctor or nurse if:

- you develop symptoms mentioned in the **SIDE EFFECTS** section (see below).
- you feel unwell while on TRASYLOL.

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### **SIDE EFFECTS**

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TRASYLOL helps most people who are given it, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. In cases of serious side effects, you may need immediate medical attention.

#### **Tell your doctor if you notice any of the following and they worry you:**

TRASYLOL can cause redness and pain at the injection site.

#### **Tell your doctor or nurse immediately if you notice any of the following:**

Symptoms of a severe allergic reaction, such as

- rash
- hives on the skin
- itchy skin
- nausea
- low blood pressure
- breathing difficulty
- faster or slower heart rate
- flushing.

#### **TRASYLOL will need to be stopped immediately and other medicines will be required to treat these symptoms.**

TRASYLOL can cause severe allergic reactions. For individuals using TRASYLOL for the first time, the risk of a serious allergic reaction is low (less than 1 person in 1000). After the first time, the risk increases to about 1 person in 20 when TRASYLOL is given.

Reduced production of urine can be a symptom of disturbances in kidney function and could be triggered by TRASYLOL particularly in patients with kidney problems. These disturbances are usually temporary with no long-term effects.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.**

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### **AFTER YOU HAVE RECEIVED TRASYLOL**

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Use a vial of TRASYLOL once only. Discard any unused portion remaining in the vial.

#### **Storage**

Store TRASYLOL in a cool, dry place away from sunlight, where the temperature is not likely to be higher than 25°C.

**If you have any further questions on TRASYLOL, or are unsure of the information given above, please see your doctor or nurse, who will be able to assist you.**

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### **PRODUCT DESCRIPTION**

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TRASYLOL is a clear solution containing aprotinin in the following strengths:

- 500,000 KIU in 50 mL
  - 1,000,000 KIU in 100 mL
  - 2,000,000 KIU in 200 mL
- (KIU = kallikrein inhibitor units)

The solution also contains

- sodium chloride,
- water,
- small amounts of sodium hydroxide and/or hydrochloric acid to adjust the acidity of the solution.

#### **Australian Registration Numbers:**

TRASYLOL 50 mL vial - AUST R 43530  
TRASYLOL 100 mL vial - AUST R 58869  
TRASYLOL 200 mL vial – AUST R 58867

#### **Manufacturer**

Bayer HealthCare AG, Germany

#### **Sponsor:**

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