

## Who can administer

Administration RESTRICTED - see [Appendix 1](#)

## Important information

- Doses of aprotinin are expressed in KIU (Kallikrein International Units)
- Test dose required - see under 'dose' below
- Aprotinin is **not a heparin-sparing agent** and it is important that adequate anticoagulation with heparin be maintained during aprotinin-therapy
- An appropriate aprotinin-specific IgG antibody test may be considered before administration of aprotinin
- If no antibody test is possible, administration of aprotinin to patients with a suspected previous exposure including in fibrin sealant products during the **last 12 months is contraindicated**

## Available preparations

Trasylol 500,000 KIU/50ml vial

## Reconstitution

Already in solution

## Infusion fluids

Not required - product ready for infusion

## Methods of intravenous administration

### **Intermittent intravenous infusion (using an electronically controlled infusion device)**

- Loading dose over 20 to 30 minutes (maximum rate 5 to 10ml/minute)
- See under 'dose' for details
- Must be administered via a central line

### **Continuous intravenous infusion**

- Maintenance dose
- See under 'dose' for details
- Must be administered via a central line

## Dose in adults

### **TEST DOSE**

- All patients should receive a **test dose** of 1ml (10,000 KIU), at least 10 minutes prior to the loading dose
- After the uneventful administration of the test dose, the therapeutic dose may be given
- A H<sub>2</sub>-antagonist and a H<sub>1</sub>-antagonist may be administered 15 minutes prior to the test dose of

aprotinin

## Cardiothoracic surgery

### Loading dose

- 100 to 200 ml (1 to 2 million KIU) given over twenty to thirty minutes after induction of anaesthesia and prior to sternotomy
- **Prime pump dose:** A further 100 to 200ml (1 to 2 million units) should be added to the pump prime of the heart-lung machine. To avoid physical incompatibility of aprotinin and heparin when adding to the pump prime solution, each agent must be added during recirculation of the pump prime to assure adequate dilution prior to admixture with the other component

### Maintenance dose

- Give 25 to 50ml (250,000 to 500,000 KIU) per hour until the end of the operation
- In general, the total amount of aprotinin administered per treatment course should not exceed 7 million KIU (700ml)

### Renal impairment

- No dosage adjustment required - but see next point
- Caution is advised in patients with impaired renal function ( $\text{CrCl} < 60\text{ml/min}$ ). Because aprotinin is renally excreted, reduced doses may be used in patients with renal failure<sup>(ref 1)</sup>

### Hepatic impairment

- No data available on dosage adjustments required

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## Monitoring

### Activated clotting time (ACT) is used to monitor patient to maintain adequate anticoagulation

- The Hemochron Signature elite is used in GUH. The current test reagent is a dried preparation of silica, kaolin, phospholipid, stabilisers and buffers. It does not contain celite so is not affected by aprotinin.<sup>(ref 1)</sup>

## Further information

- **Important: aprotinin is not a heparin-sparing agent**
- While the drug is no longer available in the USA due to concerns raised in the **BART trial**, the conclusions reached by this trial have since **been questioned**

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## Storage

- Store below 25°C

## References

- SPC June 2024
- 1: Locally agreed guidelines with perfusionists. Email on file Also, data taken from SPC

## Therapeutic classification

- Antifibrinolytic drugs and haemostatics