Aprotinin Intravenous for Adults



Who can administer

Administration RESTRICTED - see Appendix 1

Important information

- May only be used on Consultant authorisation only- and consultant must document this in the patient notes
- Doses of aprotinin are expressed in KIU (Kallikrein International Units)
- Please take care to prescribe clearly, so that there can be no misinterpretation of the doses required
- Test dose required see under 'dose' below
- Aprotinin must always be given via a central line
- Aprotinin is **not a heparin-sparing agent** and it is important that adequate anticoagulation with heparin be maintained during aprotinin-therapy
- Aprotinin is physically **incompatible with heparin**. Therefore ensure adequate dilution of these two agents if using in the same circuit
- 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
- Adverse reactions must be reported

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
- 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

Aprotinin is indicated for prophylactic use to reduce blood loss and blood transfusion in adult patients who are at high risk of major blood loss undergoing isolated cardiopulmonary bypass graft surgery (i.e. Coronary artery bypass graft surgery that is not combined with other cardiovascular surgery)

TEST DOSE

- All patients should receive a test dose of 1ml (10,000 KIU), at least 10 minutes prior to the loading dose
- This is especially important in patients with documented previous exposure to aprotinin and in those patients for whom a previous exposure is uncertain
- After the uneventful administration of the test dose, the therapeutic dose may be given
- A H₂-antagonist and a H₁-antagonist may be administered 15 minutes prior to the test dose of aprotinin

Cardiothoracic surgery

Loading dose

- Administration by central line only
- 100 to 200 ml (1 to 2 million KIU) given over twenty to thirty minutes after induction of anaesthesia and prior to sternotomyÂ
- **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

- Administration by central line only
- 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 (CrCl <60ml/min). Because aprotinin is renally excreted, reduced doses may be used in patients with renal failure (ref 1)

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. (ref 1)

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 Jan 2021
- 1: Locally agreed guidelines with perfusionists. Also, data taken from SPC

Therapeutic classification

• Antifibrinolytic drugs and haemostatics