

**TRASYLOL**  
(aprotinin injection)



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## Trasylol® for all patients undergoing CPB for CABG surgery.

Trasylol® breaks the chain of events caused by bypass-induced SIRS.

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Click here for a detailed diagram of how Trasylol® breaks the chain.

- Inhibiting multiple mediators of inflammation
- Inhibiting proinflammatory cytokine release
- Decreasing complement activation
- Reducing thrombin- and plasmin-induced platelet defects
- Stabilizing platelet membranes and preserving platelet function

Trasylol® administration may cause fatal anaphylactic or anaphylactoid reactions. Fatal reactions have occurred with an initial (test) dose as well as with any of the components of the dose regimen. Fatal reactions have also occurred in situations where the initial (test) dose was tolerated. The risk for anaphylactic or anaphylactoid reactions is increased among patients with prior aprotinin exposure and a history of any prior aprotinin exposure must be sought prior to Trasylol® administration. The risk for a fatal reaction appears to be greater upon re-exposure within 12 months of the most recent prior aprotinin exposure. Trasylol® should be administered only in operative settings where cardio-pulmonary bypass can be rapidly initiated. The benefit of Trasylol® to patients undergoing primary CABG surgery should be weighed against the risk of anaphylaxis associated with any subsequent exposure to aprotinin.

(See CONTRAINDICATIONS, WARNINGS and PRECAUTIONS in the prescribing information.)

## Safety Considerations

Trasylol is contraindicated in patients with a known or suspected aprotinin exposure during the last 12 months. Aprotinin may also be a component of some fibrin sealant products.

- In clinical studies, hypersensitivity and anaphylactic reactions were rare (<0.1%) in patients with no prior exposure to Trasylol.

**Trasylol administration increases the risk for renal dysfunction and may increase the need for dialysis in the perioperative period.**

- The incidence of serum creatinine elevations >0.5 mg/dL above pre-treatment levels was statistically higher in the high-dose aprotinin group (9.0%) compared with placebo (6.6%).
- This risk may be increased for patients with pre-existing renal impairment or those who receive aminoglycosides or drugs that alter renal function.

In clinical trials Trasylol® did not affect graft patency or increase the risk of the following perioperative events: myocardial infarction, hepatic dysfunction and mortality.

**For Trasylol® contraindications, warnings and precautions see prescribing information file.**

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