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Aprotinin Injection (marketed as Trasylol) Information

FDA Alert [12/2006]

NOTE: The full prescribing information (labeling) for Trasylol was updated on December 15, 2006 to include important new safety information as mentioned below.

This Alert highlights important revisions to the full prescribing information for Trasylol. The new labeling for Trasylol (December 2006) has a more focused indication for use, a new Warning about renal dysfunction, a revised Warning about anaphylactic reactions, and a new Contraindication. Trasylol is now indicated only for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients who are at an increased risk for blood loss and blood transfusion undergoing cardiopulmonary bypass in the course of coronary artery bypass grafting (CABG) surgery. Trasylol should be administered only in the operative setting where cardiopulmonary bypass can be started quickly. Trasylol should not be administered to any patient with a known or suspected exposure to aprotinin within the past 12 months. FDA is evaluating additional recently submitted epidemiological safety study data (discussed below), in the context of all other safety and efficacy information available on aprotinin. This review may result in other actions, including additional changes to the full prescribing information (product labeling).

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available

The new labeling for Trasylol has a more focused indication, a new Warning about renal dysfunction, a revised Warning about anaphylactic reactions, and a new Contraindication. The new labeling changes are summarized here:

Indication and Usage—more limited and focused

Trasylol is now indicated for use only in patients *who are at increased risk for blood loss and blood transfusion* in association with cardiopulmonary bypass in the course of coronary artery bypass grafting. It should be administered only in the operative setting where cardiopulmonary bypass can be rapidly initiated.

A new Warning about renal dysfunction


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

Stronger Warnings about anaphylactic reactions including a new Contraindication for previous aprotinin exposure

Anaphylactic reactions, including fatal reactions, are one of the important risks associated with

Trasylol administration. As a consequence of the higher risk for anaphylactic reactions, administration of Trasylol to patients with a known or suspected exposure during the past 12 months is contraindicated.

- **Healthcare Professional Information**


- Healthcare Professional Sheet [[PDF](#)] or [[HTML](#)] **UPDATED** (12/15/2006)
 - [Full prescribing information](#)  (Trasylol Label) **New!!**
- [FDA News](#) (12/15/2006) **New!!**

Historical Information

- Patient Information Sheet [[PDF](#)] or [[HTML](#)] (September 29, 2006)
- Healthcare Professional Sheet [[PDF](#)] or [[HTML](#)] (September 29, 2006)
- [Public Health Advisory](#) (September 29, 2006)
- [FDA Press Release](#) (September 29, 2006)
- [FDA News](#) (February 8, 2006)
- [Public Health Advisory](#) (February 8, 2006)
- [Questions and Answers](#) (February 8, 2006)
- [Regulatory History of Aprotinin from Drugs@FDA](#)

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