Trasylol (aprotinin)

Audience: Cardiovascular and other healthcare professionals

[UPDATED 12/15/2006] FDA and Bayer Pharmaceuticals notified healthcare professionals of revisions to the prescribing information for Trasylol. The new labeling has a more focused indication, a new Warning that Trasylol administration increases the risk of renal dysfunction and may increase the need for dialysis in the perioperative period, and stronger warnings about anaphylactic reactions. In addition, due to the higher risk for anaphylactic reactions, re-administration of Trasylol to patients with a known or suspected exposure during the past 12 months is contraindicated.

[UPDATED 09/29/2006] FDA held a public advisory committee meeting September 21, 2006 to discuss the safety and overall risk-benefit profile for Trasylol. The committee discussed the findings from the two published observational studies, the Bayer worldwide safety review, and the FDA review of its own post-marketing database. On September 27, 2006, Bayer told FDA that it had conducted an additional safety study of Trasylol. The preliminary findings from this new observational study of patients from a hospital database reported that use of Trasylol may increase the chance for death, serious kidney damage, congestive heart failure and strokes. While FDA conducts its evaluation of this new safety study, it is recommended that physicians should consider limiting Trasylol use to those situations where the clinical benefit of reduced blood loss is essential to medical management and outweighs the potential risks. Physicians should carefully monitor patients for the occurrence of toxicity, particularly to the kidneys, heart, or brain, and promptly report observed adverse event information to FDA's MedWatch program or Bayer.

[Posted 02/08/2006] FDA issued a public health advisory and other advisory information to notify both healthcare professionals and consumers of recently published studies of serious renal and cardiovascular toxicity following Trasylol administration to patients undergoing coronary artery bypass grafting surgery (CABG). An observational study published in The New England Journal of Medicine reported that Trasylol may be associated with increased risk of myocardial infarction, stroke and renal dysfunction. Another publication (Transfusion, on-line edition, January 20, 2006) has reported that Trasylol administration may increase the risk for renal toxicity.

The FDA is working with the authors of the publications and the manufacturer of Trasylol to carefully evaluate the risks and benefits associated with use of Trasylol in CABG. The FDA anticipates the public presentation of the recently reported information and other data at an advisory committee in the near future. The FDA will notify health care providers and patients in a timely fashion as new information becomes

available.

[December 15, 2006 – Revised Label –Bayer]
[December 15, 2006 – Healthcare Professional Sheet – FDA]
[December 15, 2006 – Drug Information Page – FDA]

[September 29, 2006 – Public Health Advisory – FDA]
[September 29, 2006 – Healthcare Professional Information Sheet – FDA]

[February 08, 2006 – Public Health Advisory – FDA]
[February 08, 2006 – Trasylol Information Page – FDA]