

FDA Public Health Advisory Aprotinin Injection (marketed as Trasylol)

This information is not current. The FDA has issued new information about this safety issue, please see <http://www.fda.gov/cder/drug/infopage/aprotinin/default.htm>

Since January, 2006, FDA has been conducting a safety review of Trasylol (aprotinin injection). The review was triggered by the results of two published research studies: one that reported an increase in the chance of kidney failure, heart attack and stroke in patients treated with Trasylol compared to those treated with other similar drugs, and the other that reported an increase in kidney dysfunction compared to another drug. On September 21, 2006, FDA held a public meeting of the Cardiovascular and Renal Drugs Advisory Committee to discuss the safety and overall risk-benefit profile for Trasylol. At that meeting, 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 Pharmaceuticals 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. FDA was not aware of these new data when it held the September 21, 2006, Advisory Committee meeting on Trasylol safety. FDA is actively evaluating these new data and their implications for appropriate use of the drug.

While FDA conducts its evaluation of this new safety study, we recommend the following to healthcare providers:

- Physicians who use Trasylol should carefully monitor patients for the occurrence of toxicity, particularly to the kidneys, heart, or brain, and promptly report observed adverse event information to Bayer Pharmaceuticals, the drug manufacturer, or to the FDA MedWatch program, by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by the Internet at <http://www.fda.gov/medwatch/index.html>.
- Physicians should consider limiting Trasylol use to those situations where the clinical benefit of reduced blood loss is essential to medical management of the patient and outweighs the potential risks.

These recommendations are similar to those provided in a February 8, 2006, FDA Public Health Advisory and information sheets for health care professionals and patients which were based on the published studies mentioned above. See <http://www.fda.gov/cder/drug/infopage/aprotinin/default.htm>.

Trasylol works to slow or prevent bleeding, and is used to reduce blood loss and the need for blood transfusion during some types of heart surgeries. Trasylol is made from the lung tissue of cattle.

In the published studies and the recently supplied Bayer study, patients were not assigned at random to receive various treatments, but rather had their treatment chosen by their physician as part of their standard medical care. Consequently, in these safety studies, patients receiving Trasylol may have had a higher chance for serious complications to begin with as compared to patients receiving no treatment or treatment with another drug intended to decrease bleeding. This possibility complicates the assessment of whether the available studies show that Trasylol treatment, rather than other factors, increased the chance for serious kidney or heart complications.

The new study was done for Bayer by a contract research organization. Existing hospital data from 67,000 records of patients undergoing coronary artery bypass graft surgery were examined. 30,000 of the patients were treated with Trasylol and 37,000 were treated with alternate products. Using complex epidemiological and statistical methods, the report suggested that patients receiving Trasylol were at increased risk for death, kidney failure, congestive heart failure and stroke.

Healthcare providers and patients are encouraged to report adverse event information to FDA via the MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by the Internet at <http://www.fda.gov/medwatch/index.html>.

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