

News release

Bayer Pharmaceuticals Corporation Informs Health Care Professionals of Important Safety Revisions to the Trasylol Label

West Haven, Connecticut - Bayer Pharmaceuticals Corporation, in collaboration with the FDA, is informing health care professionals of important safety revisions to the U.S. product information for Trasylol[®] (aprotinin injection) following an FDA Advisory Committee meeting earlier this year. These safety revisions relate primarily to renal function and hypersensitivity.

Patient safety is Bayer's primary concern and we believe updating the label and informing health care professionals about the appropriate use of Trasylol is very important.

In the U.S., Trasylol is now indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery who are at an increased risk for blood loss and blood transfusion.

Trasylol may cause anaphylactic reactions especially in patients with prior exposure to aprotinin within 12 months and is contraindicated in such patients. The high-dose regimen of Trasylol has been shown in clinical trials to increase the risk of serum creatinine level elevations greater than 0.5mg/dL above baseline. Careful consideration of the balance of benefits and risks is advised before administering aprotinin to patients with pre-existing renal impairment or those with other risk factors for renal dysfunction.

The current U.S. Prescribing Information for Trasylol is available on www.trasylol.com. If you wish to request further information, please contact Bayer Pharmaceuticals Corporation Clinical Communications at 1-800-288-8371.

About Trasylol

Trasylol[®] is indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery who are at an increased risk for blood loss and blood transfusion.

The effects of Trasylol use in CPB involve a reduction in systemic inflammatory response to surgery, which translates into a decreased need for allogeneic (blood donated from another individual), blood transfusions, reduced bleeding and decreased mediastinal re-exploration for bleeding.

Trasylo[®] 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 Trasylo[®] administration. The risk for a fatal reaction appears to be greater upon re-exposure within 12 months of the most recent prior aprotinin exposure. Trasylo[®] should be administered only in operative settings where cardio-pulmonary bypass can be rapidly initiated. The benefit of Trasylo[®] 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

Trasylo 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 Trasylo.

Trasylo 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 Trasylo did not increase the risk of the following perioperative events: graft patency, myocardial infarction, hepatic dysfunction and mortality.

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Forward-Looking Statements

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports file with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.