



Bayer HealthCare
Pharmaceuticals

Return of Residual Trasylol Stock from US Supply Chain:
US Special Access Protocol for Trasylol Remains Unchanged

Trasylol 100mL NDC # 0026-8196-36

Trasylol 200mL NDC # 0026-8197-63

May 22, 2008

Dear U.S. Hospital Pharmacists and Wholesalers/Distributors:

Bayer HealthCare Pharmaceuticals, in consultation with the FDA, has decided to remove remaining residual Trasylol stock from the U.S. market.

At the time of the worldwide marketing suspension, (November 2007), Bayer halted all commercial shipments of Trasylol from its distribution centers. In markets (including the US) where special access programs were under development, some regulatory authorities (including the FDA) did not require that existing stocks of Trasylol be actively withdrawn from the supply chain. Subsequently, Bayer has worked closely with the regulatory authorities (including the FDA) to establish these special access programs. All special access programs are now available and Bayer, after consultation with the FDA, believes that it is now appropriate to remove residual quantities of Trasylol that may remain in the US supply chain to achieve our goal that Trasylol be used only within the approved requirements of the special access program.

The US Special Access Protocol for Trasylol remains unchanged. Physicians interested in participating in the special access protocol can refer to **www.trasylol.com** for details.

Bayer has contracted with Capital Returns to facilitate the product returns of Trasylol. We ask that you take the following actions:

1. Bayer has sent this notice to hospitals and wholesalers/distributors. You are not asked to contact any customers.
2. Please verify that the return address information on the enclosed Packing Slip, shipping labels and Business Reply Card is correct and current. If there are any corrections or changes needed, please contact Capital Returns at 1-800-950-5479 for new packing slips, shipping labels and business reply cards before proceeding to the next step
3. Carry out a physical count and record this data on the Business Reply Card. Mail the enclosed postage paid Business Reply Card – **even if you do not have any Trasylol in your inventory.**
4. If you have inventory, complete the enclosed Packing slip and return your stock of Trasylol using the enclosed prepaid UPS *Authorized Return Service*SM shipping labels to:

Capital Returns, Inc.
6101 North 64th Street
Milwaukee, WI 53218



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Capital Returns will process your shipment and you will receive a refund from Bayer within 4 -6 weeks.

This product removal is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience.

For questions regarding Trasylol, please call Bayer HealthCare Pharmaceuticals toll-free at 1-888-84Bayer (1-888-842-2937).

Sincerely,

A handwritten signature in black ink that reads "Paul MacCarthy". The signature is written in a cursive style with a large, stylized "P" and "M".

Paul MacCarthy, M.D.
Vice President, US Medical Affairs

Enclosures: Business Reply Card
Packing Slip and Shipping Labels