Wyeth

August 2004

Dear Health Care Professional:

This letter is to inform you that there have been reports of glass vial breakage of PROTONIX® I.V. (pantoprazole sodium) for Injection during attempts to connect vials to spiked I.V. system adaptors. This may be a safety issue for pharmacists or nurses when preparing PROTONIX I.V. for Injection vials in combination with spiked I.V. system adaptors, both during manual assembly and while utilizing mechanical assistance. This is not a result of a quality issue for the product. Wyeth has not studied the use of PROTONIX I.V. for Injection with these systems. We are not in a position to recommend use of PROTONIX I.V. for Injection with spiked I.V. system adaptors. We are actively reviewing the situation in order to understand the issues involved. However, if a decision is made by your institution to use such an adaptor, you should contact the manufacturer of the specific system who may be able to provide assistance to you.

PROTONIX I.V. for Injection is available in 40 mg vials. It is recommended that each vial be reconstituted with 10 mL of 0.9% Sodium Chloride Injection, USP. This solution can be administered over a period of at least 2 minutes or further diluted (admixed) with 100 mL of 5% Dextrose Injection, USP, 0.9% Sodium Chloride Injection, USP, or Lactated Ringer's Injection, USP. The admixed solution should be administered intravenously over a period of approximately 15 minutes. For further information about the administration of PROTONIX I.V. for Injection, please refer to the accompanying Prescribing Information.

If you have further questions, please call Wyeth Product Quality at 1-800-999-9384.

Sincerely,

William A. Kentrup
Vice President, Quality Operations
Pharmaceutical Operating Unit