August 2, 2010

REMINDER - STABILITY OF PIPERACILLIN AND TAZOBACTAM FOR INJECTION FOLLOWING RECONSTITUTION

Dear Healthcare Professional:

This letter is a reminder to you of the stability of Piperacillin and Tazobactam for Injection following reconstitution of the product in pharmacy bulk packaging. The pharmacy bulk package bottle is for use in a hospital pharmacy admixture service only.

Piperacillin and Tazobactam for Injection, USP is supplied as a powder in the pharmacy bulk package bottle as follows:

Each Piperacillin and Tazobactam for Injection USP, 40.5 g pharmacy bulk package bottle contains piperacillin sodium equivalent to 36 grams of piperacillin and tazobactam sodium equivalent to 4.5 g of tazobactam and 54.28 mg/g piperacillin of sodium. Each pharmacy bulk package bottle contains 84.96 mEq (1,954 mg) of sodium. NDC 60505-0773-0.

Stability Prior to Reconstitution: Store at 20 to 25°C (68 to 77°F).

Stability Following Reconstitution:

- The pharmacy bulk package bottle should NOT be frozen after reconstitution. Discard unused portions after storage for 4 hours at room temperature. This time period should begin with the introduction of solvent or diluent into the pharmacy bulk package bottle.

- Stability studies in the I.V. bags have demonstrated chemical stability (potency, pH of reconstituted solution and clarity of solution) for up to 24 hours at room temperature and up to one week at refrigerated temperature. Piperacillin and Tazobactam for Injection contains no preservatives.

- Stability of Piperacillin and Tazobactam for Injection in an ambulatory intravenous infusion pump has been demonstrated for a period of 12 hours at room temperature. Stability of Piperacillin and Tazobactam for Injection is not affected when administered using an ambulatory intravenous infusion pump.

- Parenteral drug products should be inspected visually for particulate matter or discoloration prior to administration, whenever solution and container permit.

Please be sure to forward this reminder on stability of Piperacillin and Tazobactam for Injection, Pharmacy Bulk Package to all Healthcare Professionals responsible for administration of the drug following reconstitution.

For more information, refer to the accompanying full prescribing information for Piperacillin and Tazobactam for Injection, Pharmacy Bulk Package. You may also visit our website at www.apotexcorp.com.

Sincerely,

Ellen Gettenberg
Director, Marketing
Apotex Corp.

Attachment