Piperacillin and Tazobactam for Injection, USP

**PHARMACY BULK PACKAGE NOT FOR DIRECT INFUSION**

**RECONSTITUTED SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION**

To effect the development of drug-resistant bacteria and maintain the effectiveness of Piperacillin and Tazobactam for Injection, USP and other antibiotic drugs, Piperacillin and Tazobactam for Injection should be used only to treat infections that have been proven or strongly suspected to be caused by bacteria.

**DESCRIPTION**

The PHARMACY BULK PACKAGE BOTTLE is a container of sterile preparation which contains many large pyrogen-free vials. Each vial contains Piperacillin sodium and Tazobactam sodium and is intended for use in the preparation of admixtures and is not for injection in its own right.

Piperacillin and Tazobactam for Injection, USP is an inactivated antimicrobial combination, product con-

134 (14)

242 (12)

<0.5

2.6 (30)

17.1 (23)

-27 – 36

6.9 (29)
<br />

<0.5

28x218

3.375 g

Piperacillin and tazobactam pharmacokinetics were studied in pediatric patients 2 months of age and older. Each Piperacillin and Tazobactam for Injection USP, 40.5 g pharmacy bulk package bottle contains 38 grams of piperacillin and tazobactam solution equivalent as 4.5 g of piperacillin and 0.5 g of tazobactam in the combination product.

**CLINICAL PHARMACOLOGY**

**Adults**

Piperacillin and Tazobactam for Injection USP, 40.5 g pharmacy bulk package bottle contains 38 grams of piperacillin and tazobactam solution equivalent as 4.5 g of piperacillin and 0.5 g of tazobactam in the combination product.

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be drug-related were: diarrhea (17.6%), fever (2.7%), vomiting (2.7%), urinary tract infection (2.7%),

abdom en enlarged (1.4%), headache (1.4%), constipation (1.4%), liver function tests abnormal (1.4%),

thrombocythemia (1.4%), excoriations (1.4%), and sweating (1.4%).

Studies of Piperacillin and Tazobactam for injection in pediatric patients showed a similar safety profile as that described for adults.

Piperacillin therapy has been associated with an increased incidence of fever and rash in children.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov.

OVERDOSAGE

There have been postmarketing reports concerning the use of Piperacillin and Tazobactam. The majority of these events involved patients with renal impairment. Overdosage of Piperacillin and Tazobactam associated with nausea, vomiting, and diarrhea. Piperacillin and Tazobactam are not removed by peritoneal dialysis or hemodialysis.

ADVERSE EVENTS FROM CLINICAL TRIAL

During two 6-month, phase 3 trials in patients with nosocomial pneumonia, the most common adverse events were diarrhea, nausea, vomiting, abdominal pain, and headache. Piperacillin and Tazobactam were generally well tolerated, with no unusual adverse events noted.

ADVERSE EVENTS FROM CLINICAL TRIAL

In phase III trials, the most common adverse events reported by patients receiving Piperacillin and Tazobactam were diarrhea, nausea, vomiting, abdominal pain, and headache. Piperacillin and Tazobactam were generally well tolerated, with no unusual adverse events noted.

ADVERSE EVENTS FROM CLINICAL TRIAL

In a Phase II study, the most common adverse events reported by patients receiving Piperacillin and Tazobactam were diarrhea, nausea, vomiting, abdominal pain, and headache. Piperacillin and Tazobactam were generally well tolerated, with no unusual adverse events noted.

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