PRESCRIBING INFORMATION

TAZIMAX® (piperacillin and tazobactam) for injection, for intravenous use

TAZIMAX® (piperacillin and tazobactam) injection, for intravenous use

Initial U.S. approval: 1993

---------- **INDICATIONS AND USAGE**----------

TAZIMAX is a combination penicillin-class antibacterial and β-lactamase inhibitor indicated for treatment of:

• Intra-abdominal infections (1.1)

• Skin and skin structure infections (1.2)

• Female pelvic infections (1.3)

• Community-acquired pneumonia (1.4)

• Nosocomial pneumonia (1.5)

• Usage (1.6)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of TAZIMAX and other antibacterial drugs, TAZIMAX should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.(1.6)

---------- **DOSAGE AND ADMINISTRATION** ----------

• The usual daily dose of TAZIMAX for adults is 3.375 g every six hours totaling 13.5 g (12.0 g piperacillin/1.5 g tazobactam). (2.1)

• Initial presumptive treatment of patients with nosocomial pneumonia should start with TAZIMAX at a dosage of 4.5 g every six hours plus an aminoglycoside, totaling 18.0 g (16.0 g piperacillin/2.0 g tazobactam). (2.2)

• Dosage in patients with renal impairment (≤40 mL/min of CRCL) and dialysis patients should be reduced, based on the degree of actual renal function impairment. (2.3)

• For children with appendicitis and/or peritonitis the recommended TAZIMAX dosage is 100 mg piperacillin/12.5 mg tazobactam per kilogram of body weight, every 8 hours in pediatric patients 9 months of age and older. For pediatric patients 2 to 9 months of age, the recommended dosage is 80 mg piperacillin/10 mg tazobactam per kilogram of body weight, every 8 hours.(2.4)

• TAZIMAX and aminoglycosides should be reconstituted, diluted, and administered separately. Co-administration via Y-site can be done under certain conditions. (2.7)

---------- **DOSAGE FORMS AND STRENGTHS**----------

• TAZIMAX® for Injection: 2.25 g, 3.375 g, and 4.5 g lyophilized powder for reconstitution in single-dose vials and 40.5 g lyophilized powder for reconstitution in pharmacy bulk vials. (3)

• TAZIMAX® Injection: 2.25 g in 50 mL, 3.375 g in 50 mL, and 4.5 g in 100 mL frozen solution in single-dose GALAXY containers.(3, 16)

---------- **CONTRAINDICATIONS** ----------

Patients with a history of allergic reactions to any of the penicillins, cephalosporins, or β-lactamase inhibitors. (4)

----------**WARNINGS AND PRECAUTIONS** ----------

• Serious hypersensitivity reactions (anaphylactic/anaphylactoid) reactionshave been reported in patients receiving TAZIMAX. Discontinue TAZIMAX if a reaction occurs. (5.1)

• TAZIMAX may cause severe cutaneous adverse reactions, such as StevensJohnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis (5.2). Discontinue TAZIMAX for progressive rashes.

• Hematological effects (including bleeding, leukopenia and neutropenia) have occurred. Monitor hematologic tests during prolonged therapy. (5.3)

• Nephrotoxicity in critically ill patients has been observed; the use of TAZIMAX was found to be an independent risk factor for renal failure and was associated with delayed recovery of renal function as compared to other beta-lactam antibacterial drugs in a randomized, multicenter, controlled trial in critically ill patients. Based on this study, alternative treatment options should be considered in the critically ill population. If alternative treatment options are inadequate or unavailable, monitor renal function during treatment with TAZIMAX. (5.5)

• Clostridium difficile associated diarrhea: evaluate patients if diarrhea occurs. (5.7)

---------- **ADVERSE REACTIONS**----------

The most common adverse reactions (incidence >5%) are diarrhea, constipation, nausea, headache and insomnia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- **DRUG INTERACTIONS** ----------

• TAZIMAX administration can significantly reduce tobramycin concentrations in hemodialysis patients. Monitor tobramycin concentrations in these patients. (7.1)

• Probenecid prolongs the half-lives of piperacillin and tazobactam and should not be co-administered with TAZIMAX unless the benefit outweighs the risk. (7.2)

• Co-administration of TAZIMAX with vancomycin may increase the incidence of acute kidney injury. Monitor kidney function in patients receiving TAZIMAX and vancomycin. (7.3)

• Monitor coagulation parameters in patients receiving TAZIMAX and heparin or oral anticoagulants. (7.4) • TAZIMAX may prolong the neuromuscular blockade of vecuronium and other non-depolarizing muscle relaxants. Monitor for adverse reactions related to neuromuscular blockade (7.5)

----------**USE IN SPECIFIC POPULATIONS** ----------

Dosage in patients with renal impairment (≤40 mL/min of CRCL) should be reduced to the degree of actual renal function impairment. (2.3, 8.6) Revised: 5/2019