

Tazobactam Cas No. : 89786-04-9

Treatment of moderate to severe infections caused by -resistant /tazobactam-susceptible, β -lactamase producing strains of microorganisms in the following conditions: appendicitis (complicated by rupture or abscess); uncomplicated and complicated skin and skin structure infections; postpartum endometritis or pelvic inflammatory disease; community-acquired pneumonia (moderate severity only); nosocomial pneumonia (moderate to severe).

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Tazobactam

CAS No. : 89786-04-9

**Systematic (IUPAC) name**

(2S,3S,5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid 4,4-dioxide

Identifiers

CAS number 89786-04-9

ATC code J01CG02

PubChem ?

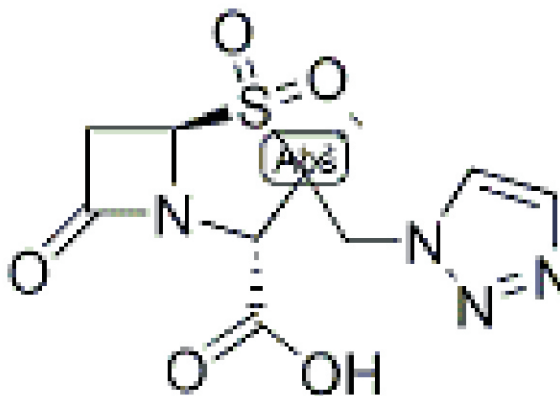
DrugBank EXPT03012

Chemical dataFormula C₁₀H₁₂N₄O₅S

Mol. mass 300.289 g/mol

Molecular Formula C₁₀H₁₁N₄NaO₅S

Molecular Weight 322.27

**Indications and Usage**

Treatment of moderate to severe infections caused by -resistant /tazobactam-susceptible, β -lactamase producing strains of microorganisms in the following conditions: appendicitis (complicated by rupture or abscess); uncomplicated and complicated skin and skin structure infections; postpartum endometritis or pelvic inflammatory disease; community-acquired pneumonia (moderate severity only); nosocomial pneumonia (moderate to severe).

Dosage and Administration

Administer by IV infusion over 30 min.

Nosocomial Pneumonia

Adults

IV Start with 4.5 g every 6 h plus an aminoglycoside (administered separately) for 7 to 14 days.

Healthy Renal Function (CrCl 90 mL/min or more)

Adults

IV 3.375 g every 6 h totaling 13.5 g (12 g/tazobactam 1.5 g) for 7 to 10 days.

Children 2 mo of age and older

IV 80 mg/tazobactam 10 mg per kg every 8 h. Children weighing more than 40 kg with healthy renal function should receive the adult dose.

Children with appendicitis and/or peritonitis 2 mo of age and older



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IV Children between 2 and 9 mo of age – 80 mg/tazobactam 10 mg per kg every 8 h. Children 9 mo of age and older weighing up to 40 kg – 100 mg/tazobactam 12.5 mg per kg every 8 h. Children weighing more than 40 kg –

Administer the adult dose.

Renal Function Impairment

Adults

IV CrCl greater than 40 mL/min – 3.375 g every 6 h (all indications), and 4.5 g every 6 h (nosocomial pneumonia). CrCl 20 to 40 mL/min – 2.25 g every 6 h (all indications), and 3.375 g every 6 h (nosocomial pneumonia). CrCl less than 20 mL/min – 2.25 g every 8 h (all indications), and 2.25 g every 6 h (nosocomial pneumonia). There are no dosage recommendations for children with renal function impairment.

Hemodialysis

Adults

IV Max dosage 2.25 g every 8 h for nosocomial pneumonia and every 12 h for other indications plus one additional dose of 0.75 g following each dialysis period.

Continuous Ambulatory Peritoneal Dialysis (CAPD)

Adults

IV 2.25 g every 8 h for nosocomial pneumonia and every 12 h for other indications.

Drug Interactions

Aminoglycosides

May form microbiologically inactive complexes and should not be mixed in the same container.

Anticoagulants/Heparin

Frequently monitor coagulation parameters.

Methotrexate

May reduce Cl of methotrexate.

Probenecid

Increases and prolongs $t_{1/2}$ of penicillin levels.

Vecuronium

Neuromuscular blockade may be prolonged.

Incompatibility

Ringer's lactate solution.

Patient Information





* Advise patient or caregiver that medication will be prepared by health care provider and administered in a health care setting.

* Review dosing schedule and prescribed length of therapy with patient. Advise patient that dose, dosing frequency, and duration of therapy are dependent on site of infection, severity of infection, and response to treatment.

* Advise patient or caregiver to immediately inform health care provider if injection-site pain or redness, skin rash, hives, itching, or shortness of breath occur during treatment.

* Advise patient or caregiver to report the following signs of superinfection to health care provider: black "furry" tongue, foul-smelling stools, vaginal itching or discharge, white patches in mouth.

* Warn patient or caregiver that diarrhea containing blood or pus may be a sign of a serious disorder and, if noted after discharge, to seek medical care and not treat at home.



Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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