711

TAZPEN

4.5 g

PRODUCT DESCRIPTION:

White to off-white sterile, lyophilised powder of piperacillin and tazobactam as the sodium salts filled into glass vials. After reconstitution, the solution should be clear, colourless to pale yellow, free from visible particles.

COMPOSITION:

Each 4.5 g vial contains: Sterile mixture of Piperacillin sodium and Tazobactam sodium equivalent to Piperacillin 4.0 g and Tazobactam 0.50 g. It contains no excipients or preservatives.

PHARMACOLOGY:

Piperacillin, a broad spectrum, semisynthetic penicillin active against many Gram-positive and Gram-negative aerobic and anaerobic bacteria, exerts bactericidal activity by inhibition of both septum and cell wall synthesis. Tazobactam, a triazolylmethyl penicillanic acid sulfone, is a potent inhibitor of many ß -lactamases, including the plasmid and chromosomally mediated enzymes that commonly cause resistance to penicillins. The presence of tazobactam in the TAZPEN formulation enhances and extends the antibiotic spectrum of piperacillin to include many ß -lactamase producing bacteria normally resistant to it. Thus, TAZPEN combines the properties of a broad-spectrum antibiotic and a ß -lactamase inhibitor.

Microbiology: Piperacillin and Tazobactam is active against most strains of the following ß -lactamase producing and non ß -lactamase producing microorganisms:

Gram-negative bacteria: *Escherichia coli, Citrobacter sp., Enterobacter sp.* (including *E. cloacae*), *Serratia sp.* (including *S. marcescens*), *Pseudomonas aeruginosa* and other *Pseudomonas sp., Neisseria gonorrhoeae, Neisseria meningitidis, Moraxella catarrhalis, Acinetobacter sp., Haemophilus influenza, Shigella sp., Campylobacter sp.*

Gram-positive bacteria: Streptococci *(S. pneumoniae, S. pyogenes, S. agalactiae, S. viridans),* Enterococci *(E. faecalis), Staphylococcus aureus (not methicillin-resistant S. aureus), S. epidermidis* (coagulase-negative staphylococci).

Anaerobic bacteria: *Bacteroides spp. including Bacteroides fragilis* group, *Peptostreptococcus spp., Fusobacterium spp., Eubacterium* group, *Clostridia spp., Veillonella spp.*

PHARMACOKINETICS:

Absorption:
Peak plasma concentrations of piperacillin sodium and tazobactam sodium are attained immediately after completion of an intravenous infusion.

Distribution:
Piperacillin and tazobactam are widely distributed into tissues and body fluids including intestinal mucosa, gallbladder, lung, female reproductive tissues (uterus, ovary, and fallopian tube), interstitial fluid and bile. Both piperacillin and tazobactam are approximately 30% bound to plasma proteins in adults.

Distribution of piperacillin and tazobactam into cerebrospinal fluid is low in adult subjects with non-inflamed meninges, as with other penicillins.

Both Piperacillin and Tazobactam cross the placenta. Piperacillin is distributed into milk. It is not known whether tazobactam is distributed into milk.

Elimination:
Piperacillin is metabolized to a minor microbiologically active desethyl metabolite. Tazobactam is metabolized to a single metabolite that lacks pharmacological and antibacterial activities. Both piperacillin and tazobactam are eliminated via the kidney by glomerular filtration and tubular secretion.

Piperacillin is excreted rapidly as unchanged drug with 68% of the administered dose excreted in the urine. Tazobactam and its metabolite are eliminated primarily by renal excretion with 80% of the administered dose excreted as unchanged drug.

In adults, the plasma half-life of piperacillin and of tazobactam ranged from 0.7 to 1.2 hours.

Impaired liver function: The half-life of piperacillin and of tazobactam increases by approximately 25% and 18%, respectively, in patients with hepatic cirrhosis compared to healthy subjects.

Impaired renal function: The half-lives of piperacillin and of tazobactam increase with decreasing creatinine clearance. In adults with creatinine clearance below 20 mL/min, the increase in half-life is two-fold for piperacillin and four-fold for tazobactam compared to subjects with normal renal function.

Children: Piperacillin and tazobactam pharmacokinetics were studied in paediatric patients 2– 9 months of age. The clearance of both compounds is slower in the younger patients compared to older children and adults.

INDICATIONS:

TAZPEN is indicated for the treatment of systemic and/or local bacterial infections caused by susceptible organisms (detected/suspected) in the conditions listed below:

1. Lower respiratory tract infections
2. Urinary tract infections (complicated and uncomplicated)
3. Intra-abdominal infections
4. Skin and skin structure infections
5. Bacterial septicaemia
6. Polymicrobic infections including those where aerobic and anaerobic organisms are suspected (intra-abdominal, skin and skin structure, lower respiratory tract)
7. Bacteria infections in neutropenic adults or children (in combination with an aminoglycoside).

Antimicrobial therapy should be adjusted, if appropriate, once the results of culture(s) and antimicrobial susceptibility testing are known.

DOSAGE AND ADMINISTRATION

Piperacillin/tazobactam must be given by slow intravenous infusion (e.g. over 20-30 minutes) or slow intravenous injection (over at least 3-5 minutes).

Duration of Therapy
The duration of therapy should be guided by the severity of the infection and the patient's clinical and bacteriological progress.

Dosage
Neutropenic patients with signs of infection (e.g. fever) should receive immediate empirical antibiotic therapy before laboratory results are available.

Adults and Children Aged 12 Years and Older:
In general, the recommended total daily dosage is 12 g of piperacillin/1.5 g of tazobactam given in divided doses every 8 hours. The total daily dose depends on the severity and localization of the infection and can vary from 2.25 g to 4.5 g piperacillin/tazobactam administered every 6 or 8 hours.

For bacterial infections in neutropenic patients, the recommended dose is 4 g piperacillin/0.5 g tazobactam administered every 6 hours in combination with an aminoglycoside.

Pediatric Neutropenia:
<50 kg: For children with normal renal function and weighing less than 50 kg, the dose should be adjusted to 80 mg of piperacillin/10 mg of tazobactam per kilogram of body weight every 6 hours, in combination with the appropriate dose of an aminoglycoside.

>50 kg: For children weighing over 50 kg, follow the adult dosing, in combination with the appropriate dose of an aminoglycoside.

Children under the Age of 12 Years:
The following table summarises the treatment frequency and the dose per body weight for children under 12 years of age by indication or condition:

Dose per weight and treatment frequency	Indication/condition
80 mg Piperacillin/10 mg Tazobactam per kg body weight/ every 6 hours (in combination with an aminoglycoside)	Neutropenic children with fever suspected to be due to bacterial infections*

* Not to exceed the maximum 4 g/0.5 g per dose over 30 minutes.

Until further experience is available, piperacillin/tazobactam should not be used in children who do not have neutropenia.

Elderly:
No dose adjustment is required for the elderly with normal renal function or creatinine clearance values above 40 mL/min.

Use in Patients with Renal Impairment
The intravenous dose should be adjusted to the degree of actual renal impairment as follows (each patient must be monitored closely for signs of substance toxicity; medicinal product dose and interval should be adjusted accordingly):

Adults and Children 12 Years and Older:

Creatinine clearance (mL/min)	Piperacillin/tazobactam (recommended dose)
>40	No dose adjustment necessary
20-40	Maximum dose suggested: 4 g/0.5 g every 8 hours
<20	Maximum dose suggested: 4 g/0.5 g every 12 hours

For patients on hemodialysis, one additional dose of piperacillin/tazobactam 2 g/0.25 g should be administered following each dialysis period, because haemodialysis removes 30%-50% of piperacillin in 4 hours.

Children under the Age of 12 Years: Creatinine clearance (mL/min)	Piperacillin/tazobactam (recommended dose)
>50	No dose adjustment needed.
≤50	70 mg piperacillin/8.75 mg tazobactam/kg every 8 hours.

For children on haemodialysis, one additional dose of 40 mg piperacillin/5 mg tazobactam/kg should be administered following each dialysis period.

The pharmacokinetics of piperacillin/tazobactam have not been studied in pediatric patients with renal impairment. Each patient must be monitored closely for signs of drug toxicity. Drug dose and interval dose should be adjusted accordingly. In patients with renal insufficiency or hemodialysis patients, intravenous dosages and administration intervals should be adjusted to the degree of renal function impairment.

Use in Children Aged Below 2 Years
The safety and efficacy of piperacillin/tazobactam in children 0 - 2 years of age has not been established.

No data from controlled clinical studies are available.

Use in Patients with Hepatic Impairment
No dosage adjustment is necessary in patients with hepatic impairment.

Co-administration of Piperacillin/Tazobactam with Aminoglycosides
Due to the *in vitro* inactivation of the aminoglycoside by β-lactam antibiotics, piperacillin/tazobactam and the aminoglycoside are recommended for separate administration. Piperacillin/tazobactam and the aminoglycoside should be reconstituted and diluted separately when concomitant therapy with aminoglycosides is indicated (see Section **Incompatibilities**).

In circumstances where co-administration is preferred, piperacillin/tazobactam containing EDTA supplied in vials is compatible for simultaneous co-administration via Y-site infusion only with the following aminoglycosides under the following conditions:

Aminoglycoside	Piperacillin/ tazobactam dose (g)	Piperacillin/ tazobactam Diluent Volume (mL)	Aminoglycoside Concentration Range‡ (mg/mL)	Acceptable Diluents
Amikacin	4.5	150	1.75–7.5	0.9% sodium chloride or 5% dextrose
Gentamicin	4.5	150	0.7–3.32	0.9% sodium chloride or 5% dextrose

‡The dose of aminoglycoside should be based on patient weight, status of infection (serious or life-threatening) and renal function (creatinine clearance).

Compatibility of piperacillin/tazobactam with other aminoglycosides has not been established. Only the concentration and diluents for amikacin and gentamicin with the dosages of piperacillin/tazobactam listed in the table above have been established as compatible for co-administration via Y-site infusion. Simultaneous co-administration via Y-site infusion in any manner other than listed above may result in inactivation of the aminoglycoside by piperacillin/tazobactam.

Geriatric Population
Patients over 65 years are not at an increased risk of developing adverse effects solely because of age. However, dosage should be adjusted in the presence of renal insufficiency.

Administration: TAZPEN may be given by slow intravenous injection (3-5 minutes) or by infusion (20-30 minutes).

Directions for Reconstitution and Dilution: Diluents for reconstitution:

- 0.9% (9 mg/ml) sodium chloride solution for injection
- Sterile water for injections
- Dextrose 5%

IV injection: Reconstitute each vial with the volume of diluent shown in the table below, using one of the above diluents. Shake until dissolved.

Vial Size (piperacillin/tazobactam)	Minimum volume of diluent to be added to vial
4.50 g (4 g/0.5 g)	20 mL

IV infusion: Reconstitute each vial with at least 20 mL using one of the reconstitution diluents above. Shake until dissolved. The reconstituted solution may be further diluted (recommended volume per dose of 50-150 mL) with a compatible IV solution listed as follows: 0.9% Sodium Chloride for Injection; Dextrose 5%.

Administer by infusion over a period of at least 30 min. During the infusion, it is desirable to discontinue the primary infusion solution.

Note:* Maximum recommended volume per dose of Sterile Water for Injection is 50 mL.

ADVERSE REACTIONS

Table 1. Adverse Drug Reactions (ADRs) by System Organ Class and Council for International Organizations of Medical Science (CIOMS) Frequency Category Listed in Order of Decreasing Medical Seriousness or Clinical Importance Within Each Frequency Category and SOC.

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Frequency not known (cannot be estimated from available data)
Infections and infestations		Candida infection*		Pseudo-membranous colitis	
Blood and Lymphatic system disorders		Thrombocytopenia, anaemia*	Leukopenia	Agranulocytosis	Pancytopenia*, neutropenia, haemolytic anaemia*, thrombocytosis*, eosinophilia*
Immune system disorders					Anaphylactoid shock*, anaphylactic shock*, anaphylactoid reaction*, anaphylactic reaction*, hypersensitivity*
Metabolism and nutrition disorders			Hypokalaemia		
Psychiatric disorders		Insomnia			Delirium*
Nervous system disorders		Headache	Seizure*		
Vascular disorders			Hypotension, phlebitis, thrombophlebitis, flushing		
Respiratory, thoracic and mediastinal disorders				Epistaxis	Eosinophilic pneumonia*
Gastrointestinal disorders	Diarrhoea	Abdominal pain, vomiting, constipation, nausea, dyspepsia		Stomatitis	
Hepatobiliary disorders					Hepatitis*, jaundice

FRONT SIDE

Product	**TAZPEN - Piperacillin & Tazobactam for Injection 4.5 g**		
Buyer/Country	Mylan / Malaysia	Component	Pack Insert
Dimension	**420 mm X 200 mm**	Pack	--
New Item Code	**50107133 (1200013576)**	Old Item Code	1035036 (1200007851)
Colour Shades	Black	No. of Colours	1

Change Control No.	PR# 3958585
Design/Style	Front & Back Printing. To be supplied in folded size of 55 X 40 mm. Brand name facing front side.
Substrate	40/45 GSM Paper.
Special Instructions	Printing clarity to be clear & sharp.
Autocartonator Requirements	NA

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

Skin and subcutaneous tissue disorders		Rash, pruritus	Erythema multiforme*, urticaria, rash maculo-papular*	Toxic epidermal necrolysis*	Stevens-Johnson syndrome*, dermatitis exfoliative, drug reaction with eosinophilia and systemic symptoms (DRESS)*, acute generalised exanthematous pustulosis (AGEP)*, dermatitis bullous, purpura
Musculoskeletal and connective tissue disorders			Arthralgia, myalgia		
Renal and urinary disorders					Renal failure, tubulointerstitial nephritis*
General disorders and administration site conditions		Pyrexia, injection site reaction	Chills		
Investigations		Alanine aminotransferase increased, aspartate aminotransferase increased, protein total decreased, blood albumin decreased, Coombs direct test positive, blood creatinine increased, blood alkaline phosphatase increased, blood urea increased, activated partial thromboplastin time prolonged	Blood glucose decreased, blood bilirubin increased, prothrombin time prolonged		Bleeding time prolonged, gamma-glutamyltransferase increased

*Adverse Drug Reaction (ADR) identified post marketing

Piperacillin therapy has been associated with an increased incidence of fever and rash in cystic fibrosis patients.

SIDE EFFECTS:

Rarely the significant leukopenia may be associated with prolonged therapy. Very rarely, interstitial nephritis may occur. Hepatitis and cholestatic jaundice have been reported with some penicillins and beta-lactamase inhibitors. In common with other beta-lactam antibiotics, hemolytic anemia has been reported rarely with piperacillin and piperacillin/tazobactam. Many of the patients treated in clinical trials were severely ill and had multiple underlying disease and physiological impairments, making it difficult to determine causal relationship of adverse experiences to therapy with piperacillin and tazobactam.

SPECIAL WARNINGS AND PRECAUTIONS

Serious and occasionally fatal hypersensitivity reactions including anaphylactoid and severe cutaneous adverse reactions have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with piperacillin/tazobactam, careful inquiry should be made concerning previous hypersensitivity reactions to penicillin, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, piperacillin/tazobactam must be discontinued immediately and appropriate alternative therapy instituted. Not to be used in patients with known hypersensitivity to penicillin.

Piperacillin/tazobactam may cause severe cutaneous adverse reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (see Section **Adverse Reactions**). If patients develop a skin rash, they should be monitored closely and piperacillin/tazobactam discontinued if lesions progress.

Rare cases of haemophagocytic lymphohistiocytosis (HLH) have been observed following therapy (>10 days) with piperacillin tazobactam, often as a complication of DRESS. HLH is a pathologic immune activation which leads to excessive systemic inflammation and can be life threatening and early diagnosis and rapid initiation of immunosuppressive therapy is essential. Characteristic signs and symptoms include fever, hepatosplenomegaly, cytopenias, hyperferritinaemia, hypertriglyceridaemia, hypofibrinogenaemia, and haemophagocytosis. If piperacillin tazobactam is suspected as possible trigger, treatment should be discontinued.

Antibiotic-induced pseudomembranous colitis may manifest as severe, persistent diarrhea which may be life-threatening. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment.

Bleeding manifestations have occurred in some patients receiving β-lactam antibiotics. These reactions sometimes have been associated with abnormalities of coagulation tests such as clotting time, platelet aggregation and prothrombin time, and are more likely to occur in patients with renal failure (see Section **Drug Interactions)**. If bleeding manifestations occur, the antibiotic should be discontinued and appropriate therapy instituted.

This product contains 2.84 mEq (65 mg) of sodium per gram of piperacillin which may increase a patient's overall sodium intake. Hypokalemia may occur in patients with low potassium reserves or in those who are receiving concomitant medications that may lower potassium levels; periodic electrolyte determinations may be advisable in such patients.

Leukopenia and neutropenia may occur, especially during prolonged therapy. Therefore, periodic assessment of hematopoietic function should be performed.

As with treatment with other penicillins, neurological complications in the form of convulsions (seizures) may occur when high doses are administered, especially in patients with impaired renal function (see Section **Adverse Reactions).**

As with other antibiotic preparations, use of this drug may result in overgrowth of non-susceptible organisms, including fungi. Patients should be carefully monitored during therapy. If superinfection occurs, appropriate measures should be taken.

Use in Patients with Hepatic Impairment
See Section **Dosage and Administration.**

Renal Impairment
Due to its potential nephrotoxicity (see Section **Adverse Reactions**), piperacillin/tazobactam should be used with care in patients with renal impairment or in hemodialysis patients. Intravenous dosages and administration intervals should be adjusted to the degree of renal function impairment **(**see Section **Dosage and Administration).**

In a secondary analysis using data from a large multicenter, randomized-controlled trial when glomerular filtration rate (GFR) was examined after administration of frequently used antibiotics in critically ill patients, the use of piperacillin/tazobactam was associated with a lower rate of reversible GFR improvement compared with the other antibiotics. This secondary analysis concluded that piperacillin/tazobactam was a cause of delayed renal recovery in these patients.

Combined use of piperacillin/tazobactam and vancomycin may be associated with an increased incidence of acute kidney injury **(**see Section **Drug Interactions).**

USE IN PREGNANCY AND LACTATION:

Studies in mice and rats have not demonstrated any embryotoxic or teratogenic effects of the piperacillin-tazobactam combination. There are no adequate and well-controlled studies with the piperacillin-tazobactam combination or with piperacillin or tazobactam alone in pregnant women. Piperacillin and tazobactam cross the placenta. Pregnant women should be treated only if the expected benefit outweighs the possible risks to the pregnant woman and fetus.

Piperacillin is excreted in low concentrations in human milk; tazobactam concentrations in human milk have not been studied. Women who are breastfeeding should be treated only if the expected benefit outweighs the possible risks to the woman and child.

CONTRAINDICATIONS:

The use of TAZPEN is contraindicated in patients with a history of allergic reactions to any of the penicillins and/or cephalosporins or ß-lactamase inhibitors.

DRUG INTERACTIONS:

Probenecid: Concurrent administration of probenecid and Piperacillin/Tazobactam produced a longer half-life and lower renal clearance for both piperacillin and tazobactam. However, peak plasma concentrations of neither drug are affected.

Vancomycin: No pharmacokinetic interaction is found between TAZPEN and vancomycin.

Aminoglycosides: No interaction is found between TAZPEN and tobramycin. Whenever TAZPEN is used concurrently with another antibiotic, especially an aminoglycoside, the drug must not be mixed in intravenous solutions or administered concurrently due to physical incompatibility.

The inactivation of aminoglycosides in the presence of penicillin class drugs has been recognised. It has been postulated that penicillin-aminoglycoside complexes form; these complexes are microbiologically inactive and of unknown toxicity. Hence whenever TAZPEN is used concurrently with another antibiotic, especially an aminoglycoside, the drug must not be mixed in IV solutions or administered concurrently due to physical incompatibility.

Heparin: Coagulation parameters should be tested more frequently and monitored regularly during simultaneous administration of high doses of heparin, oral anticoagulants, or other drugs that may affect the blood coagulation system and/or the thrombocyte function.

Vecuronium: Piperacillin when used concomitantly with vecuronium has been implicated in the prolongation of the neuromuscular blockade of vecuronium. TAZPEN could produce the same phenomenon if given along with vecuronium. Due to their similar mechanism of action, it is expected that the neuromuscular blockade produced by any of the non-depolarising muscle relaxants could be prolonged in the presence of piperacillin. Caution is indicated when piperacillin is used perioperatively with vecuronium and similar neuromuscular-blocking agents.

Methotrexate: Limited data suggests that co-administration of methotrexate and piperacillin may reduce the clearance of methotrexate due to competition for renal secretion. If concurrent therapy is necessary, serum concentrations of methotrexate as well as the signs and symptoms of methotrexate toxicity should be frequently monitored.

Effects on laboratory tests: As with other penicillins, the administration of piperacillin/tazobactam may result in a false-positive reaction for glucose in the urine using a copper-reduction method. It is recommended that glucose tests based on enzymatic glucose oxidase reactions be used.

Incompatibilities
Whenever TAZPEN is used concurrently with another antibiotic, the drug must be administered separately. The mixing of TAZPEN with an aminoglycoside *in vitro* can result in substantial inactivation of the aminoglycoside.

Because of chemical instability, TAZPEN should not be used in solutions containing only sodium bicarbonate.

TAZPEN should not be mixed with other drugs in a syringe or infusion bottle since compatibility has not been established.

OVERDOSE AND TREATMENT:

There have been post-marketing reports of overdose with piperacillin and tazobactam. The majority of those events experienced including nausea, vomiting, and diarrhea have also been reported with the usual recommended dosages. Patients may experience neuromuscular excitability or convulsions if higher than recommended doses are given intravenously (particularly in the presence of renal failure).

Treatment should be supportive and symptomatic according to the patient's clinical presentation. Excessive serum concentrations of either piperacillin-tazobactam may be reduced by haemodialysis. In case of severe, anaphylactic reactions, the usual counter measures are to be initiated.

AVAILABILITY:

4.5 g: One vial packed in a carton / Ten vials packed in a carton

STORAGE:

Store below 30°C. Protect from light. Keep out of reach of children.

Reconstituted solution should be used immediately. Discard any unused portion after 24 hours if stored at room temperature (15-30°C), or after 48 hours if stored at refrigerated temperature (2-8°C). Vials should not be frozen after reconstitution.

The reconstituted solution may be further diluted with one of the recommended compatible solvents at the suggested dilution volume (see section Directions for Reconstitution and Dilution) and should be used immediately. From a microbiological point of view, the reconstituted and diluted solutions should be used immediately.

Reconstitution Instructions:
Use disposable 21G needle size (0.8 mm hypodermic needle) for reconstitution of the product. Pierce the needle beveled edge facing upwards into the rubber stopper, where needle should be perpendicular to the rubber stopper and in the concave portion of the rubber stopper.

For further information, please consult your physician or pharmacist.

Date of Revision: November, 2025

Mylan

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Bangalore – 560076, India.

Importer and Product Registration Holder in Malaysia:
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BACK SIDE

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