Summary of Product Characteristics

TAZPEN
Piperacillin & Tazobactam for Injection
4.5 g

1. NAME OF THE MEDICINAL PRODUCT

TAZPEN

1.2 Strength

Strength – 4.5 g

1.3 Pharmaceutical Form and Pack sizes

Form – Lyophilized for Injection

Pack size:
1 vial in a carton
10 vials in a carton

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains: Sterile mixture of Piperacillin Sodium USP equivalent to Piperacillin 4 g and Tazobactam Sodium equivalent to Tazobactam 500 mg.

3. PHARMACEUTICAL FORM

Lyophilized for Injection. Clear and colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is indicated in the following:
1. Urinary tract infections
2. Respiratory tract infections
3. Abdominal infections
4. Septicemia
5. Infections in immunocompromised patients
6. Meningitis
7. Bone and joint infections
8. Uncomplicated gonorrheal infections
9. Infections in pediatric patients.

4.2 Posology and method of administration

Piperacillin and Tazobactam should be administered by intravenous infusion over 30 minutes Normal Renal Function (Creatinine Clearance >/=90 mL/min).

The usual total dose of Piperacillin and Tazobactam for adults is 3.375 g every six hours totaling 13.5 g (12 g piperacillin sodium/1.5 g tazobactam sodium).

Initial presumptive treatment of patients with nosocomial pneumonia should start with Piperacillin and Tazobactam at a dosage of 3.375 g every four hours plus an aminoglycoside. Treatment with the aminoglycoside should be continued in patients from whom Pseudomonas aeruginosa is

isolated. If Pseudomonas aeruginosa is not isolated, the aminoglycoside may be discontinued at the discretion of the treating physician.

Renal Insufficiency
In patients with renal insufficiency (Creatinine Clearance <90 mL/min), the intravenous dose of Piperacillin and Tazobactam should be adjusted to the degree of actual renal function impairment. In patients with nosocomial pneumonia receiving concomitant aminoglycoside therapy, the aminoglycoside dosage should be adjusted.

4.3 Contra-indications
Penicillin hypersensitivity or immediate-type cephalosporin hypersensitivity, Hypersensitivity to b-lactam antibiotics.

Pregnancy and lactation: Piperacillin sodium: It is not yet known whether the drug is safe to use during pregnancy. Small amounts of the drug are secreted in breast milk and it is probably best for mothers taking it to avoid breast-feeding as there is a possibility of sensitizing the infant, though no other adverse effects are likely.

Tazobactam Sodium: No information is available. Tazobactam is therefore contraindicated in pregnancy. No information is available.

Mother taking the drug should not breast-feed their infants.

4.4 Special warnings and precautions for use

Animal studies have shown that piperacillin exhibits the safety typical of all penicillins. Prolonged administration of piperacillin did not demonstrate clinically relevant adverse effects. A transient rise in serum enzymes has been noted in dogs.

No toxic effects on the proximal tubule of the kidney have been demonstrated. No teratological effects were seen in mice following administration of piperacillin before and during pregnancy. A slight decrease in fetal survival rate in rats was noted in association with the administration of three times the maximum recommended adult dose throughout pregnancy.

4.5 Interaction with other medicinal products and other forms of interaction
Probenecid: Concurrent administration of probenecid and piperacillin/ tazobactam prolongs the half-life and lowers the renal clearance for both components of the compound without influencing the peak plasma concentrations. Antibiotics: No interaction is found between tazobactam and either Vancomycin or Tobramycin, but physical incompatibility occurs if piperacillin/ tazobactam is mixed in the same intravenous solution or administered concurrently with an aminoglycoside.

4.6 Effects on ability to drive and use machines

Not Applicable

4.7 Undesirable effects

Body System	Adverse Reaction
Infections and infestations	Candidal superinfection
Blood and lymphatic system disorders	Leucopenia, neutropenia, thrombocytopenia
Immune system disorders	Hypersensitivity reaction

Metabolism and nutritional disorders	Blood albumin decreased, blood glucose decreased, blood protein total decreased, hypokalaemia
Nervous system disorders	Headache, insomnia
Vascular disorders	Hypotension, phlebitis, thrombophlebitis, Flushing
Gastrointestinal disorders	Diarrhoea, nausea, vomiting, Constipation, dyspepsia, jaundice, stomatitis
Hepatobiliary disorders	Alanine aminotransferase increased, aspartate aminotransferase increased
Skin and subcutaneous tissue disorders	Rash including maculopapular rash, Pruritus, urticaria
Musculoskeletal, and connective tissue disorders	Arthralgia, myalgia
Renal and urinary disorders	Blood creatinine increased, Tubulointerstitial nephritis, renal failure
General disorders and administration site conditions	Pyrexia, injection-site reaction, Chills

5. Pharmacological properties

Piperacillin sodium and tazobactam sodium is an injectable antibacterial combination product consisting of the semi-synthetic antibiotic piperacillin sodium and -lactamase inhibitor Tazobactam sodium for intravenous administration. Piperacillin sodium exerts bactericidal activity by inhibiting septum formation and cell wall synthesis. In vitro, piperacillin is active against a variety of gram-positive and gram negative aerobic and anaerobic bacteria. Tazobactam sodium has very little intrinsic microbiologic activity due to its very low level binding to penicillin-binding proteins; however, it is a (beta)-lactamase inhibitor of the Richmond-Sykes class III (Bush class 2b & 2b‘) penicillinases and cephalosporinases. It varies in its ability to inhibit class II and IV (2a & 4) penicillinases. Tazobactam does not induce chromosomally-mediated (beta)-lactamases at tazobactam levels achieved with the recommended dosage regimen.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

None

6.2 Incompatibilities

Not Applicable

6.3 Shelf-life

24 months from the date of manufacture.

6.4 Special precautions for storage

Store below 30°C. Protect from light. Reconstituted solution should be used immediately after constitution. Any remaining portion should be discarded after 24 hours at 20°C to 25°C or 48 hours under refrigeration at 2°C to 8°C.

6.5 Nature and contents of Container

Lyophilized for Injection in a Type I tubular, flint glass vial closed with a bromobutyl rubber stopper and flip off maroon red aluminium seal.

Presentation:
1 vial in a carton
10 vials in a carton

6.6 Instructions for use and disposal and other handling

Reconstituted solution should be used immediately after constitution. Any remaining portion should be discarded after 24 hours at 20°C to 25°C or 48 hours under refrigeration at 2°C to 8°C.

7. REGISTRANT/MARKETING AUTHORIZATION HOLDER

Mylan Laboratories Limited

[Beta Lactam Division]
No. 152/6 & 154/16, Doresanipalya,
Bilekahalli, Bannerghatta Road,
Bangalore - 560 076.

8. NAME AND ADDRESS OF THE MANUFACTURER

Mylan Laboratories Limited
[Beta Lactam Division]
No. 152/6 & 154/16, Doresanipalya,
Bilekahalli, Bannerghatta Road,
Bangalore - 560 076.

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