

Brand Name: TEROMAC 4.5

Composition: Piperacillin Sodium & Tazobactam for injection

Dosage Form: injection

Category: broad-spectrum antibiotic (β -lactam/ β -lactamase inhibitor combination)

Packaging Type: vial +wfi.

PACKAGING: 4.5 gm

Brief Product Introduction:

TEROMAC 4.5 is a powerful combination injectable antibiotic developed by **AstraEureka Pharmaceutical**, a trusted **manufacturer of high-potency injectable compositions**. It combines **Piperacillin**, a broad-spectrum penicillin-class antibacterial, with **Tazobactam**, a β -lactamase inhibitor that extends its spectrum against resistant pathogens. TEROMAC 4.5 is indicated in severe systemic infections caused by susceptible Gram-positive and Gram-negative bacteria, including β -lactamase producing strains.

Composition:

Each vial contains:

- Piperacillin Sodium (Sterile) IP
equivalent to Anhydrous Piperacillin.....4000 mg
- Tazobactam Sodium (Sterile) IP
equivalent to Tazobactam.....500 mg

Key Ingredients:

1. **Piperacillin 4000 mg:** A ureidopenicillin active against a wide range of bacteria including *Pseudomonas aeruginosa*, *Enterobacteriaceae*, and *Streptococci*.
2. **Tazobactam 500 mg:** Inhibits β -lactamase enzymes, preventing the degradation of Piperacillin and restoring its activity against resistant strains.

Key Benefits:

1. Broad-spectrum activity covering Gram-positive, Gram-negative, and anaerobic bacteria
2. Effective against β -lactamase producing organisms
3. Reduces bacterial resistance development when used appropriately
4. Suitable for monotherapy in polymicrobial infections
5. Clinically proven efficacy in critically ill patients

Indications:

1. Lower respiratory tract infections including pneumonia

2. Intra-abdominal infections
3. Skin and soft tissue infections
4. Urinary tract infections
5. Gynecological infections
6. Septicemia
7. Bone and joint infections
8. Hospital-acquired infections including ventilator-associated pneumonia

Directions for Use:

1. Administer only under the supervision of a qualified healthcare professional
2. Reconstitute the vial using sterile diluent before administration
3. Administer via **intravenous route** (IV infusion or IV bolus)
4. Use aseptic techniques to prevent contamination
5. Inspect the solution for particulate matter or discoloration before use

Dosage and Administration:

1. **Recommended Adult Dose:** 4.5 g (Piperacillin 4000 mg + Tazobactam 500 mg) every 6–8 hours
2. **Dose adjustment:** Required in patients with renal impairment
3. **Route of Administration:** Intravenous (IV)
4. Infuse over 20–30 minutes
5. Duration of therapy depends on infection type and clinical response

Safety Information:

1. Use with caution in patients with renal insufficiency; adjust dose accordingly
2. Monitor renal, hepatic, and hematologic function during prolonged therapy
3. Hypersensitivity reactions may occur, especially in penicillin-allergic individuals
4. Prolonged use may lead to superinfection, including fungal overgrowth
5. Not recommended during pregnancy or lactation unless clearly indicated

Mechanism of Action:

- **Piperacillin:** Inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins (PBPs), leading to cell lysis and death.
- **Tazobactam:** Irreversibly inhibits a broad range of β -lactamases produced by resistant bacteria, allowing Piperacillin to remain active against organisms that would otherwise be resistant.
- This synergistic mechanism results in enhanced antibacterial coverage, especially against multidrug-resistant strains.

Contraindications:

1. Known hypersensitivity to penicillins, cephalosporins, or any components of the formulation
2. Severe renal impairment without appropriate dose adjustment
3. History of antibiotic-associated colitis

Side Effects:

1. Common: Nausea, diarrhea, headache, injection site reactions
2. Less Common: Rash, fever, elevated liver enzymes, eosinophilia
3. Rare: Anaphylaxis, seizures (especially in patients with CNS disorders or renal failure), thrombocytopenia, leukopenia

Important Notice:

- TEROMAC 4.5 should be used only under medical supervision
- Not a substitute for oral antibiotics in mild infections
- Complete full course of therapy to prevent resistance
- Reconstituted solution should be used immediately or stored per label guidelines
- Keep out of reach of children

Storage Condition:

1. Store below 25°C in a dry place.
2. Protect from light and moisture.
3. Reconstituted solution should be stored as per stability data and used within recommended time.
4. Do not freeze the reconstituted solution.

Packing Information:

- Supplied in a **4.5 gm sterile vial**.
- Individually w.f.i.packed in a carton with product insert.