

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

# Ceftazidime & Tazobactam for Injection

**TamProCef®**
**1.125 g / 2.25 g**

टेम्प्रोसेफ 1.125 ग्रा / 2.25 ग्रा

Single Dose Vial

For IM/IV Use Only

## Composition :

Each Vial Contains:

 Ceftazidime (Sterile) IP  
 Eq. to Anhydrous Ceftazidime 1000 mg  
 Tazobactam Sodium (Sterile) IP  
 Eq. to Anhydrous Tazobactam 125 mg

## Composition :

Each Vial Contains:

 Ceftazidime (Sterile) IP  
 Eq. to Anhydrous Ceftazidime 2000 mg  
 Tazobactam Sodium (Sterile) IP  
 Eq. to Anhydrous Tazobactam 250 mg

## Description

Ceftazidime is a third-generation cephalosporin antibiotic. Like other third-generation cephalosporins, it has broad spectrum activity against Gram-positive and Gram-negative bacteria. Unlike most third-generation agents, it is active against *Pseudomonas aeruginosa*, however it has weaker activity against Gram-positive microorganisms and is not used for such infections.

## Mechanism of Action

Ceftazidime / Tazobactam improves the patient's condition by performing the following functions:

- Inhibiting the bacterial cell wall synthesis.
- Inhibiting the growth of bacteria.

## Pharmacology

Ceftazidime binds to one or more of the Penicillin-Binding Proteins (PBPs) which inhibits the final transpeptidation step of peptidoglycan synthesis in Bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall Assembly resulting in bacterial cell death.

**Absorption :** Peak plasma concentrations after 1 hr (IM), 5 min (IV bolus).

**Distribution :** Widely distributed in body tissues and fluids; CFS

(Therapeutic concentrations when meninges are inflamed). Crosses the Placenta and enters breast milk.

**Protein-Binding :** 10%

**Excretion :** Mainly by the kidneys via the urine by glomerular filtration (80-90% as unchanged drug within 24 hr); passively excreted in bile but only a small proportion is eliminated. Clearance enhanced in cystic fibrosis: 2 hr

(Elimination half-life), prolonged in neonates and renal impairment.

## Uses :

Ceftazidime / Tazobactam is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Skin and skin structure infections
- Bacterial infections
- Lower respiratory tract infections
- Skin and skin-structure infections
- Urinary tract infections
- Septicemia
- Bone and joint infections

## Dosage in terms of Ceftazidime

- 1 g 8 hourly or 2g 12 hourly severe Infections : 2g 8 Hourly or 3g 12 hourly

## Direction for use :

Dissolve the contents of vial in 10mL sterile water for injections.

For Intravenous

Solutions of ceftazidime-tz in 5% Dextrose and 0.9% Sodium Chloride

Injection are stable for at least 6 hours at room temperature in plastic tubing, drip chambers and volume control devices of common IV infusion sets.

Instructions for reconstitution: See table for addition volumes and solution concentrations, which may be useful when fractional doses are required.

## PREPARATION OF SOLUTION

### INTRAVENOUS

Vial size	Diluent	Amount of Diluent to be added (mL)	Approximate Concentration (mg/mL)	Approximate available volume (mL)	Approximate displacement volume (mL)
1g	Water for injection	10mL	95	10.9mL	0.9mL

Ceftazidime may be reconstituted for intramuscular use with 0.5% or 1% Lidocaine Hydrochloride. INTRAMUSCULAR

Vial size	Diluent	Amount of Diluent to be added (mL)	Approximate Concentration (mg/mL)	Approximate available volume (mL)	Approximate displacement volume (mL)
1g	0.5% lidocaine	3mL	260	3.6mL	0.6mL
1g	1% lidocaine	3mL	260	3.7mL	0.7mL

Ceftazidime (at the given concentration) has been shown to be compatible with the following diluent solutions:-

Solvents use for ceftazidime-tz concentration:

Sodium Chloride 0.9%  
 Ringer Solution  
 Ringer Lactate Solution  
 Glucose 5%  
 Glucose 10%  
 Glucose 5% and Sodium Chloride 0.9%  
 Glucose 5% and Sodium Chloride 0.45%  
 Glucose 5% and Sodium Chloride 0.2%  
 Dextran 40%/10% and Sodium Chloride 0.9%  
 Dextran 70%/6% and Sodium Chloride 0.9%

## Side-effects:

The following is a list of possible side-effects that may occur in medicines that contain Ceftazidime / Tazobactam. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Injection site inflammation
- Rash
- Fever
- Diarrhea
- Nausea
- Headache

## Precautions & How to Use:

Before using Ceftazidime / Tazobactam, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid activities that cause bruising
- Do not drive or operate machinery
- Elderly or Infants
- Gastrointestinal disease
- Hypersensitivity to penicillins
- If you develop bloody or watery diarrhea contact your doctor immediately

## Special Precautions for Ceftazidime + Tazobactam:

History Of Penicillin Allergy; Severe Renal Impairment; Pregnancy, Lactation

## Drug Interactions

If you use other drugs or over the counter products at the same time, the effects of Ceftazidime / Tazobactam may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. Ceftazidime / Tazobactam may interact with the following drugs and products:

- Aminoglycoside antibiotics
- Bumetanide
- Chloramphenicol
- Desogestrel
- Ethinyl Estradiol
- Furosemide

## Contraindications

Hypersensitivity to Ceftazidime / Tazobactam is a contraindication. In addition, Ceftazidime / Tazobactam should not be used if you have the following conditions:

- Clostridium difficile* bacterial infection
- Hypersensitivity
- Hypersensitivity to cephalosporins
- Pseudomembranous colitis
- Seizures associated with use of this drug

Keep the medicine out of reach of children.

**Storage :** Store at a temperature not exceeding 30° C. Protect from light & moisture.

**PREPARATION:** Dry Powder for Injection filled in clear glass vial packed in monocation along with 10 mL ampoule of Sterile Water for Injections IP in a tray with Digital testset.

## Marketed by:

**Aequitas Healthcare Pvt. Ltd.**  
 (ISO 9001:2015 Certified)

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