CEFTARVA® T (Ceftriaxone Sodium & Tazobactam Sodium 1.125g), CEPHALOSPORIN ANTIBIOTIC

CEFTARVA® T is supplied as sterile powder in glass vial. CEFTARVA® T IV Injection: Combipack containing sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone Anhydrous 1000mg tazobactam Sodium equivalent to Tazobactam USP 125mg and 10 ml Water for Injection IP for IV injection.

CEFTARVA® T is a sterile, semisynthetic, broad spectrum cephalosporin antibiotic. Tazobactam sodium is a penicillinic acid sulfone Beta-lactamase inhibitor with a structure similar to that of sulbactam & clavulanic acid. It inactivates susceptible Beta-lactamase by irreversibly binding to the catalytic region of the enzyme. The combination of Tazobactam and ceftriaxone sodium CEFTARVA® T is active against all the organisms resistant to Ceftriaxone.

FORMULATIONS AVAILABLE: INJECTION
COMPOSITION
Each vial contains sterile Ceftriaxone Sodium IP equivalent to Ceftriaxone Anhydrous 1000mg tazobactam Sodium equivalent to Tazobactam USP 125mg and 10 ml Water for Injection IP for IV injection.

PHARMACOKINETICS
Ceftriaxone interferes with the biosynthesis of the peptidoglycan component of the bacterial cell wall by binding to and inactivating penicillin-binding proteins (PBPs). Tazobactam is a penicillanic acid sulfone derivative with B-lactamase inhibitory properties. It enhances the activity of B-lactam antibacterials against B-lactamase-producing bacteria.

Distribution
Ceftriaxone: 98% bound to plasma proteins; crosses the blood brain barrier. Tazobactam: About 30% bound to plasma proteins; widely distributed to tissues and body fluids.

Excretion
Ceftriaxone: Elimination half-life is about 8.7 hours; 33-67% removed as unchanged drug. Tazobactam: Removed mainly via kidneys with 80% of an administered dose as unchanged drug.

INDICATIONS
To reduce the development of drug-resistant bacteria and maintain the effectiveness of CEFTARVA® T Injection, it should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. CEFTARVA® T Injection is mainly indicated in the following conditions:
- Lower respiratory tract infections and community-acquired pneumonia, Acute bacterial otitis media, Skin and skin structure infections, Urinary tract infections, Uncomplicated gonorrhea.
- Pelvic inflammatory disease, Bacterial septicemia, Bone and joint infections, Intra-abdominal infections, Bacterial meningitis, Pre-operative prophylaxis of infections associated with surgery.

CEFTARVA® T (Ceftriaxone Sodium & Tazobactam Sodium 1.125g) : 1000/125 mg once daily
or in equally divided doses twice a day.

Pregnancy Related Information
Use with caution
Breast Feeding Related Information
Use with caution
Indications for Ceftriaxone + Tazobactam
It is a combination of third generation Cephalosporins Ceftriaxone and Beta-lactamase inhibitor Tazobactam. It enhances the activity of beta lactam antibacterials against beta lactamase producing bacteria.
1. Pneumonia
2. Lower respiratory tract infection

Typical Dosage for Ceftriaxone + Tazobactam
Adult: 1000 mg of Ceftriaxone + 125 mg of Tazobactam / 500 mg of Ceftriaxone + 62.5 mg of Tazobactam / 250 mg of Ceftriaxone + 31.25 mg of Tazobactam to be given once a day depending upon the severity of the infection. Maximum daily dose: 4 g
Children: 50-75 mg / kg every 12 hours. Maximum daily dose: 2 g.

Ceftriaxone

About Ceftriaxone
Third Generation Cephalosporin antibiotic (Parenteral).

Mechanism of Action of Ceftriaxone
Ceftriaxone is a 3rd generation cephalosporin which exerts its bactericidal action against both gram positive & gram negative organisms by inhibiting bacterial cell wall synthesis. Ceftriaxone inhibits transpeptidase & thus prevents cross linking of bacterial cell wall. Transpeptidase & associated proteins constitute various types of specific binding proteins which have affinity for cephalosporins like Ceftriaxone.

Pharmacokinetics of Ceftriaxone
Absorption: Orally not well absorbed & should be given parenterally. Distribution: widely distributed & good CSF penetration, Metabolism: A portion of the drug is metabolized in the body. Excretion: Excreted through urine & bile. A small portion of drug appears in breast milk.

Onset of Action for Ceftriaxone
Sudden

Duration of Action for Ceftriaxone
8 hours

Side Effects of Ceftriaxone
1. Nausea
2. Vomiting
3. Diarrhoea
4. Superinfection
5. Skin rash
6. Urticaria
7. Pseudomembranous colitis
8. Pain at site of injection

Contra-indications of Ceftriaxone
Hypersensitivity to Ceftriaxone

Special Precautions while taking Ceftriaxone
1. Hepatic impairment
2. Renal impairment

Pregnancy Related Information
Use with caution

Old Age Related Information
May be used

Breast Feeding Related Information
Use with caution

Children Related Information
May be used

Neonates: Use with caution

Indications for Ceftriaxone
1. Meningitis
2. Septicaemia
3. Typhoid
4. UTI
5. Prophylaxis in surgical infections
6. Lower respiratory tract infections
7. Pneumonia
8. Pelvic inflammatory disease
9. STD
10. Bacteraemia

Interactions for Ceftriaxone
Alcohol: Disulfiram like reaction. Aminoglycosides & frusemide: Nephrotoxicity potentiated.
Chloramphenicol: Decreased efficacy of ceftriaxone.

**Typical Dosage for Ceftriaxone**

**Adults:** 1g to 2gm I.M. or I.V. Once daily or two times daily  
Maximum adult dose: Up to 4gm/day  
Meningitis & Endocarditis: 1 to 2gm I.M. or I.V twice daily; two weeks for meningitis & four weeks for endocarditis  
Gonorrhoea: 250mg once daily  

**Children:** 50 to 100 mg/kg/day I.M or I.V. two times daily  
Maximum child dose: 2g/day  
Meningitis & Endocarditis: 50 to 100 mg/kg/day twice daily; two weeks for meningitis & four weeks for endocarditis

**Schedule:**

- **Effects of Missed Dosage Ceftriaxone**
  Take the missed dose as soon as noticed and if it is the time for next dose then skip the missed dose. Continue the regular schedule. Do not double the dose.

- **Effects of Overdose Ceftriaxone**
  Symptoms of over dosage include neuromuscular disorders & some times seizure may get precipitated. Treatment is supportive.

**Tazobactam**

**About Tazobactam**
A Penicillanic acid sulfone beta-lactamase inhibitor, penams, To increase the antibacterial activity of penicillins against ?-lactamase?producing organisms.

**Mechanism of Action of Tazobactam**
Tazobactam is a Penicillanic acid sulfone beta lactamase inhibitor. Subactam has no significant antimicrobial activity, despite sharing the ?-lactam ring that is characteristic of beta-lactam antibiotics. This similarity in chemical structure helps the Tazobactam to act as a competitive inhibitor of beta-lactamase enzyme secreted by certain bacteria that are resistant to beta-lactam antibiotics. This inhibition restores the antibacterial activity of beta-lactam antibiotics against ?-lactamase secreting resistant bacteria. It is usually given in combination with Piperacillin.

**Side Effects of Tazobactam**
1. Gastrointestinal disturbances  
2. Headache  
3. Dizziness  
4. Insomnia  
5. Rash  
6. Pain  
7. Hypertension  
8. Edema  
9. Pruritus  
10. Agitation  
11. Local reactions  

**Contra-indications of Tazobactam**
- Hypersensitivity to Tazobactam  
- Renal impairment  
- Cystic fibrosis  
- Haematopoiesis  
- Monitor electrolytes  
- Discontinue if bleeding disorders occur

**Pregnancy Related Information**
Use with caution

**Old Age Related Information**
Use with caution

**Breast Feeding Related Information**
Use with caution

**Children Related Information**
Contraindicated

**Indications for Tazobactam**
1. Skin infections  
2. Pneumonia  
3. Postpartum endometritis  
4. Pelvic inflammatory disease  
5. Appendicitis  
6. Peritonitis  

**Typical Dosage for Tazobactam**
IV Infusion over 30 minutes.  
**Adults:** 3 to 4 grams of Piperacillin, in combination with 0.375 to 0.5 grams of Tazobactam, every 6 - 8 hours for 7 - 10 days.
Directions for Use
I.V. injection should be administered over at least 2–4 minutes.
I.V. infusion should be over a period of 30 minutes.
After reconstitution the solution should be administered by deep
I.M. injection. Doses greater than 1g should be divided and injected
at more than one site.
Reconstitute ceftriaxone/tazobactam with the appropriate diluent,
e.g., Water for Injection IP, Normal Saline Water, or Dextrose
Solutions.
Strength Amount of diluent for IM Amount of diluent for IV
(g) (ml) (ml)
1g 3.6 9.6
Use reconstituted solution in the vial immediately.
INCOMPATIBILITY
Vancomycin, aminoglycosides, and fluconazole are physically
incompatible with ceftriaxone/tazobactam in admixtures. When any
of these drugs are to be administered concomitantly by intermittent
intravenous infusion, it is recommended that they be given
sequentially, with thorough flushing of the intravenous lines (with
one of the compatible fluids) between the administrations.
Do not use diluents containing calcium, such as Ringer’s solution or
Hartmann’s solution, to reconstitute SUPRAWAR vials or to further
dilute a reconstituted vial for IV administration. Particulate formation
can result.
NOTE: Parenteral drug products should be inspected visually for
particulate matter before administration.
STORAGE AND HANDLING INSTRUCTIONS
Store in a cool, dry place. Protect from light.
Keep out of reach of children.
Discard if reconstituted solution contains visible particulate matter.
DISCARD UNUSED PORTION.
How supplied
Vial with diluent in a carton
For further details, please contact:
Medical Advisor
Taj Pharmaceuticals Limited
Plot No.23-28, Hosur Road, Electronics City,
Bangalore - 560 100. India
Manufactured by:
Taj Pharma India Pvt. Ltd.
Plot No.14, EPRP, Phase-1, Jhamajri,
Baddi, Dist. Solan, HP - 173205
Marketed by:
Taj Pharma UK Limited
212 Great West Road
Brentford, Middlesex
TW8 9GS
TM - Trade Mark of Taj Pharmaceuticals Limited
“Mfd. under the technical guidance of TAJ GROUP, MUMBAI”
CEPHALOSPORIN ANTIBIOTIC

CEFTARVA-T
(Ceftriaxone Sodium & Tazobactam Sodium 1.125g)

www.tajpharma.com

CEFTARVA-T is supplied as sterile powder in glass vial.
CEFTARVA-T IV Injection: Combi-pack containing sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone Anhydrous 1g and Tazobactam Sodium equivalent to Tazobactam USP 150mg and 10 ml Water for Injection IP for IV injection.

CEPHALOSPORIN ANTIBIOTIC

CEFTARVA-T
(Ceftriaxone Sodium & Tazobactam Sodium 1.125g)

CEFTARVA-T is a sterile, amphoteric, broad-spectrum cephalosporin antibiotic. Tazobactam is a potent and selective beta-lactamase inhibitor with a higher degree of stability than ceftriaxone & cephalosporins. It enhances the spectrum and activity of ceftriaxone, making it more effective against a wide range of bacteria. Tazobactam inhibits the action of certain types of beta-lactamase enzymes, effectively widening the antibiotic's effectiveness. Together, these components make CEFTARVA-T a powerful choice in the treatment of serious infections.