PROMICEF TAZO ® (Ceftriaxone & Tazobactam for Injection 4.5 gm)

Composition:

Each vial contains: Sterile Ceftriaxone Sodium IP Equivalent to Anhydrous Ceftriaxone 4 gm Sterile Tazobactam Sodium IP Equivalent to Tazobactam 500 mg

Ceftriaxone sodium:

Ceftriaxone is a third-generation semisynthetic broad-spectrum cephalosporin and bactericidal in action. It is white yellow to pale orange crystalline which is readily soluble in water.

Tazobactam sodium:

Tazobactam is a compound which inhibit the action of bacterial beta-lactamase. It is added to extend spectrum of B-lactam antibiotic. Tazobactam sodium is a derivative of penicillin nucleus, is a penicillanic acid sulfone.

MECHANISM OF ACTION:

CEFTRIAXONE:

Ceftriaxone is bactericidal in action. The bactericidal activity of ceftriaxone results from inhibition of bacterial cell wall synthesis. Ceftriaxone has high degree of stability in the presence of betalactamase, both penicillanase and cephalosporinase of Gram-Positive and Negative bacteria.

TAZOBACTAM:

Tazobactam a derivate of penicillin nucleus is a penicillanic acid sulfone.

Being a B-lactamase inhibitor, it is systematic with many B-lactam antibiotic such as penicillins and cephalosporines. Tazobactam appears to be weaker enzyme inducer than other B-lactamase inhibitors. The combinations of Ceftriaxone with Tazobactam is active against all organism sensitive to Ceftriaxone. In addition, it demonstrates synergistic activity (reduction in MICs for the combinations versus those of each component) in a variety of organisms.

PHARMACOKINETICS:

Ceftriaxone has the advantage of betalactamase stability, good activity against target proteins and excellent ability to penetrate bacterial cell walls. The basic pharmacokinetics and drug disposition characteristics of ceftriaxone are typical of Beta lactams, with the marked exception of having significantly longer half-life of 8 hours giving it the potential once a day dosing, because of its extensive proteinbinding ability. Following IV /IM administration ceftriaxone is widely distributed into body tissue & fluids Execration is largely through urinary tract and via tubular filtration.

Antimicrobial spectrum:

The combination of ceftriaxone and Tazobactam offers a wide anti-microbial spectrum as follows.

A) Gram Positive: - *Staphylococcus aureus, Staphylococcus epidermis, Staphylococcus pneumoniae,*

Streptococcus agalactiae, Streptococcus pyogenes, Streptococcus pneumoniae, Cornybacterium pyogenes, Enterococcus faecalis, Listeria monocytogenes

B) Gram Negative: - *E*-coli, Klebsiella species, Pseudomonas aeruginosa,

Bordetella bronchioseptica, Brucella spp, Haemophillus spp, Pasteurella spp.

C) Anaerobes: - *Bacterioides fragilis*, *Clostridium* spp, *Peptostreptococcus* spp.

INDICATIONS:

- Mastitis
- Respiratory tract infections
 (Bronchopneumonia, Pneumonia)
- Uro-genital tract infections (Metritis, Nephritis, Pyometra, Cystitis)
- Gastro-intestinal tract infection
- Bacterial septicaemia
- Meningitis
- Skin and soft tissue infection
- Post operative bacterial infections or surgical prophylaxis
- To prevent secondary bacterial infections

DOSAGE AND ADMINISTRATION:

This Injection may be administered by IV, IM route after reconstitution. This Injection comes in a composite pack containing vial of dry powder and Sterile Water for Injections IP. Sterile Water for Injection IP provided in this pack should be used to dissolve the dry powder present in the vial just prior to use. 20 ml Sterile Water for Injection IP is sufficient to prepare the solution. The reconstituted solution should be used immediately after preparation.

DOSAGE: 5-10 mg /kg body weight in livestock & 25 mg /kg body weight in equines.

WITHDRAWAL PERIOD:

Milk: 7 days, Meat: 28 days

For I.M. / I.V. Use

CONTRA- INDICATIONS / SAFETY /PRECAUTION:

Ceftriaxone is contraindicated in animal with known allergy to cephalosporin class of antibiotics. Careful inquiry should be made to determine whether the animal had pervious history of hypersensitivity reactions to cephalosporin penicillins or others drugs. It is safe to be administered in young & pregnant animals. It does not produce any impairment of fertility, embryo toxicity and teratogenicity.

DRUG INTERACTION:

In Vitro studies indicate a synergetic action of aminoglycosides + ceftriaxone though clinically importance has not been determined. Ceftriaxone and intravenous calcium products should not be coadministered to prevent precipitation events leading to end - organ damage (Emily *et al*: 2010)

STORAGE:

Store below 30C. Protect from light and moisture.

PRESENTATION:

Available in 4.5 g vial.

FOR VETERINARY USE ONLY.

NOT FOR HUMAN USE. FOR ANIMAL TREATMENT ONLY



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