

MAXIZONE SB

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **MAXIZONE SB** (Ceftriaxone and Sulbactam for Injection I.P. 1.5 gm and Sterile Water for Injection I.P. 10 ml)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The bactericidal activity of Ceftriaxone & Sulbactam is due to the Ceftriaxone component and the ability of Ceftriaxone to interfere with the biosynthesis of the peptidoglycan component of the bacterial cell wall by binding to and inactivating penicillin-binding proteins (PBPs).

INDICATIONS: It is indicated for treatment of LRTI..

DOSAGE AND ADMINISTRATION: *Adults:* The usual adult daily dose (in terms of Ceftriaxone) is 1-2 grams given once a day (or in equally divided doses twice a day) depending on the type and severity of the infection. The total daily dose should not exceed 4 grams. Dosage regimen for (Ceftriaxone-Sulbactam) should be adjusted in patients with marked decrease in renal function (creatinine clearance of < 30ml/min) and to compensate for reduced clearance less than 15ml/min patient should receive a maximum of 500mg of sulbactam every 12 hours (maximum dose 1 gram of sulbactam). *Pediatric patients:* For treatment of serious infections: Recommended total daily dose in terms of Ceftriaxone is 50-75 mg/kg given in divided doses every 12 hours. The total daily dose (in terms of Ceftriaxone) should not exceed more than 2 grams. When treating infection caused by Streptococcus pyogenes, therapy should be continue for at least 10 days *Method of administration:* Dissolve the contents of the vial in 4 ml of Sterile water for Injection I.P. for IM use or 8.5 ml for IV use. Prick the ampoule of Sterile. Water for Injection only once & discard the ampoule. The reconstituted solution should be used immediately and not to be frozen. There is no relevant use of abiraterone in the paediatric population.

CONTRAINDICATION: Ceftriaxone Injection is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics. In patients hypersensitive to penicillin, consider the possibility of allergic cross-reactions. The use of sulbactam is contraindicated in individuals with a history of hypersensitivity reactions to any of the penicillins.

WARNINGS & PRECAUTIONS: *Warnings:* Serious or occasionally fatal anaphylactic reactions have been reported in patients receiving beta-lactam antibiotics. These reactions are more likely to occur in individuals with a history of hypersensitivity reactions to multiple allergens. Pseudo membranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics), therefore it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use *Precautions:* Transient elevations of BUN and serum creatinine have been observed, at recommended doses, the nephrotoxic potential of ceftriaxone is same as other cephalosporins. Since Ceftriaxone is excreted both via renal and bile patients with renal failure normally require no adjustment in dosage when usual doses of Ceftriaxone are administered. Dosage adjustments are not necessary in patients with hepatic dysfunction; however, in patients with both renal failure and hepatic dysfunction, dosage should not exceed more than 2g daily with close monitoring of serum concentrations.

DRUG INTERACTIONS: Ceftriaxone has an N-methylthiotriazine side-chain and may have the potential to increase the effects of anticoagulants and to cause a disulfiram- like reaction with alcohol. Unlike many cephalosporins, probenecid does not affect the renal excretion of Ceftriaxone.

ADVERSE REACTIONS: The most frequent adverse drug reactions are inflammation at injection site with pain and tenderness. Other common adverse drug reactions that can occur with the combination are hypersensitivity including pruritus, fever or chills. Common gastrointestinal side effects include,

diarrhea, nausea and vomiting. • Other side effects: Hematological complications, Elevation of hepatic enzymes, elevation of BUN, headache, dizziness, vaginitis, flatulence, dyspepsia, palpitations and epistaxis.

MARKETED BY:



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(Additional information is available on request)