

SULBACIN

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

Abbreviated Prescribing information for SULBACIN (Sultamicillin Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Ampicillin: The mode of action of ampicillin, considered to be a 2-step process. In the first step, the drug binds to primary receptors called membrane-bound penicillin-binding proteins. Inactivation of penicillin-binding proteins by bound antibiotic has immediate arresting actions on their function. The second stage comprises the physiological effects caused by this receptor-ligand interaction. Penicillin-binding proteins are involved in the late stages of peptidoglycan synthesis in the cell wall. Because peptidoglycan maintains the integrity of the cell wall, which resides in a hypotonic environment, its disruption causes lysis and cell death.

Sulbactam: It is a beta-lactamase inhibitor and inhibits the action of any bacteria producing the enzyme after binding to it and thereby not allowing its action on the antibiotic. Sulbactam protects ampicillin from degradation by most beta-lactamases.

DOSAGE AND ADMINISTRATION: As directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substances (ampicillin and Sulbactam); to any other penicillin or to any of the excipient, History of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta lactam agent (e.g. cephalosporin, carbapenem or monobactam).

WARNINGS & PRECAUTIONS: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. Serious anaphylactoid reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated. Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. General: A high percentage of patients with mononucleosis who receive ampicillin develop a skin rash. Thus, ampicillin class antibiotics should not be administered to patients with mononucleosis. Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued.

DRUG INTERACTION: Concurrent use of probenecid with Ampicillin/Sulbactam may result in increased and prolonged blood levels of ampicillin and sulbactam, the concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs Ampicillin/Sulbactam and aminoglycosides should not be reconstituted together due to the in vitro inactivation of aminoglycosides by the ampicillin component of Ampicillin/Sulbactam, Anticoagulants : warfarin, Methotrexate, Drug/Laboratory Test Interactions high urine concentration of ampicillin. High urine concentrations of ampicillin may result in false positive reactions when testing for the presence of glucose in urine Benedict's Solution or Fehling's Solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions be used. Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated

estriol, estriol-glucuronide, conjugated estrone and estradiol has been noted. This effect may also occur with Ampicillin/Sulbactam.

ADVERSE REACTIONS: Diarrhea, rash, pruritis, itching, nausea, vomiting, candidiasis, fatigue, malaise, headache, chest pain, flatulence, abdominal distension, glossitis, urine retention, dysuria, edema, facial swelling, erythema, chills, tightness in throat, substernal pain epistaxis and mucosal bleeding, atypical lymphocytosis, Gastritis, stomatitis, black “hairy” tongue and enterocolitis. Urticaria, erythema multiforme, and an occasional case of exfoliative, Agranulocytosis, Anemia, thrombocytopenic purpura, thrombocytopenia, eosinophilia, agranulocytosis, leukopenia, severe skin reactions, such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), dermatitis exfoliative, erythema multiforme, Acute generalized exanthematous pustulosis (AGEP), Transient and reversible increase in transaminases. A moderate elevation of serum glutamic oxaloacetic transaminase (SGOT) Jaundice, Seizures, vertigo, headache, neurotoxic reactions (Cramps).

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IN/SULBACIN TABLET 375 mg/Jan-22/02/ABPI

(Additional information is available on request)