Pharmacode 6367

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

SULBACIN TABLETS

For oral administration

COMPOSITION:
Each film coated tablet contains: Sultamicillin Tosilate Di hydrate Ph.Eur./BP ... 375mg equivalent to Sulbactam 147mg, Ampicillin 220mg

DESCRIPTION OF PRODUCT: Capsule shaped, biconvex, white, film coated tablets having SULBACIN debossed centrally on one side along the length

PHARMACODYNAMICS:
Sultamicillin is a double ester of a broad spectrum antibiotic ampicillin with sulbactam, a semisynthetic b-lactamase inhibitor, which extends the antibacterial spectrum of ampicillin to include some b-lactamase producing strains of bacteria that would otherwise be resistant.

ACTIONS: Microbiology: Biochemical studies with cell-free bacterial systems have shown sulbactam to be an irreversible inhibitor of most important b-lactamases that occur in penicillin-resistant organisms. It possesses significant antibacterial activity against *Neisseriaceae, Acinetobacter calcoaceticus, Bacteroides sp, Branhamella catarrhalis* and *Pseudomonas cepacia*. The potential for sulbactam sodium's preventing the destruction of penicillins and cephalosporins by resistant organisms was confirmed in whole organism studies using resistant strains, in which sulbactam sodium exhibited marked synergistic effects with penicillins and cephalosporins. Since sulbactam also binds to some penicillin-binding proteins, some sensitive strains are rendered more susceptible to the combination than to the ß-lactam antibiotic alone.
The bactericidal component in SULBACIN Tablets is ampicillin, which like benzyl penicillin, acts against sensitive organisms during the active multiplication by inhibiting the biosynthesis of cell wall mucopeptide.
Sultamicillin is effective against a wide range of gram-positive and gram-negative bacteria including: *Staphylococcus aureus* and *S. epidermidis* (including penicillin-resistant and some methicillin-resistant strains); *Streptococcus pneumoniae, Streptococcus faecalis* and other *Streptococcus sp; Haemophilus influenzae* and *parainfluenzae* (both b-lactamase- positive and -negative strains); *Moraxella catarrhalis;* anaerobes including *Bacteroides fragilis* and related species; *Escherichia coli; Klebsiella sp; Proteus sp* (both indole-positive and indole-negative); *Enterobacter sp; Morgan ella morganii; Citrobacter sp; Neisseria meningitidis* and *Neisseria gonorrhoeae.*

Pharmacokinetics: Following oral administration in humans, during absorption sultamicillin is hydrolyzed to provide sulbactam and ampicillin in a 1 :1 molar ratio in the systemic circulation. The bioavailability of an oral dose is 80% of an equal IV dose of sulbactam and ampicillin. Food does not interfere with the systemic bioavailability of sultamicillin. Peak serum levels of ampicillin following sultamicillin are approximately twice those of an equal dose of oral ampicillin. Elimination half-lives are approximately 0.75 and 1 hr for sulbactam and ampicillin, respectively in healthy volunteers. 50-75% of each agent is excreted in the urine unchanged. Elimination half-lives are increased in the elderly and in patients with renal dysfunction. Probenecid is known to decrease the renal tubular secretion of both ampicillin and sulbactam. In view of this coadministration of probenecid with sultamicillin results in increased and prolonged blood levels of ampicillin and sulbactam.

INDICATIONS:
SULBACIN Tablets is suitable for the treatment of infections by susceptible organisms which may be seen in the following clinical conditions:
Intra Abdominal Infections, Skin and Soft Tissue Infections, Upper and Lower Respiratory Tract Infections, ENT Infections, U rinary Tract Infections and Gonorrhoea.
SULBACIN Tablets may be administered for the continuation of therapy following injectable SULBACIN Tablets.

DOSAGE AND ADMINISTRATION:
In adults the usual dose of SULBACIN Tablets is 1-2 tablets (375- 750 mg) twice daily for 5-14 days.
For children above 30 kg the dose is same as for adults.
Treatment is usually continued until 48 hours after pyrexia and other a bnormal signs have resolved.
Tablets are to be swallowed whole, with plenty of water.
In patients with severe impairment of renal function (creatinine clearance less than 30 ml/min), the elimination kinetics of sulbactam and ampicillin are similarly affected and hence the plasma ratio of one to the other will remain constant The dose of sultamicillin in such patients should be administered less frequently in accordance with usual practice for ampicillin.
When creatinine clearanee is not known it may be calculated from the serum creatinine value, as fol lows:

Males: $\frac{\text{weight (kg) x (140-Age)}}{\text{72 x serum creatinine}}$

Females: 0.85 x above value

OVERDOSAGE
Limited information is available on the acute toxicity of ampicillin sodium and sulbactam sodium in humans. Overdosage of the drug would be expected to produce manifestations that are principally extensions of the adverse reactions reported with the drug. The fact that high CSF concentrations of b-lactam antibiotics may cause neurologic effects, including seizures, should be considered. Haemodialysis procedure may enhance elimination of SULBACIN Tablets from the body if overdosage occurs in patients with impaired renal function.

CONTRAINDICATIONS
SULBACIN Tablets is contraindicated in individuals with a history of an allergic reaction to any of the Penicillins & Cephalosporins

WARNINGS AND PRECAUTIONS
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy including sultamicillin. Some patients with infectious mononucleosis may develop skin rash after SULBACIN Tablets administration. The ampicillin group of antibiotics should not be administered to such patients. Super infections with Pseudomonas aeruginosa or fungi may occur during therapy, they should be suitably treated.
The principal route of excretion of sulbactam and ampicillin following oral administration of sultamicillin is via the urine. Because renal function is not fully developed in neonates, this should be considered when using sultamicillin in neonates.
It is advisable to check periodically for organ system dysfunction during prolonged therapy; this includes renal, hepatic and hematopoietic systems.
Effects on the Ability to Drive or Operate Machinery: None known.
Use in pregnancy & lactation:Animal reproduction studies have revealed no evidence of impaired fertility or harm tot he fetus due to sultamicillin. Sulbactam crosses the placental barrier. However, safety for use in human pregnancy and lactation has not been established. Caution should be exercised when sultamicillin is administered to a nursing woman.
Low concentration of ampicillin and sulbactam are excreted in the milk.

ADVERSE REACTIONS
Adverse effects of SULBACIN Tablets are similar to other antibiotics of the Penicillin group and they include rash, allergic reaction, anaphylactic shock and anaphylactoid reaction, gastrointestinal disorders like diarrhea and very rarely, pseudomembranous colitis. In some patients respiratory adverse effect like dyspnea is also reported.
Skin/Skin Structures related adverse reactions are infrequently observed & include rash, itching, along with angioedema, dermatitis and urticaria. Rare reports of exfoliative dermatitis, toxic epidermal necrolysis, erythema multiforme and Stevens-Johnson syndrome were seen with the therapy. In the urinary system rare reports of interstitial nephritis were observed. Haematological disorders such as Anaemia, hemolytic anaemia, thrombocytopenia, thrombocytopenia purpura, eosinophilia, leukopenia, neutropenia, agranulocytosis, abnormal platelet aggregation have been reported with SULBACIN Tablets use, but their incidence is rare and they are readily reversible. The Central and Peripheral Nervous System adverse reactions include dizziness & rare events of convulsions.
Elevation of liver enzymes may also be noted Sultamicillin is generally well tolerated. Other side effects like drowsiness/sedation, fatigue/malaise and headache have been rarely observed. The majority of the side effects observed were of mild or moderate severity and were generally tolerated with continued treatment.

DRUG INTERACTIONS
Allopurinol: The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes as compared to patients receiving ampicillin alone.
Anticoagulants: Penicillins can produce alterations in platelet aggregation and coagulation tests. These effects may be additive with anticoagulants.
Drugs like chloramphenicol, erythromycin, sulfonamides and tetracyclines, which are bacteriostatic drugs, may interfere with the bactericidal effect of penicillins.
There have been case reports of reduced oral contraceptive effectiveness in women taking ampicillin, resulting in unplanned pregnancy. Although the association is weak, patients should be given the option to use an alternate or additional method of contraception while taking ampicillin. Coadministration of Methotrexate & penicillin has resulted in decreased clearance of methotrexate and a corresponding increase in methotrexate toxicity.
Probenecid: Probenecid decreases renal tubular secretion of ampicillin and sulbactam when used concurrently; this effect results in increased and prolonged serum concentrations, prolonged elimination half-life, and increased risk of toxicity.
Laboratory Test Interactions: False-positive glycosuria may be observed in urinalysis using Benedict's reagent, Fehling's reagent and Clinitest. 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.

STORAGE:
Store below 30°C. Protect from light and moisture.
Keep medicines out of reach of children.

NATURE & CONTENT OF CONTAINER(PRESENTATION):
A cold-formed blister with a printed aluminium foil as lidding is the container. 10 tablets are packed in this blister.
Blister/s & a leaflet in turn are packed in carton/s.
Pack of 1 Blister and 10 Blister available.

SHELFLIFE: 24 Months.

Product Registration Holder:
Healol Pharmaceuticals Sdn.Bhd
74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju,
53300 Kuala Lumpur, Malaysia.

MAL No.: MAL20061565AZ

Manufactured in India by:
UNICHEM LABORATORIES LTD.
Village Bhatauli Kalan, Baddi,
Dist. Solan (H.P.) - 173 205.

13016942
Date of Revision : May, 2026

175 mm

120 mm

120 mm

Company Name : UNICHEM LABORATORIES LTD.		**Date:** 26-05-2026
Agency Name: Unicorn Creation		**Open Size:** 120 x 175 mm
Product: Sulbacin Tablets - Leaflet	**Packing:** -----	**Folded Size:** 120 x 35 mm
Item Code: 13016942	**Location:** Baddi I	**No. of Folds:** ----------
Specification: 54 gsm Maplitho Paper	**Market :** Malaysia with 30°C	**Pharmacode:** 6367
Colour Code: Text in black		
Reason: Pack of 1 Blister and 10 Blister available added.		