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

SULBACIN

1. Generic Name

Sultamicillin Tablets

2. Qualitative and quantitative composition

Each film coated tablet contains:

Sultamicillin Tosilate Dihydrate Ph.Eur. ……..375 mg

(Equivalent to Sulbactam – 147 mg and Ampicillin I.P. – 220 mg)

Colour: Titanium Dioxide I.P.

The excipients used are Starch, Lactose, Sodium Starch Glycolate, Hydroxy Propyl Cellulose, Magnesium Stearate, Hydroxypropyl Methyl Cellulose, Titanium Dioxide, Diethyl Phthalate, Methanol and Methylene Chloride.

3. Dosage form and strength

Dosage form: Film Coated Tablets

Strength: Sultamicillin Tosilate Dihydrate - 375 mg (equivalent to Sulbactam – 147 mg and Ampicillin I.P. – 220 mg)

4. Clinical particulars

4.1 Therapeutic indication

It is indicated for the treatment of intra-abdominal infections, obstetrics and gynaecological infections, skin and soft tissue infections, bone and joint infections, upper and lower respiratory tract infections, ENT infections, urinary tract infections, gonorrhoea and surgical prophylaxis.

4.2 Posology and method of administration

Dose: As directed by physician.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more apt to occur in individuals with a history of penicillin hypersensitivity and/or hypersensitivity reactions to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before therapy with a penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, and other allergens. If an allergic reaction occurs, unsay should be

discontinued and the appropriate therapy instituted. 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. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

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. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted.

Patients should be counselled that antibacterial drugs should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When the medication is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

4.5 Drugs interactions

Probenecid decreases the renal tubular secretion of ampicillin and sulbactam. 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 as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients.

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: The changes in platelets aggregation and prothrombin time observed with penicillin may be increased on simultaneous administration of anticoagulants (e.g. warfarin).

Methotrexate: The concurrent administration of methotrexate and penicillin resulted in reduced methotrexate clearance and consequentially in methotrexate toxicity.

Drug/Laboratory Test Interactions: Administration of Ampicillin/Sulbactam will result in 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.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Fertility

In animal studies, Ampicillin and Sulbactam had no effect on fertility.

Pregnancy

Data on a limited number of exposed pregnancies indicate no adverse effect of Ampicillin and Sulbactam on pregnancy or on health of the foetus/new born child. However, data on first trimester exposure are lacking. In animal studies with ampicillin and sulbactam no teratogenicity was observed. Ampicillin and Sulbactam should be used during pregnancy only if clearly needed.

Labor and Delivery: Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine tone, frequency of contractions, height of contractions, and duration of contractions. However, it is not known whether the use of Ampicillin/Sulbactam in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Nursing Mothers: Low concentrations of ampicillin and sulbactam are excreted in the milk; therefore, caution should be exercised when Ampicillin/Sulbactam is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of Ampicillin/Sulbactam have been established for paediatric patients one year of age and older for skin and skin structure infections as approved in adults. Use of Ampicillin/Sulbactam in paediatric patients is supported by evidence from adequate and well-controlled studies in adults with additional data from paediatric pharmacokinetic studies, a reported controlled clinical trial conducted in paediatric patients and post-marketing adverse events surveillance. The safety and effectiveness of Ampicillin/Sulbactam have not been established for paediatric patients for intraabdominal infections.

4.7 Effects on ability to drive and use machines

No studies on ability to drive and use machines under influence of ampicillin and sulbactam have been carried out. However, patients should be made aware that due to undesirable effect reactivity may be decreased.

4.8 Undesirable effects

Adult Patients: Ampicillin/Sulbactam is generally well tolerated. The following adverse reactions have been reported.

Systemic Adverse Reactions:

The most frequently reported adverse reactions were diarrhea in 3% of the patients and rash in less than 2% of the patients.

Additional systemic reactions reported in less than 1% of the patients were: rash, prutitis, 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.

Pediatric Patients: Available safety data for paediatric patients treated with Ampicillin/Sulbactam demonstrate a similar adverse events profile to those observed in adult patients. Additionally, atypical lymphocytosis has been observed in one paediatric patient receiving Ampicillin/Sulbactam.

Adverse Laboratory Changes:

Adverse laboratory changes without regard to drug relationship that were reported during reported clinical trials were:

Hepatic: Increased AST (SGOT), ALT (SGPT), alkaline phosphatase, and LDH.

Hematologic: Decreased hemoglobin, hematocrit, RBC, WBC, neutrophils, lymphocytes, platelets and increased lymphocytes, monocytes, basophils, eosinophils, and platelets.

Blood Chemistry: Decreased serum albumin and total proteins.

Renal: Increased BUN and creatinine.

Urinalysis: Presence of RBC's and hyaline casts in urine.

The following adverse reactions have been reported with ampicillin-class antibiotics and can also occur with Ampicillin/Sulbactam.

Gastrointestinal: Gastritis, stomatitis, black "hairy" tongue and enterocolitis. Onset of Pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Colitis should be considered, which can be life-threatening or fatal.

Hypersensitivity Reactions: Urticaria, erythema multiforme, and an occasional case of exfoliative dermatitis have been reported. These reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, the drug should be discontinued, unless the opinion of the physician dictates otherwise. Serious and occasional fatal hypersensitivity (anaphylactic) reactions can occur with a penicillin.

Hematologic: In addition to the adverse laboratory changes listed above for Ampicillin/Sulbactam, Agranulocytosis has been reported during therapy with penicillins. Anemia, thrombocytopenic purpura, thrombocytopenia, eosinophilia, agranulocytosis, and leukopenia are reported during ampicillin-sulbactam therapy. All of these reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

Impairment of blood coagulation.

Severe Cutaneous Adverse Reactions: Ampicillin and sulbactam for injection may cause severe skin reactions, such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), dermatitis exfoliative, erythema multiforme, and Acute generalized exanthematous pustulosis (AGEP). If patients develop a skin rash they should be monitored closely and ampicillin and sulbactam for injection discontinued if lesions progress.

Liver: Transient and reversible increase in transaminases. A moderate elevation of serum glutamic oxaloacetic transaminase (SGOT) is reported, commonly in infants; its significance is unknown. Jaundice

Central Nervous System: Seizures, vertigo, and headache, neurotoxic reactions (Cramps)

Opportunistic Infections: During therapy, there is a possibility of superinfection with some bacteria or mycotic organisms. In such cases, discontinuation of therapy and substitution of appropriate treatment is warranted.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

By reporting side effects, you can help provide more information on the safety of this medicine

4.9 Overdose

Neurological adverse reactions, including convulsions, may occur with the attainment of high CSF levels of beta-lactams. Ampicillin may be removed from circulation by haemodialysis. The molecular weight, degree of protein binding and pharmacokinetics profile of sulbactam suggest that this compound may also be removed by haemodialysis.

5. Pharmacological properties

5.1 Mechanism of Action

Ampicillin is a semi-synthetic, non-beta-lactamase resistant amino-penicillin, and sulbactam is a beta-lactamase inhibitor with structure similar to that of ampicillin.

Ampicillin

The mode of action of ampicillin, like any other beta-lactam antibiotics, on sensitive organisms, can be considered to be a 2-step process. In the first step, the drug binds to primary receptors called membrane-bound penicillin-binding proteins. These proteins perform vital roles in cell cycle related, the morphogenetic formation of cell wall peptidoglycan.

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.

5.2 Pharmacodynamic properties

Pharmacotherapeutic group: Combinations of penicillin, inclusion beta-lactamase inhibitor, ATC code: J01CR01

Ampicillin

Ampicillin is a broad spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin sensitive organisms.

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.

MICROBIOLOGY

Ampicillin is similar to benzyl penicillin in its bactericidal action against susceptible organisms during the stage of active multiplication. It acts through the inhibition of cell wall mucopeptide biosynthesis. Ampicillin has a broad spectrum of bactericidal activity against many gram-positive and gram-negative aerobic and anaerobic bacteria. (Ampicillin is, however, degraded by beta-lactamases and therefore the spectrum of activity does not normally include organisms which produce these enzymes.)

A wide range of beta-lactamases found in microorganism's resistant to penicillins and cephalosporins have been shown in biochemical studies with cell free bacterial systems to be irreversibly inhibited by sulbactam. Although sulbactam alone possesses little useful antibacterial activity except against the Neisseriaceae, whole organism studies have shown that sulbactam restores ampicillin activity against beta-lactamase producing strains. In particular, sulbactam has good inhibitory activity against the clinically important plasmid mediated beta-lactamases most frequently responsible for transferred drug resistance. Sulbactam has no effect on the activity of ampicillin against ampicillin susceptible strains.

The presence of Sulbactam in the Ampicillin/Sulbactam formulation effectively extends the antibiotic spectrum of ampicillin to include many bacteria normally resistant to it and to other beta-lactam antibiotics. Thus, Ampicillin/Sulbactam possesses the properties of a broadspectrum antibiotic and a beta-lactamase inhibitor.

While in vitro studies have demonstrated the susceptibility of most strains of the following organisms, clinical efficacy for infections other than those included in the indications section has not been documented.

Gram-Positive Bacteria: *Staphylococcus aureus* (beta-lactamase and non-beta-lactamase producing), *Staphylococcus epidermidis* (beta-lactamase and non-beta-lactamase producing), *Staphylococcus saprophyticus (beta-lactamase and non-beta-lactamase producing), Streptococcus faecalis† (Enterococcus), Streptococcus pneumoniae† (formerly D. pneumoniae), Streptococcus pyogenes†, Streptococcus viridans†*.

Gram-Negative Bacteria: *Hemophilus influenzae* (beta-lactamase and non-beta-lactamase producing), *Moraxella (Branhamella) catarrhalis* (beta-lactamase and non-beta-lactamase producing), *Escherichia coli* (beta-lactamase and non-beta-lactamase producing), *Klebsiella* species (all known strains are beta-lactamase producing), *Proteus mirabilis* (beta-lactamase and non-beta-lactamase producing), *Proteus vulgaris*, *Providencia rettgeri*, *Providencia stuartii*, *Morganella morganii*, and *Neisseria gonorrhoeae* (beta-lactamase and non-betalactamase producing).

Anaerobes: *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, *Bacteroides* species, including *B. fragilis.*

These are not beta-lactamase producing strains and, therefore, are susceptible to ampicillin alone.

Susceptibility Testing Diffusion Technique: For the Kirby-Bauer method of susceptibility testing, a 20 mcg (10 mcg ampicillin + 10 mcg sulbactam) diffusion disk should be used. The method is one outlined in the NCCLS publication M2-A4[1].With this procedure, a report from the laboratory of "Susceptible" indicates that the infecting organism is likely to respond to

Ampicillin/Sulbactam therapy and a report of "Resistant" indicates that the infecting organism is not likely to respond to therapy. An "Intermediate" susceptibility report suggests that the infecting organism would be susceptible to Ampicillin/Sulbactam if a higher dosage is used or if the infection is confined to tissues or fluids (e.g., urine) in which high antibiotic levels are attained.

Dilution Techniques: Broth or agar dilution methods may be used to determine the minimal inhibitory concentration (MIC) value for susceptibility of bacterial isolates to ampicillin/ sulbactam. The method used is one outlined in the NCCLS publication M7-A2[2].Tubes should be inoculated to contain 10^5 to 10^6 organisms/mL or plates "spotted" with 10^4 organisms. The recommended dilution method employs a constant ampicillin/sulbactam ratio of 2:1 in all tubes with increasing concentrations of ampicillin. MIC's are reported in terms of ampicillin concentration in the presence of sulbactam at a constant 2 parts ampicillin to 1 part sulbactam.

Recommended ampicillin/sulbactam, Susceptibility Ranges[1,2,3]

	Resistant	**Intermediate**	**Susceptible**
Gram (-) and Staphylococcus			
Bauer/Kirby	≤11 mm	12–13 mm	≥14 mm
Zone Sizes	≥32	16	≤ 8
MIC (mcg of ampicillin/mL)	≤19	-	≥20
Hemophilus influenzae		-	≤ 2
Bauer/Kirby	≥ 4		
Zone Sizes			
MIC (mcg of ampicillin/mL)			

[1] The non-beta-lactamase producing organisms which are normally susceptible to ampicillin, such as *Streptococci*, will have similar zone sizes as for ampicillin disks.

[2]*Staphylococci* resistant to methicillin, oxacillin, or nafcillin must be considered resistant to Ampicillin/Sulbactam.

[3]The quality control cultures should have the following assigned daily ranges for ampicillin/sulbactam:

		Disks	**Mode MIC(mcg/mL ampicillin/ mcg/mL sulbactam)**
E. coli	(ATCC 25922)	20–24 mm	2/1
S. aureus	(ATCC 25923)	29–37 mm	0.12/0.06
E. coli	(ATCC 25923)	29–37 mm	8/4

5.3 Pharmacokinetic properties

Ampicillin/Sulbactam is excreted mainly in the bile and urine with a plasma half-life of 1-2 hours. Ampicillin and Sulbactam are also rapidly distributed to a large number of tissues, body fluids, and secretions. The half-life of sulbactam and ampicillin is about 1 hour in young adults and about 2 hours in elderly subjects. About 80% of both substances is excreted renally 8 hours after administration of single dose of Ampicillin/Sulbactam. The simultaneous administration of Ampicillin and Sulbactam causes no clinically relevant deviations in the kinetic parameters of the two substances when administered individually.

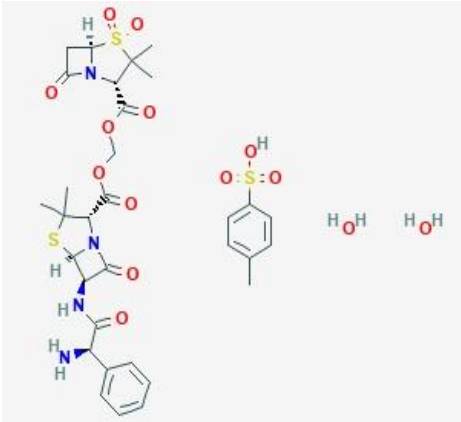
6. Nonclinical properties

6.1 Animal Toxicology

While reversible glycogenosis was observed in laboratory animals, this phenomenon was dose and time-dependent and is not expected to develop at the therapeutic doses and corresponding plasma levels attained during the relatively short periods of combined ampicillin/sulbactam therapy in man. Pre-clinical data reveal no special hazard for humans based on conventional studies of repeated-dose toxicity and genotoxicity. Long term studies to evaluate the carcinogenic potential have not been performed. In studies performed on rats and rabbits at doses up to ten times the human dose, the combination of Ampicillin and Sulbactam was not teratogenic and did not have any adverse effects on fertility (rat).

7. Description

Sultamicillin is [(2*S*,5*R*)-3,3-dimethyl-4,4,7-trioxo-4λ^6-thia-1-azabicyclo[3.2.0]heptane-2carbonyl]oxymethyl (2*S*,5*R*,6*R*)-6-[[(2*R*)-2-amino-2-phenylacetyl]amino]-3,3 dimethyl-7oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate;4-methylbenzenesulfonic acid; dehydrate having molecular formula of $C_{32}H_{42}N_4O_{14}S_3$ and molecular weight is 802.9 with chemical structure as below:



Sultamicillin Tablets are capsule shaped, biconvex, white, film coated tablet having SULBACIN debossed centrally on one side along the length.

The excipients used are Starch, Lactose, Sodium Starch Glycolate, Hydroxy Propyl Cellulose, Magnesium Stearate, Hydroxypropyl Methyl Cellulose, Titanium Dioxide, Diethyl Phthalate, Methanol and Methylene Chloride.

8. Pharmaceutical particulars

8.1 Incompatibilities

None stated

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

SULBACIN is available in blister pack of 10 tablets.

8.4 Storage and handing instructions

Store in a cool & dry place. Protect from light and moisture.

9. Patient Counselling Information

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Package leaflet: Information for the user

SULBACIN

(Ampicillin and Sulbactam)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or nurse.

- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours

The name of your medicine is SULBACIN Tablet

What is in this leaflet?

9.1 What SULBACIN is and what it is used for

9.2 Before you are given SULBACIN

9.3 How SULBACIN should be given

9.4 Possible side effects

9.5 How to store SULBACIN

9.6 Contents of the pack and other information

9.1 What SULBACIN is and what it is used for

SULBACIN contains two active ingredients, Ampicillin and Sulbactam.

SULBACIN is an antibacterial combination consisting of the semisynthetic antibiotic ampicillin sodium and the beta-lactamase inhibitor sulbactam sodium.

SULBACIN is indicated for the treatment of intra-abdominal infections, obstetrics and gynaecological infections, skin and soft tissue infections, bone and joint infections, upper and lower respiratory tract infections, ENT infections, urinary tract infections, gonorrhoea and surgical prophylaxis.

9.2 Before you are given SULBACIN

Know that you are allergic to ampicillin, sulbactam, penicillin, cephalosporins, any other antibiotic or any of the ingredients contained in SULBACIN

- have ever had a skin rash or swelling of the face or neck when taking an antibiotic
- have ever had a serious complaint, such as liver problems, when taking an antibiotic.

If any of the above statements apply to you, you should not be given SULBACIN.

Speak to your doctor before being given SULBACIN if you:

- Have history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before therapy with a penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, and other allergens.
- Are being treated for kidney problems
- Are not passing water well

Tell your doctor if you are using the following medicines (or any other medicines):

- If medicines to help you stop blood clots (such as warfarin), are taken with ampicillin/sulbactam then extra blood tests may be needed.
- Ampicillin/Sulbactam can affect how methotrexate works.
- If you are taking allopurinol, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid, your doctor may decide to adjust your dose of ampicillin/sulbactam.
- If you are taking oral contraceptives, the effect of contraceptives may be reduced.

Pregnancy and breast-feeding

You should let your doctor know if you are pregnant, think you might be pregnant or are breastfeeding before being given this medicine. Your doctor will decide if this medicine is suitable for you.

Driving and using machines

No studies on ability to drive and use machines under influence of ampicillin and sulbactam have been carried out. However, do not drive if you feel affected.

9.3 How SULBACIN should be given

As directed by physician

9.4 Possible side effects

Like many medicines SULBACIN may cause side effects in some patients, particularly when treatment is first started, although not everybody gets them.

The primary adverse effects for ampicillin-sulbactam include seizure, rash, pruritis, diarrhea, enterocolitis, pseudomembranous colitis, vomiting, agranulocytosis, hemolytic anemia, eosinophilia, and immune thrombocytopenia.

Common Adverse Effects

The following adverse reactions have been reported with ampicillin-class antibiotics and can also occur with SULBACIN.

Gastrointestinal: Gastritis, stomatitis, black "hairy" tongue and enterocolitis. Onset of Pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Colitis should be considered, which can be life-threatening or fatal.

Hypersensitivity Reactions: Urticaria, erythema multiforme, and an occasional case of exfoliative dermatitis have been reported. Whenever such reactions occur, the drug should be

discontinued, unless the opinion of the physician dictates otherwise. Serious and occasional fatal hypersensitivity (anaphylactic) reactions can occur with a penicillin.

Hematologic: Agranulocytosis has been reported during therapy with penicillins. Anemia, thrombocytopenic purpura, thrombocytopenia, eosinophilia, agranulocytosis, and leukopenia are reported during ampicillin-sulbactam therapy. All of these reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Impairment of blood coagulation.

Severe Cutaneous Adverse Reactions: Ampicillin and sulbactam for injection may cause severe skin reactions, such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), dermatitis exfoliative, erythema multiforme, and Acute generalized exanthematous pustulosis (AGEP). If patients develop a skin rash they should be monitored closely and ampicillin and sulbactam for injection discontinued if lesions progress.

Central Nervous System: Seizures, vertigo, and headache

Opportunistic Infections:

During therapy, there is a possibility of superinfection with some bacteria or mycotic organisms. In such cases, discontinuation of therapy and substitution of appropriate treatment is warranted.

9.5 How to store SULBACIN

Store in a cool and dry place. Protect from light and moisture.

9.6 Contents of the pack and other information

Sultamicillin Tosilate Dihydrate Ph.Eur. ……..375 mg

(Equivalent to Sulbactam – 147 mg and Ampicillin I.P. – 220 mg)

The excipients used are Starch, Lactose, Sodium Starch Glycolate, Hydroxy Propyl Cellulose, Magnesium Stearate, Hydroxypropyl Methyl Cellulose, Titanium Dioxide, Diethyl Phthalate, Methanol and Methylene Chloride.

SULBACIN is available in blister pack of 10 tablets.

10. Details of manufacturer

Manufactured by:

Torrent Pharmaceuticals Ltd

Indrad – 382721, Dist. Mehsana, India.

At: Plot No. 16, Vardhman Industrial Estate,

Vill – Bahadarpur Saini, N.H. 58, Haridwar – 247667 (Uttarakhand)

OR

Torrent Pharmaceuticals Ltd

Indrad – 382721, Dist. Mehsana, India.

At: Plot No. 21, 22, Pharmacity, Selaqui, Dehradun – 248011 (Uttarakhand)

11. Details of permission or licence number with date

Mfg Lic No. 24/UA/LL/SC/P/2015 issued on 01.01.2018

OR

Mfg Lic No. 92/UA/LL/SC/P-2017

12. Date of revision

Jan 2022

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

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