

## Unicam

### Sultamicillin

#### Tablets and Powder for Suspension

#### Composition:

Each tablet contains Sultamicillin in tosylate equivalent to 375 mg Sultamicillin. Each 5 ml oral suspension contains Sultamicillin 250 mg.

#### Properties and Clinical Pharmacology:

Unicam is a double ester in which ampicillin and the Beta-lactamase inhibitor sulbactam are linked via a methylene group. The tosylate salt is a prodrug of sulbactam and ampicillin in a 1:1 molar ratio in the systemic circulation. The bioavailability of an oral dose is 80% of an equal intravenous dose of sulbactam and ampicillin. Administration of Unicam does not affect the systemic bioavailability of Unicam. Following oral administration of Unicam, peak serum levels of ampicillin are approximately twice those of an equal dose of ampicillin. Elimination half-lives are approximately 45 min. And 1 hour for sulbactam and ampicillin, respectively, with 50-75% of each agent being excreted unchanged in the urine. Sulbactam is an irreversible inhibitor of most important beta-lactamases that occur in penicillin-resistant organisms.

#### Microbiology:

Unicam is effective against a wide range of gram-positive and gram-negative bacteria including: *Staphylococcus aureus* and *epidermidis* (including penicillin and some methicillin resistant strains); *Streptococcus*; *Haemophilus influenzae* and *parainfluenzae* (both beta-lactamase positive and negative strains); *Bránhamella catarrhica*; anaerobes including Bacteroides and related species; *Escherichia coli*; *Klebsiella*; *Proteus* (both indole-positive and indole-negative); and *Enterobacter*; *Morganella morganii*; *Citrobacter*; *Nisseria meningitidis*; and *Nisseria gonorrhoeae*.

#### Indications:

Unicam is indicated for infections caused by susceptible microorganisms. Typical indications are: Upper respiratory tract infections including sinusitis, otitis media and tonsillitis. Lower respiratory tract infections including bacterial pneumonias and bronchitis. Urinary tract infections and pyelonephritis. Skin and soft tissue infections. Gonococcal infections.

#### Intra abdominal Infections:

Unicam oral form may be also indicated in patients requiring Ampicillin/Sulbactam therapy following treatment with parental forms.

#### Contraindications:

Sultamicillin is contraindicated in individuals with history of allergic reactions to any of the penicillins.

#### Precautions:

**Pregnancy:** Safety studies revealed no evidence of impaired fertility or harm to the fetus in animals. Although the safe use of injectable forms in pregnancy was confirmed in human studies, it is not yet well documented for oral forms.

**Infants:** Because of the incompletely developed renal function in neonates, caution should be considered when using Unicam in neonates.

#### Drug Interactions:

The concurrent administration of allopurinol and ampicillin increases the incidence of rashes. However there are no enough data that address the interactions of concurrent administration of Sultamicillin and allopurinol.

#### Adverse Reactions:

Unicam is generally well tolerated. Minor reactions may be observed such as:

Gastrointestinal: Diarrhea, nausea, vomiting and abdominal pain.

Skin Rash and Itching

Miscellaneous: Drowsiness, fatigue and headache have been rarely observed.

#### Dosage and Administration:

**Adults:** 375- 750 mg twice daily.

#### Children:

\* Weighing less than 30 kg: 25-50 mg/kg/day in 2 divided doses depending on the severity of the infection.

\* Weighing more than 30 kg: adult dose is administrated.

#### Treatment of Gonorrhoea:

Recommended dose is 2.25 gm (six 375 mg tablets) as a single oral dose. **In patients with severe renal impairment** (Creatinine Clearance < 30 ml/min): The oral dose should be reduced or the same dose administered less frequently in accordance with usual practice for ampicillin.

#### How Supplied:

Unicam 375 mg tablet: Pack of 12 tablets, store at a temperature not exceeding 30°C, protected from light & moisture.

Unicam powder for suspension: A bottle containing 3 g Sultamicillin + 2 Packs of purified water for reconstitution, 20 ml each, to yield 60 ml suspension of 250 mg / 5 ml sultamicillin, store powder at a temperature not exceeding 25°C.

Shake the suspension well before use.

The reconstituted oral suspension should be discarded after 14 days if kept in refrigerator or 7 days if kept at room temperature.

#### Product of:

Medical Union Pharmaceuticals,  
Abu-Sultan, Ismailia, Egypt.

Issue Date: 6/2/2008, Revision Date:13/1/2008



## يونيكام

### سلتاميسيلين

#### أقراص - مغلي

#### التركيب:

يحتوي القرص على سلتاميسيلين ٣٧٥ ميليغرام. يحتوي كل مل من المغلي على سلتاميسيلين ٢٥٠ مجم.

#### الخواص:

سلتاميسيلين عبارة عن إستر مزيج من الأميسيلين ومادة سولبيكام التي ترتبط على أترزم بيسيتا -الكاميلار . خلال عملية الامتصاص، يتم تعاملي السمتخضر عن طريق نقله داخل الخلية الميثاني الأميسيلين والاميسيلين على التوالي بمسئمة ١:١ في الوريد والسوية، وتعمل الإتاحة الحيوية على نسبة ٨٠٪ من الجرعة الصموية المعطاة عن طريق الحقن عن مادي الأميسيلين والسولبيكام، كما أن الإتاحة الحيوية للسمتخضر لا تتأثر بالمعاطم. وقد تميزت ذروة تركيزات الأميسيلين من البلازما بعد تعاطي سمتخضر يونيكام بقرص على نصفها ما تصل إلى أعلى مسالة تعاطي مادة الأميسيلين منفردة عن طريق الفم. بلغ نصف صامت الطراحي السمتخضر ٤٥ دقيقة في ساعة على شكل من السولبيكام والسولبيكام على التوالي، وحوالي ٥٠-٧٥٪ من عنصرى السمتخضر يتم إخراجها في البول بحالتها الأصلية.

#### المجال البكتيري:

يعتبر يونيكام سمتخضر فعال ضد مجال واسع من البكتيريا الموجبة والسالبة الجرام مثل البكتيريا الغنوبية (المسارفة) للبسيسيليا والبكتريا السحجية، الهميفوقيلان، البشيريشيا، كلستريديا، بروتياس، وبسومريا.

#### فواص الاستخدام:

يستخدم سمتخضر يونيكام في علاج الإصابات البكتيرية المسببة للإلتهابات الجهاز التنفسي العلوي والسفلي، إصابات الجهاز الوريدي، والجهاز المعوي، وإصابات الجلد والأنسجة الرخوة، والسيلان.

#### موانع الاستخدام:

حساسية لأي من مركبات السيلينيل.

#### الاحتياطات:

العمل: في دراسات الأمان لم تثبت أي آثار ضارة على قوة الإخصاب أو على الإحة نتيجة استعمال يونيكام في الحيوان. وقد ثبتت أمان إستخدام يونيكام بحقن الوريدية والعمل في الحيوانات الأثام.

الدراسات الأكلينيكية على السلامة لاستعمال الأقراص والمغلي أثناء الحمل في الإنسان في طي العمل.

#### تفاعلات دوائية:

استخدام مادة الألبوريدينول مع الأميسيلين يزيد من نسبة حدوث الطغخ الحثي.

#### الأعراض الجانبية:

نادر ما يحدث إسهال، غثيان، طفح جلدي، صداع أو دوام.

#### الجرعة:

الكبار (شامل كبار السن): ٣٧٥- ٧٥٠ مجم مرتين يوميا.

الأطفال كل ٣ ساعات: ٢٥٠- ٥٠٠ مجم / اليوم مقسمة على جرعتين.

الإطفال ٣٠٠ مجم أو أكثر: تعطى يومين جرعة الكبار.

يصح باستمرار العلاج لمدة ٥-١٤ يوم تبعا للحالة وشدة الإصابة.

#### علاج السيلان:

٢,٢٥٠ مجم (سنة أقراص كل منها ٣٧٥٠) تؤخذ كجرعة واحدة عن طريق الفم.

#### علاج مرضى الفشل الكلوي:

تعطى الجرعات طبقا لما هو متبع مع الأميسيلين في هؤلاء المرضى.

#### العلاج الوقائي:

علاج بكتيري على ١٢ قرص كل منها ٣٧٥٠ مجم، تحفظ في درجة حرارة لا تزيد عن ٢٠°C، بعيدا عن الضوء والرطوبة. زجاجة تحتوي على ٣ مجم سلتاميسيلين + ٢ كيس مغلي للسمتخضر، يحفظ كل كيس على ١٠٠ مل، لكل، ١٠٠٠ كيلوغرام من المغلي بتركيز ٢٥٠٠ مجم / ٥٠ مل، ويحفظ المسحوق في درجة حرارة لا تزيد عن ٢٥°C.

زجاجة زجاجية جيل أبيض للإستعمال. تحفظ العبوة والتبالة بعد التعصير وتكون مسالحة للإستخدام لمدة ٤ أيام عند حفظه بالتلاجة و٧ أيام عند الحفظ في درجة حرارة الغرفة.

#### التأجير:

شركة المهن الطبية للأدوية

أبو سلطان - الإسماعيلية - مصر

تاريخ الإصدار: ٢٠٠٦/٢/١٦، إعادة مراجعة: ٢٠٠٨/١/١٣



## UNICAM

(Subactam/Ampicillin) Sultamicillin Tablets and Oral Suspension

#### For the medical profession only:

**TRADE NAME UNICAM** (Subactam/Ampicillin) **IMV** FORM 300mg Vials, 150ml mg Vials, 750 mg Vials, 375 mg Vials.

#### Each 3000 mg vial contains:

Subactam sodium (equivalent to 1000mg Subactam) and Ampicillin sodium (equivalent to 2000mg Ampicillin) + water for injection 4ml x 2.

#### Each 1500 mg vial contains:

Ampicillin sodium (equivalent to 1000mg Ampicillin) + water for injection 5ml x 1.

#### Each 750 mg vial contains:

Subactam sodium (equivalent to 500mg Subactam) and Ampicillin sodium (equivalent to 500mg Ampicillin) + water for injection 2ml x 1.

#### Each 375 mg vial contains:

Subactam sodium (equivalent to 250mg Subactam) and Ampicillin sodium (equivalent to 250mg Ampicillin) + water for injection 2ml x 1.

#### DESCRIPTION:

Subactam sodium is a derivative of the beta-lactam nucleus. Chemically it is sodium penicillanic sulfone and is an off-white crystalline powder highly soluble in water. The molecular weight is 352.22. Unicam sodium is derived from the penicillin nucleus, 6-aminopenicillanic acid. Chemically, it is (6S)-6-aminopenicillanic sodium salt and has a molecular weight of 371.26. UNICAM IMV, brand of subactam sodium/ampicillin sodium combination is available as a powder for suspension. It is available in concentrations of filling: 2000mg, 500mg + 1000mg, 250 mg + 500mg, 125 mg + 250mg of subactam and ampicillin respectively.

**INDICATIONS:** Unicam sodium in combination with off-white bacterial systems has shown subactam to be an irreversible inhibitor of most important beta-lactamases that occur in penicillin-resistant organisms. It possesses significant antibacterial activity only against *Neisseria meningitidis*, *Acinetobacter calcoaceticus*, *Bacteroides*, *Bránhamella catarrhica*, and *Pseudomonas aeruginosa*. The potential for subactam sodium to prevent the selection of penicillin- and cephalosporin-resistant organisms was confirmed in whole organism studies using resistant strains, in which subactam sodium exhibited marked synergistic effects on penicillin and cephalosporins. Since subactam sodium is not bactericidal, some sensitive strains are rendered more susceptible to the combination than the beta-lactam antibiotic alone. The biochemical component of the combination is ampicillin which has a broad spectrum of activity against many gram-positive and gram-negative active microorganisms by the inhibition of synthesis of cell wall peptidoglycan. UNICAM IMV is a soluble agent; a wide range of Gram-positive and Gram-negative bacteria are sensitive to subactam sodium and ampicillin including penicillin-resistant and some methicillin-resistant strains; *Streptococcus pneumoniae*; *Streptococcus faecalis* group; *Streptococcus species*; *Staphylococcus aureus* and *Staphylococcus* (both beta-lactamase positive and negative strains); *Bránhamella catarrhica*; anaerobes, including *Bacteroides fragilis* and related species; *Escherichia coli*; *Klebsiella species* (both indole-positive and indole-negative); *Morganella morganii*; *Citrobacter species*; *Enterobacter species*; *Nisseria meningitidis* and *Nisseria gonorrhoeae*. Subactam sodium influences readily into most body tissues and fluids in the body. Penetration into brain and spinal fluid is also good when meninges are inflamed.

High concentrations of subactam and ampicillin are achieved in the blood following intravenous or intramuscular administration and both components are excreted in the urine. Subactam sodium has a half-life of approximately one hour. The half-life of ampicillin is approximately one hour.

**CONTRAINDICATIONS:** NOTE: For information on use in penicillate patients (see PRECAUTIONS-Pharmacokinetics/Use IN SPECIAL SITUATIONS).

**Intra-abdominal Infections** caused by beta-lactamase producing strains of *Escherichia coli*; *Klebsiella species* (including *K. pneumoniae*); *Bacteroides species* (including *B. fragilis*); *Streptococcus pneumoniae*.

**Gonococcal Infections** caused by beta-lactamase producing strains of *Escherichia coli* and *Bacteroides species* (including *B. fragilis*).

NOTE: This agent is not recommended for use in patients less than 10 years old. While ampicillin and subactam for injection is indicated only for the conditions listed above, infections caused by ampicillin-susceptible organisms are also amenable to treatment with ampicillin and subactam for injection when other measures are failed.

Therefore, mild infections caused by ampicillin-susceptible organisms and beta-lactamase producing organisms are amenable to treatment with ampicillin and subactam for injection should not require the addition of another antibiotic. Appropriate culture and susceptibility studies should be performed before treatment in order to isolate and identify the organisms responsible, which will determine their sensitivity to ampicillin and subactam for injection. Therapy may be instituted prior to obtaining the results from bacteriological and susceptibility studies, when there is reason to believe the infection may involve any of the organisms listed above.

NOTE: The results of susceptibility studies should be reported to the physician. The results are known, therapy should be adjusted if appropriate. To reduce the possibility of drug resistance, the medication should be taken exactly as directed. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Appropriate therapy should be instituted. Appropriate culture and other bacteriological studies should be kept in mind through therapy, if superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

the last dose of the antibiotic. If, in this case, patients should contact their physician as soon as possible.

**Use in Pregnancy and Lactation:** Animal reproduction studies have revealed no evidence of impaired fertility or harm to the fetus due to subactam and ampicillin. However, safety data for pregnancy and lactation has not been established.

#### ADVERSE REACTIONS:

**Adult Patients:** Ampicillin and subactam for injection is generally well tolerated. The following adverse reactions have been reported:

**Local Adverse Reactions:** Pain at IM injection site - 16%. Pain at IV injection site - 2%. Thrombocytosis - 2%.

**Systemic Adverse Reactions:** The most frequently reported adverse reactions were diarrhea (3% of the patients) and rash (less than 2% of the patients). Additional systemic reactions reported in less than 1% of the patients were: skin, nausea, vomiting, candidiasis, fatigue, malaise, headache, chest pain, flatulence, abdominal distension, glossitis, urticaria, anguria,