Injection, Tablets and Syrup
SUMOXIL®

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SUMOXIL, an antibiotic, is used to treat a wide variety of infections, including: gonorrhea, middle ear infections, skin infections, upper and lower respiratory tract infections, and infections of the genital and urinary tract. In combination with other drugs, it is also used to treat duodenal ulcers caused by H. pylori bacteria (ulcers in the wall of the small intestine near the exit from the stomach).

SUMOXIL can be taken with or without food. If you are using SUMOXIL suspension, shake it well before using.

Each Tablet contains:
Antibacterials

SUMOXIL
Amoxicillin and Clavulanate potassium USP

Dosage form/s
Injection, Tablets and Syrup

Composition:
SUMOXIL Injection
Each vial contains
Amoxycillin Sodium IP sterile
equivalent to Amoxycillin ..... 1000 mg
Clavulanate potassium USP sterile
Clavulanic acid ..... 200 mg

SUMOXIL 625 Tablets
Each film-coated tablet contains
Amoxycillin trihydrate IP
equivalent to Amoxycillin . . . . . 500 mg
Clavulanic acid ..... 125 mg
(Present as clavulanate potassium USP)
colour :Titanium dioxide

SUMOXIL Syrup
Each 5 ml (on reconstitution)contains
Amoxycillin trihydrate IP
equivalent to Amoxycillin . . . . . 200 mg
Clavulanate Potassium USP
equivalent to Clavulanic acid ..... 28.5 mg
Pharmacology

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Pharmacodynamics :

SUMOXIL is a formulation of amoxycillin and clavulanic acid. Amoxycillin has a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms. Amoxycillin is, however, susceptible to degradation by (beta)-lactamases, and therefore, the spectrum of activity does not include organisms which produce these enzymes. The formulation of amoxycillin and clavulanic acid in SUMOXIL protects amoxycillin from degradation by (beta)-lactamase enzymes and effectively extends the antibiotic spectrum of amoxycillin to include many bacteria normally resistant to amoxycillin and other (beta)-lactam antibiotics.

Amoxycillin/clavulanic acid has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections

Gram-Positive Microorganisms:
Aerobes
Staphylococcus aureus
Coagulase-negative Staphylococci
(including Staphyloccocci epidermidis)
Streptococcus pyogenes
Bacillus anthracis
Corynebacterium species
Streptococcus viridans
Enterococcus faecium
Enterococcus faecalis
Listeria monocytogenes
Streptococcus agalactiae
Anaerobes
Clostridium species
Peptococcus species
Peptostreptococcus species
Gram-Negative Microorganisms:
Aerobes
Escherichia coli
Proteus mirabilis
Proteus vulgaris
Klebsiella species
Salmonella species
Shigella species

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Bordetella pertussis
Gardnerella vaginalis
Legionella species
Brucella species
Neisseria meningitidis
Neisseria gonorrhoeae
Haemophilus influenzae
Moraxella catarrhalis
Pasteurella multocida
Vibrio cholerae
Helicobacter pylori
Yersinia enterocolitica
Anaerobes
Bacteroides species including B. fragilis

Fusobacterium species

Pharmacokinetics :

Combining clavulanic acid with amoxycillin causes no appreciable alteration of the pharmacokinetics of either drug compared with their separate administration. After oral administration, both components achieve maximum plasma concentration in about an hour. Absorption is unaffected by food, milk, ranitidine or pirenzepine. The tissue and body fluid distribution of both components is generally adequate to achieve antibacterial levels, although the concentrations may be somewhat low in bronchial secretions and cerebrospinal fluid. The pharmacokinetic profile of amoxycillin and clavulanic acid in children parallels that in adults.

Indications

SUMOXIL is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below:

Lower Respiratory Tract Infections - caused by (beta)-lactamase producing strains of H. influenzae and M. catarrhalis .

Otitis Media - caused by (beta)-lactamase producing strains of H. influenzae and M. catarrhalis.

Sinusitis - caused by (beta)-lactamase producing strains of H. influenzae and M. catarrhalis .

Skin and Skin Structure Infections - caused by (beta)-lactamase producing strains of S. aureus, E. coli and Klebsiella spp.

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Bone and Joint Infections :
Other infections e.g. intra-abdominal sepsis and dental infections

While SUMOXIL is indicated only for the conditions listed above, infections caused by ampicillin-susceptible organisms are also amenable to treatment with SUMOXIL due to its amoxycillin content. Therefore, mixed infections caused by ampicillin-susceptible organisms and (beta)-lactamase producing organisms susceptible to SUMOXIL should not require the addition of another antibiotic. Because amoxycillin has greater in vitro activity against S. pneumoniae than does ampicillin or penicillin, the majority of S. pneumoniae strains with intermediate susceptibility to ampicillin or penicillin are fully susceptible to amoxycillin and SUMOXIL .
Dosage And Method of Administration

SUMOXIL Injection

SUMOXIL Intravenous may be administered either by intravenous injection or intermittent infusion. It is not suitable for intramuscular administration.

Usual dosages for the treatment of infection.
Adults and children over 12 years Usually 1.2 g thrice daily. In more serious infections, increase frequency to 6 hourly intervals. Maximum adult daily dose should not exceed 7.2 g IV route.
Children 3 months - 12 years Usually 30 mg/kg SUMOXIL 8 hourly.In more serious infections, increase frequency to 6 hourly.

Each 30 mg of SUMOXIL I.V. provides 5 mg clavulanic acid and 25 mg amoxycillin. Therapy can be started parenterally and continued with the oral preparation. Treatment with SUMOXIL should not extend beyond 14 days without review.

Dosage for Surgical Prophylaxis
Procedures lasting for less than 1 hour are covered in adults by 1.2 g SUMOXIL I.V. given at induction of anaesthesia. Longer operation require subsequent doses of 1.2 g SUMOXIL I.V. (up to 4 doses in 24 hours), and this regimen can be continued for several days if the procedure has significantly increased risk of infection. Clear clinical signs of infection at operation will require a normal course of intravenous or oral SUMOXIL therapy post-operatively.

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Renal Impairment

Adults

Mild impairment No change in doseage
Moderate impairment 1.2 g I. V stat followed by 600 mg I.V q 12 hourly
Severe impairment 1.2 g I. V stat followed by 600 mg I.V q 12 hourly . An additional 600 mg IV dose may need to be given during dialysis and at the end of dialysis.

Children

Similar reductions in dosage should be made for children.

Hepatic Impairment

Dose with caution; monitor hepatic function at regular intervals.

Preparation

1.2 g vial : To reconstitute dissolve contents in 20 mL of Water for Injection I.P. (final volume 20.9 mL)

A transient pink colouration may appear during reconstitution. Reconstituted solutions are normally a pale, straw colour.

Intravenous injection

The stability of SUMOXIL intravenous solution is concentration dependent, thus SUMOXIL intravenous should be used immediately upon reconstitution and given by slow intravenous injection over a period of 3-4 minutes. SUMOXIL intravenous solutions should be used within 20 minutes of reconstitution. SUMOXIL may be injected directly into a vein or via a drip tube.

Intravenous infusion:

SUMOXIL intravenous may be infused in water for injection I.P. or sodium chloride intravenous injection I.P. (0.9% w/v). Add without delay*, 1.2 g reconstituted solution to 100 mL infusion fluid. Infuse over 30-40 minutes and complete within 4 hours of reconstitution.

Solutions should be made up to full infusion volume immediately after reconstitution. Any residual antibiotic solutions should be discarded.

Stability and Compatibility

Intravenous infusions of SUMOXIL may be given in a range of different intravenous fluids. Satisfactory antibiotic concentrations are retained at 5°C and at room temperature (25°C) in the recommended volumes of the following infusions fluids. If reconstituted and maintained at room temperature, infusions should be completed within the time stated.

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Reconstituted solutions should not be frozen.
Intravenous infusion fluids Stability period 25°C
Water for Injections I.P 4 hours
Sodium chloride Intravenous Infusion I.P. (0.9% w/v) 4 hours
Sodium Lactate Intravenous Infusion I.P. (one sixth molar) 4 hours
Compound Sodium Chloride Intravenous Infusion I.P. (Ringers solution) 3 hours
Compound Sodium Lactate Intravenous Infusion I.P. (Ringer-Lactate Solution; Hartmann's Solution) 3 hours
Potassium Chloride and Sodium Chloride
Intravenous infusion B.P. 3 hours

SUMOXIL is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solutions of SUMOXIL should therefore, not be added to such infusions but may be injected into the drip tubing, over a period of 3-4 minutes.

For storage at 5°C, the reconstituted solution should be added to pre-refrigerated infusion bags which can be stored for up to 8 hours. Thereafter, the infusion should be administered immediately after reaching room temperatures.

Oral Administration

Tablets should be swallowed whole without chewing. If required, tablets may be broken in half and swallowed without chewing. To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of SUMOXIL is optimized when taken at the start of a meal. Treatment should not be extended beyond 14 days without review.

SUMOXIL Tablets

Usual dosages for the treatment of infection.
Adults and Children over 12 years.
Mild to Moderate Infections
One 625 mg tablet twice a day.

Severe Infections :

One 1 g tablet twice a day.

Dentoalveolar abscess one SUMOXIL 625 mg tablet twice a day for five days.

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Renal Impairment
Adults
1 g tablet should only be used in patients with a glomerular filtration rate >30 mL/min.
Mild impairment
(Creatinine clearance > 30 mL/min)

No change in dosage.
Moderate impairment
(Creatinine clearance 10-30 mL/min)
One 625 mg tablet twice a day. 1 g tablet should not be administered.

Severe impairment
(Creatinine clearance <10 - 30 mL/min)

Not more than one 625 mg tablet every 24 hours.
Hepatic Impairment

Dose with caution; monitor hepatic function at regular intervals.

SUMOXIL 625mg and 1g tablets are not recommended in children of 12 years and under.
SUMOXIL Syrup
Usual dosages for the treatment of infection.

Patients aged 12 weeks (3 months) and older.
Mild to Moderate infections
25/3.6 mg/kg/day b.i.d
Severe Infections and Otitis media, sinusitis, lower respiratory infections 45/6.4 mg/kg/day
b.i.d
Infants with immature kidney function
For infants with immature renal function SUMOXIL Syrup 228 mg/5 mL is not recommended.

Renal Impairment
For children with GFR of > 30 mL/min no adjustment in dosage is required. For children with a GFR of < 30 mL/min SUMOXIL Syrup 228/5 mL is not recommended.

Hepatic Impairment
Dose with caution; monitor hepatic function at regular intervals. There is, as yet, insufficient evidence on which to base a dosage recommendation.

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Contraindications :

SUMOXIL is contraindicated in patients with a history of allergic reactions to any penicillin. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics , e.g. cephalosporins. It is also contraindicated in patients with a previous history of cholestatic jaundice/hepatic dysfunction associated with amoxycillin- clavulanate.

Warnings and Precautions :

Before initiating therapy with SUMOXIL , careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, SUMOXIL should be discontinued and the appropriate therapy instituted. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including SUMOXIL , and has ranged in severity from mild to life-threatening. Mild cases of Pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against C. difficile colitis .

If the parenteral administration of high doses is necessary, the sodium content must be taken into account in patients on a sodium restricted diet.

Change in liver function tests have been observed in some patients receiving amoxycillin- clavulanate. The clinical significance of these changes is uncertain but SUMOXIL should be used with caution in patients with evidence of severe hepatic dysfunction. Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for several weeks after treatment has ceased.

SUMOXIL should be avoided if infectious mononucleosis is suspected since the occurrence of morbilliform rash has been associated with this condition following the use of amoxycillin. In patients with moderate or severe renal impairment SUMOXIL Syrup 228 mg/5 mL is not recommended. Erythematous rashes have been associated with glandular fever in patients receiving amoxycillin. SUMOXIL should be avoided if glandular fever is suspected. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxycillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxycillin crystalluria.

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SUMOXIL Syrup 228 mg/5mL contains 12.5mg aspartame per 5mL dose and therefore care should be taken in phenylketonuria.

While SUMOXIL possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic function, is advisable during prolonged therapy.
Drug Interactions

Probenecid :Probenecid decreases the renal tubular secretion of amoxycillin. Concurrent use with SUMOXIL may result in increased and prolonged blood levels of amoxycillin. Co-administration of probenecid cannot be recommended.

Anticoagulants: Prolongation of bleeding time and prothrombin time have been reported in some patients receiving amoxycillin/clavulanic acid. SUMOXIL should be used with care in patients on anti-coagulation therapy.

Allopurinol : The concurrent administration of allopurinol and amoxycillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxycillin alone. There are no data with SUMOXIL and allopurinol administered concurrently.

Contraceptives : In common with other broad-spectrum antibiotics, SUMOXIL may reduce the efficacy of oral contraceptives.

Renal Impairment: Please refer dosage and administration.

Hepatic Impairment: Please refer dosage and administration .

Pregnancy (Category B) : There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Lactation : SUMOXIL may be administered during lactation. With the exception of the risk of sensitization, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the infant.

Paediatrics: As per directions given in dosage and administration.
Undesirable Effects

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Amoxycillin- clavulanate is generally well tolerated. The majority of side effects observed in clinical trials were of a mild and transient nature and less than 3% of patients discontinued therapy because of drug-related side effects. From the original premarketing studies, where both paediatric and adult patients were enrolled, the most frequently reported adverse effects were diarrhoea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%) and vaginitis (1%). The overall incidence of side effects, and in particular diarrhoea, increased with the higher recommended dose. Other less frequently reported reactions include: Abdominal discomfort, flatulence, and headache.

Overdosage

Following overdosage, patients have experienced primarily gastrointestinal symptoms including stomach and abdominal pain, vomiting, and diarrhoea. Rash, hyperactivity, or drowsiness have also been observed in a small number of patients.

In the case of overdosage, discontinue SUMOXIL , treat symptomatically, and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed.

Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxycillin. Crystalluria, in some cases leading to renal failure, has also been reported after amoxycillin overdosage in adults and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxycillin crystalluria.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of both amoxycillin and clavulanate. Both amoxycillin and clavulanate are removed from the circulation by hemodialysis.

Incompatibilities

SUMOXIL intravenous should not be mixed with blood products, other proteinaceous fluid such as protein hydrolysates or with intravenous lipid emulsions. If SUMOXIL is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions.

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Shelf-life
SUMOXIL 625 Tablets 18 months
SUMOXIL Syrup 18 months
SUMOXIL Injection 2 years

Packaging information
SUMOXIL 625 Tablets Blister of 6 tablets
SUMOXIL Syrup Bottle of 30ml
SUMOXIL Injection Vial of 1.2g

Storage and handling instructions
SUMOXIL Injection store below 25° C.
SUMOXIL 625 tablets store in a dry place below 25 °C.