

Product Detail

Zailin Granules

Basic Information

Generic name: Amoxicillin Granules

Originally used name: Amoxicillin granules

Trade name: Zailin

Chinese Phonetic Alphabet: Amoxicillin Keli

This product contains Amoxicillin as its main ingredient. Chemically it is (2S,5R,6R)-3,3-dimethyl-6-[(R)-(-)-2-amino-2-(4-hydroxyphenyl)acetamido]-7-oxo-4-thia-1-azadicyclo-[3,2,0] heptane-2-carboxylic acid trihydrate. It has the following chemical structure:

The amoxicillin molecular formula is $C_{16}H_{19}N_3O_5S \cdot 3H_2O$, and the molecular weight is 419.45.

Properties and Appearance

This is a yellowish granules and powder with fragrant smell and sweet taste.

Indication

Amoxicillin is indicated for treatment of the infections (including lower respiratory tract infection, typhoid and urinary tract infections) when caused by susceptible strains (Only betalactamase – negative) of microorganisms :

1. Otitis media, sinusitis, pharyngitis, tonsillitis due to *S. pyogenes*, *Streptococcus pneumoniae*, *S.A* and *H influenzae*.
2. Infection of genitourinary tract due to *Escherichia coli*, *P. mirabilis* and *Enterococcus faecalis*.
3. Infection of skin and soft tissue due to *Streptococcus spp.* or *E.coli*.
4. Infections of lower respiratory tract due to *Streptococcus spp.* *Streptococcus pneumoniae*, or *H influenzae*.
5. Acute uncomplicated Gonorrhoea.
6. Typhoid and Leptospirosis. Amoxicillin, in combination with lansoprazole and clarithromycin, is indicated for treatment of patients with *H. pylori* infection and duodenal ulcer disease.

Specification

0.125g (calculated as $C_{16}H_{19}N_3O_5S$).

Dosage and Administration

Oral administration: Open the sachet, add granule to cold water, shake well before drink.

For children: The recommended daily dose is 20 to 40 mg/kg body weight, for every 8 hours; The recommended dose for neonates and premature: 50mg each time, For infants under 3 months of age: daily dose is 30mg/kg body weight, every 12 hours.

Recommended dose of Amoxicillin granules for children		
Age	0.125g/bag/each time	Daily dose
Under 1 year	0.5 bags	Three times daily or follow the advice of a doctor
Between 1 and 3 years	1 bag	
Between 3 and 5	1.5 bags	
Between 5 and 10	2 bags	

Over 10 years	2 or 3 bags	
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For adult: 0.5g (4 bags) each time, every 6 to 8 hours. The daily dose shall not exceed 4g (32 bags).

Adverse Effects

1. Gastrointestinal tract reactions such as nausea, vomiting, diarrhoea and pseudomembranous colitis.
2. Anaphylactic reactions such as skin eruption, drug fever, and asthma.
3. Anaemia, thrombocytopenia, eosinophilia, and others.
4. Slightly rise in AST (SGOT) and/or ALT (SGPT).
5. Super- infection due to Monilia or drug-fast bacteria.
6. Rare case of central nervous system symptoms such as agitation, anxiety, insomnia , dizziness and behavioral changes may also be found occasionally.

Contraindications

A history of allergic reaction to any of the penicillins is a contraindication

Precautions

1. Patients with acute epidemic infection adenitis should avoid this product because of possibility of erythra..
2. Patients prescribed long-term treatment with this product should have hepatic function, renal function, and routine blood examinations.
3. Amoxicillin may result in a false positive result when testing for the presence of glucose in the urine using Benedict or Fehling's solution.
4. This product should be cautiously used in the following cases:
 - (1). Patients with a hypersensitive history including asthma and allergic cold.
 - (2). Dose adjustment may be required for aged patients and the patients with seriously impaired renal function.
 - (3). 0.25 to 0.5g (2 to 4 bags) each 12 hours may be given for the patients whose endogenous creatinine clearance rate is between 10 and 30ml/min; or 0.25 to 0.5g (2 to 4 bags) each 24 hours for the patients whose endogenous creatinine clearance rate is below 10ml/min.

Administration for Pregnant Women and Nursing Mothers

It is shown in an animal reproduction test that 10 times of the dose for human does not show impairment of fertility, their embryos and gets of rat and mouse. However, no sufficient study on human is available now. Because of the fact that that the impact to human cannot be predicted from the result of the animal experience, pregnant woman should only use this product only when it is necessary.

Small amount of Amoxicillin may be excreted into mother's milk. Amoxocillin used by nursing mother may lead to sensitization of infants.

Use in Children

Amoxicillin can be used by children

Use in Aged People

Dose adjustment may be required in aged people with impaired renal function.

Drug Interaction

1. Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of amoxicillin and probenecid may result in increased serum levels of amoxicillin and prolonged half-life.
2. Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the anti-bacterial activities of Amoxicillin. However, the clinical significance of this interaction is not well established.

Overdose

A prospective clinical study of 51 pediatric patients suggested that overdoses of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms. Overdosage which resulting oliguric renal insufficiency has been reported in a small number of patients. These renal impairment are reversible after discontinuation of medication.

Pharmacological and Toxicological Action

Amoxicillin is a kind of penicillin antibiotics. It exhibits good antimicrobial activities against, *Streptococcus Spp* (including *S pneumoniae*, *S hemolytic strains*), *S.A spp* (betalactamase – negative strains) *Enterococcus faecalis*, *Escherichia coli*, *H influenzae*. *P. mirabilis* and *neisseria gonorrhoeae*.

Amoxicillin acts through the inhibition of biosynthesis of cell wall mucopeptide so as to turn the bacteria into glomeration and cause breakage and lysis of bacteria .

Pharmacokinetics

Following oral administration, amoxicillin is absorbed rapidly, and about 75 to 90% may be absorbed via the gastrointestinal tract. The peak concentration level of the drug in blood, C_{max} , are 5.1mg/L, 10.8mg/L, and 20.6mg/L, respectively, the time to reach peak value is 1 to 2 hrs, for orally taken doses of 0.25g, 0.5g and 1g. This product is well distributed in the majority of tissues and body fluids. The average concentrations in the sputum of the patients of pneumonia or an AECB may reach 0.52mg/L and 0.53mg/L, respectively, 2 to 3 hours and 6 hours after they orally take 0.5g of this product, at the same time, the concentrations in the blood are 11mg/L and 3.5mg/L, respectively. The concentration in the auris media fluid of the children patients suffering from Chronic otitis media may reach 6.2mg/L 1 or 2 hours after they orally take 1g of this product. The concentration in the cerebrospinal fluid of the patients suffering from tuberculosis meningitis may reach 0.1~1.5mg/L 2 hours after they orally take 1g of this product, corresponding to 0.9%~21.1% of the concentration in the blood in the corresponding time. This product may penetrate through the placenta, yielding a concentration in the cord blood equal to 1/4~1/3 of the concentration in the mother's blood, and trace of this product may also be found in human milk, sweat, and tear. The serum protein binding rate of this product is 17%~20%. $T_{1/2\beta}$, is 1 to 1.3 hrs after taken, 24%~33% of the dose is metabolized via the liver, 45%~68% of the taken dose is excreted unchanged within 6hrs after taken, part of the taken dose is excreted via the biliary tract. The serum half-life may be prolonged to 7 hours for the patients with serious hepatic function insufficiency. This product may be eliminated by hemodialysis but not by peritoneal dialysis.

Storage

Keep it tightly sealed in a dark, cold and dry place.

Package

Packaged in aluminum foil bags covered with plastic film, 18 bags each box.

Shelf Life

36 months.

Acting Standard

WS-10001-(HD-0102)-2002

License Number

GYZ H46020605

Manufacturer

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