



1.6.3 Patient information leaflet (PIL)

49098单 0.25g阿莫西林胶囊说明书130*180mm/董

AMOXIMED
AMOXYCILLIN BP 250 / 500 mg CAPSULES

POM
COMPOSITION:
Amoxicillin trihydrate BP available as:
Amoxicillin 250: gelatin capsules containing the equivalent of 250 mg amoxicillin
Amoxicillin 500: gelatin capsules containing the equivalent of 500 mg amoxicillin

PHARMACOLOGICAL CLASSIFICATION:
Penicillins.

PHARMACOLOGICAL ACTION:
Amoxicillin is a penicillimase-susceptible penicillin. Amoxicillin exhibits in vitro, bactericidal activity against a wide range of Gram-negative and Gram-positive organisms including: (in vitro sensitivity does not necessarily imply in-vivo efficacy)

Gram-positive bacteria:	Gram-negative bacteria:
Staphylococcus aureus *	Neisseria gonorrhoea
(penicillin sensitive)	Neisseria meningitidis **
Streptococcus pyogenes	Haemophilus influenzae
Streptococcus viridans *	Bordetella pertussis
Streptococcus faecalis *	Escherichia coli
Streptococcus pneumoniae *	Salmonella typhi
Corynebacterium species *	Salmonella species
Clostridium species *	Shigella species
Bacillus anthracis *	Brucella species
Proteus mirabilis	

* Sensitivity tests must be performed
** Except type b-strains causing meningitis in children

Amoxicillin is well absorbed orally. After oral administration, there is no significant difference between the peak serum levels in fasting and non-fasting subjects. The presence of food does not interfere with the absorption of amoxicillin. Amoxicillin may, therefore, be taken with meals.
There is a linear/dose response in peak serum levels after oral administration.
There is insufficient evidence at present to show that Amoxicillin penetrates into the cerebro-spinal fluid in therapeutic quantities and it should, therefore, not be used in the treatment of cerebro-spinal infections.
Approximately 60% of an oral dose of amoxicillin is excreted unchanged in the active form into the urine within six hours.

INDICATIONS:
Infections caused by susceptible non-penicillinase-producing organisms including:
Upper respiratory tract infections Skin & soft tissue infections
Lower respiratory tract infections Gonorrhoea
Otitis media Non-specific urethritis
Upper urinary tract infections Typhoid Fever
Lower urinary tract infections Gastro-intestinal tract infections

CONTRA-INDICATIONS:
Allergy to penicillins or any of the cephalosporins.
Patients with infectious mononucleosis since they are especially susceptible to amoxicillin induced skin rashes; patients with lymphatic leukaemia and patients with hyperuricaemia being treated with allopurinol may also be at increased risk of developing skin rashes.

DOSAGE AND DIRECTIONS FOR USE:
Adults and children with a mass of more than 40 kg: 250 mg to 500 mg three times per day. The latter dosage is for the more severe infections.

Age and Mass	% of Adult Dose	Usual Total Daily Dose Range*
Adults (65 kg)	100%	750 mg - 1.5 g
12 years (40 kg)	75%	525 mg - 1,125 mg
7 years (23 kg)	50%	375 mg - 750 mg

1 year (10 kg)	25%	187 mg - 375 mg
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* Administered in divided doses three times per day.

For in-between ages, in-between percentages are used, e.g. at 10 years 66% and at three years 33% of the adult dose. The above percentage method of calculating dosage is based on the formula:-
% Adult dose = $\frac{\text{surface Area of child}}{\text{Surface Area of adult}} \times 100$

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Gastro-intestinal disturbances, including diarrhoea, nausea and vomiting occur frequently. Allergic reactions may occur presenting as a pruritic skin rash, an erythematous skin reaction or urticaria. In this event withdrawal of Amoxicillin is necessary.
Should a serious anaphylactic reaction occur Amoxicillin should be discontinued and the patient treated with Adrenalin, corticosteroids and antihistamines.
Treatment with Amoxicillin may give rise to a maculopapular rash during therapy or within a few days after completion thereof. The incidence of maculopapular rash is especially high in patients suffering from infectious mononucleosis.
Pseudomembranous colitis has been reported. Super-infections with non-susceptible organisms may occur.
Caution must be exercised in treating patients with dehydration or oliguria because of the possibility of crystalluria.
The use of this antibiotic may lead to the appearance of resistant strains of organisms and sensitivity testing should therefore, be carried out wherever possible, to ensure the appropriateness of the therapy.

SPECIAL PRECAUTIONS:
The dose should be reduced in patients with renal failure. Caution is needed when administering Amoxicillin to patients with syphilis, as the Jarisch-Herxheimer reaction may occur in these patients. Amoxicillin may decrease the efficacy of oestrogen-containing oral contraceptives. Due to Amoxicillin's effect on intestinal flora the absorption of other medicines may be affected.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "side-effects and special precautions". Treatment is symptomatic and supportive.

IDENTIFICATION:
Amoxicillin 250 mg: Opaque yellow body and an opaque red cap, printed in black ink "250" on one section.
Amoxicillin 500 mg: Opaque yellow body and an opaque red cap, printed in black ink "500" on one section.

PRESENTATION:
AMOXYCILLIN 250 (CAPSULES): White containers containing 1000 and box of 10 x 10 capsules.
AMOXYCILLIN 500 (CAPSULES): White containers containing 500 and box of 10 x 10 capsules.

STORAGE INSTRUCTIONS:
Store in a dry place below 30°C. Protect from Light.
KEEP MEDICINES OUT OF REACH OF CHILDREN.

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