



1.6 Product Information

1.6.1 Prescribing information (Summary of Product Characteristics)

(1) Name of the medicinal product

Amoxicillin capsules

(2) Qualitative and quantitative composition

Amoxicillin capsules contains amoxicillin trihydrate equivalent to amoxicillin 250 mg.

(3) Pharmaceutical form

Hard capsule

(4) Clinical particulars

(4.1) 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

(4.2) Contraindications

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.

(4.3) Dosage and direction for use

Adults and children with a mass of more than 40 kg:

250 mg to 250 mg three times per day. The latter dosage is for the more severe infections.

Age and mass	% of adults 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 (23 kg)	25%	187 mg-375 mg

* 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=(surface area of child/surface area of adult)*100



(4.4) 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.

(4.5) Special warnings and precautions for use

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.

(4.6) Known symptoms of over dosage and particulates of its treatment

See "Side-effects and special precautions". Treatment is symptomatic and supportive.

(5) Identification

Amoxicillin 250 mg: opaque yellow body and opaque red cap, printed in black ink "250" on one section

Amoxicillin 500 mg: opaque yellow body and opaque red cap, printed in black ink "500" on one section

(6) Presentation

AMOXYCILLIN 250 (CAPSULES): White containers containing 1000 and box of 10*10 capsules

AMOXYCILLIN 500 (CAPSULES): White containers containing 500 and box of 10*10 capsules

(7) Storage instructions

Store in a dry place below 30°C. Protect from light.

Keep medicine out of reach of children



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CSPC

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