

(For the use of a Registered Medical Practitioner, Hospital or a Laboratory)  
**AMOXICILLIN CAPSULES BP 500 mg**  
**AEROCILLIN™**

**COMPOSITION**

Each hard gelatin capsule contains:  
Amoxicillin Trihydrate B.P.  
Eqv. to Amoxicillin.....500mg  
Excipients.....q.s.  
Approved colour used in empty capsule shell.

**DESCRIPTION**

The name of your medicine is Amoxicillin. It contains the active ingredient amoxicillin trihydrate. This belongs to a group of antibiotics called penicillins. Amoxicillin can be used to treat bacterial infections of: the respiratory tract (nose, throat and lungs), the skin and soft tissue, the urinary system (bladder and kidneys), the female reproductive system, the ear, nose and throat, the gums and teeth, the blood, bone and abdomen. Amoxicillin can also be used in combination with other medicines to treat stomach ulcers, as well as in patients with heart disease who need protection from infection during dental treatment.

**CLINICAL PHARMACOLOGY**

Amoxicillin is stable in the presence of gastric acid and is rapidly absorbed after oral administration. The effect of food on the absorption of amoxicillin from the tablets and suspension of Amoxicillin has been partially investigated. Formulations have been studied only when administered at the start of a light meal. However, food effect studies have not been performed with the 500-mg formulations. Amoxicillin diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. The half-life of amoxicillin is 61.3 minutes. Most of the amoxicillin is excreted unchanged in the urine; its excretion can be delayed by concurrent administration of probenecid. In blood serum, amoxicillin is approximately 20% protein-bound. Orally administered doses of 500-mg amoxicillin capsules result in average peak blood levels 1 to 2 hours after administration in the range of 3.5 mcg/mL to 5.0 mcg/mL and 5.5 mcg/mL to 7.5 mcg/mL, respectively.

**SIDE EFFECT**

Allergic reactions, which may cause an itchy skin rash, swelling of the face, lips, tongue or throat, difficulty in breathing, speaking or swallowing, dizziness or collapse, flat red spots under the skin surface or bruising of the skin. This is due to an allergic reaction caused by inflammation of blood vessel walls, a delayed allergic reaction which can occur 7 to 14 days after taking this medicine. The signs may include rashes, fever, joint pain or swollen lymph nodes, itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, other severe skin reactions causing small pus-containing blisters, changes in skin colour, flaky skin, peeling, redness or blistering of the skin, mouth, eyes or genitals. These may be associated with fever, headaches and body aches, blood disorders, which may cause fever, chills, sore throat, ulcers in the mouth or throat, unexplained bleeding or bruising.

**DOSAGE**

Adults, Elderly and Children over 10 years old: The usual dose is 500 mg three times a day. Children under 10 years old: For severe infections your doctor may give your child 500 mg three times a day. Oral suspensions containing amoxicillin are recommended for infants, as well as children who cannot swallow capsules. People with kidney problems: Your doctor may have to lower your dose. If you take more Amoxicillin than you should If you take more Amoxicillin than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. Signs of an overdose may include feeling sick, being sick, diarrhoea or crystals in the urine, which may be seen as cloudy urine, or difficulty in passing urine.

**INDICATIONS AND USAGE**

Amoxicillin is indicated in the treatment of infections due to susceptible (ONLY  $\beta$ -lactamase-negative) strains of the designated microorganisms in the conditions listed below: Infections of the ear, nose, and throat – due to *Streptococcus* spp. ( $\alpha$ - and  $\beta$ - hemolytic strains only), *S. pneumoniae*, *Staphylococcus* spp., or *H. influenzae*, Infections of the genitourinary tract – due to *E. coli*, *P. mirabilis*, or *E. faecalis*. Infections of the skin and skin structure – due to *Streptococcus* spp. ( $\alpha$ - and  $\beta$ -hemolytic strains only), *Staphylococcus* spp., or *E. coli*. Infections of the lower respiratory tract – due to *Streptococcus* spp. ( $\alpha$ - and  $\beta$ -hemolytic strains only), *S. pneumoniae*, *Staphylococcus* spp., or *H. influenzae*. Gonorrhoea, acute uncomplicated (ano-genital and urethral infections) – due to *N. gonorrhoeae* (males and females). *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence Amoxicillin, in combination with clarithromycin plus lansoprazole as triple therapy, is indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or 1-year history of a duodenal ulcer) to eradicate *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence

**CONTRAINDICATION**

- If patient are allergic to penicillin or similar types of antibiotics such as cephalosporins. If you have ever had an allergic reaction (such as a rash) when taking an antibiotic you should tell your doctor before you take Amoxicillin.
- If patient have ever had an allergic reaction to amoxicillin or any of the ingredients listed toward the end of this leaflet.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn or shows signs of tampering.

**STORAGE:** Store below 25°C. Protect from light.

Keep all medicines out of reach of children.

**WARNINGS AND PRECAUTIONS**

Talk to your doctor or pharmacist before taking Amoxicillin Capsules if you: suffer from kidney problems or kidney disease and have glandular fever.

**PRESENTATION:** Each Pack contains 10×10 Capsules.

**Manufactured for:** Area Biotech Pvt Ltd.  
**Marketed and Exported By:**  
**AREA IMPORTERS & EXPORTERS PVT. LTD.**  
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