

Amoclaz 375

Amoxicillin & Clavulanate Potassium Tablets USP 375 mg

Composition :

Each film coated tablet contains:

Amoxicillin Trihydrate USP

Eq. to Amoxicillin 250 mg

Diluted Potassium Clavulanate BP

Eq. to Clavulanic acid 125 mg

Excipients q.s.

Colour : Titanium Dioxide USP

Indications:

It is indicated for the treatment of the following infections in adults and children:

Acute bacterial sinusitis (properly diagnosed)

acute otitis media

Acute exacerbation of chronic bronchitis (properly diagnosed)

Community acquired pneumonia

cystitis

pyelonephritis

Skin and soft tissue infections in particular cellulitis, animal bites, abscess

severe dental disease with spread of cellulitis.

Bone and joint infections, in particular osteomyelitis.

Official guidance on the proper use of antibacterial agents should be considered.

Dosage: As directed by the physician.

Contraindications: Hypersensitivity to the active substances, to any of the penicillins or any of the excipients. History of a severe immediate hypersensitivity reaction (eg, anaphylaxis) to another beta-lactam agent (eg, a cephalosporin, carbapenem or monobactam). History of jaundice/liver failure due to amoxicillin / clavulanic acid.

Special warnings and precautions for use: Before starting therapy with amoxicillin / clavulanic acid, previous hypersensitivity reactions should be carefully investigated penicillin, cephalosporins or other beta-lactam agents. If an allergic reaction occurs, amoxicillin/clavulanic acid therapy should be discontinued and appropriate alternative therapy instituted. This presentation is not suitable for use when there is a high risk that the presumptive pathogens have reduced sensitivity or resistance to beta-lactam agents that are not mediated by beta-lactamases susceptible to inhibition by clavulanic acid. Amoxicillin / clavulanic acid should be avoided if infectious mononucleosis is suspected. Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic impairment.

In patients with renal impairment, the dose should be adjusted according to the degree of commitment.

Interaction with other drugs and other forms of interaction Oral anticoagulants:

Oral anticoagulants and penicillin-based antibiotics have been widely used in practice without reports of interaction.

Methotrexate: Penicillin may reduce the excretion of methotrexate, causing a potential increase in toxicity.

Probenecid: Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increase and prolongation of blood levels of amoxicillin but not clavulanic acid.

Fertility, pregnancy and breastfeeding

Pregnancy: The use of amoxicillin/clavulanic acid during pregnancy in humans does not indicate a increased risk of congenital malformations. Use should be avoided during pregnancy, unless deemed essential by the physician.

Breastfeeding: Both substances are excreted in breast milk (nothing is known about the effects of clavulanic acid on the breastfeed infant). Consequently, diarrheal infection and mucus membrane

fungus is possible in the infant, so breastfeeding may have to be discontinued. The possibility of sensitization must be taken into account.

Amoxicillin/clavulanic acid should only be used during breastfeeding after evaluation benefit/risk by the responsible physician.

Lactation: Both substances are excreted in breast milk (nothing is known about the effects of clavulanic acid in the breastfeed infant). Consequently, diarrheal and fungal infection of mucous membranes is possible in the infant, so breastfeeding may have to be discontinued.

Do not take :

*if you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine

*if you have ever had a severe allergic reaction to any other antibiotic. This may include a rash or swelling of the face or throat.

*If you have ever had liver problems or jaundice (yellowing of the skin) when took an antibiotic.

→ Do not take if any of the above apply to you. If in doubt, talk to your doctor or pharmacist before taking this medicine.

Other medicines with amoxicillin and clavulanic acid tablets

Tell your doctor or pharmacist if you are using, have recently used or might use any other medication.

*If you are taking allopurinol (used for gout), you may be more likely to have an allergic skin reaction.

*If you are taking probenecid (used for gout), your doctor may decide to adjust your dose.

*If medications are needed to help stop blood clots

(such as warfarin), additional blood tests may be needed.

Amoxicillin and clavulanic acid pills can affect how methotrexate (medicine used to treat cancer or rheumatic diseases) works.

Amoxicillin and clavulanic acid tablets can affect how mycophenolate mofetil (a drug used to prevent rejection of transplanted organs) works.

Undesirable effects:

The most common adverse drug reactions reported are diarrhoea, nausea and vomiting.

Overdose: Symptoms and signs of overdose Gastrointestinal symptoms and disturbance of fluid and electrolyte balances may be evident. Amoxicillin crystalluria, in some cases leading to renal failure has been observed. Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses.

Storage:

Stored below 30°C in a dry & dark place.

Keep the medicine out of reach of children.

Presentation: 3 Blisters of 7 tablets.

