

Vitaclav[®]

Svitaclav

Amoxicillin and Clavulanic Acid Tablets

625

500mg/125mg

Composition: Each film-coated tablet contains:

Amoxicillin trihydrate BP
equivalent to Amoxicillin 500 mg
Diluted potassium clavulanate BP
equivalent to Clavulanic acid 125 mg
Excipients q.s.
Color: Titanium dioxide BP

Indications

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

Acute bacterial sinusitis (adequately diagnosed)
Acute otitis media
Acute exacerbation of chronic bronchitis (adequately diagnosed)
Community-acquired pneumonia
Cystitis
Pyelonephritis
Skin and soft tissue infections, particularly cellulitis, animal bites, and severe dental abscess with spreading cellulitis.
Bone and joint infections, particularly osteomyelitis.
Official guidance on the appropriate 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 to any of the excipients. History of a severe immediate hypersensitivity reaction (e.g., anaphylaxis) to another beta-lactam agent (e.g., a cephalosporin, carbapenem, or monobactam). History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid.

Special warnings and precautions for use: Before initiating therapy with amoxicillin/clavulanic acid, careful inquiry should be made regarding previous hypersensitivity reactions to penicillins, cephalosporins, or other beta-lactam agents.

If an allergic reaction occurs, therapy with amoxicillin/clavulanic acid must be discontinued and appropriate alternative therapy instituted. This formulation is not suitable for use when there is a high risk that the suspected pathogens have reduced susceptibility or resistance to beta-lactam agents that is 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 impairment.

Interaction with other medicinal products 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, potentially leading to increased toxicity.

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

Fertility, pregnancy, and breastfeeding

Pregnancy: Use of amoxicillin/clavulanic acid during human pregnancy does not indicate an increased risk of congenital malformations. Use should be avoided during pregnancy unless considered essential by the physician.

Breastfeeding: Both substances are excreted in breast milk (nothing is known about the effects of clavulanic acid on the breastfed infant). Consequently, diarrhea and fungal infections of the mucous membranes are possible in the infant, so breastfeeding may need to be discontinued. The possibility of sensitization must be taken into account. Amoxicillin/clavulanic acid should only be used during breastfeeding after a benefit/risk assessment by the attending physician.

Breastfeeding: Both substances are excreted in breast milk (nothing is known about the effects of clavulanic acid on the breastfed infant). Consequently, diarrhea and fungal infections of the mucous membranes are possible in the infant, so breastfeeding may need to be discontinued.

Do not take:

*if you are allergic to amoxicillin, clavulanic acid, penicillin, or any other ingredient of this medicine
*if you have ever had a severe allergic reaction to any other antibiotic. This may include a skin rash or swelling of the face or throat.

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

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

Other medicines and amoxicillin/clavulanic acid tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

*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 medicines to help stop blood clots (such as warfarin) are needed, additional blood tests may be required.

Amoxicillin/clavulanic acid tablets may affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
Amoxicillin/clavulanic acid tablets may affect how mycophenolate mofetil (a medicine used to prevent organ transplant rejection) works.

Undesirable effects: The most frequently reported adverse drug reactions are diarrhea, nausea, and vomiting.

Overdose: Symptoms and signs of overdose. Gastrointestinal symptoms and disturbances of fluid and electrolyte balance 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: Store below 25°C in a dry place. Protect from light.

Keep medicines out of the reach of children.

Presentation: 2 blisters of 7 tablets.



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