

**CONSUMER INFORMATION****PR AMOXI-CLAV**  
Amoxicillin/Clavulanic Acid  
Tablets USP

This leaflet is designed specifically for consumers. This leaflet is a summary and will not tell you everything about AMOXI-CLAV. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

AMOXI-CLAV is an antibiotic which is used to treat various bacterial infections, as determined by your doctor. It contains two medicinal ingredients: one is a penicillin called amoxicillin and the other is clavulanic acid.

**What it does:**

AMOXI-CLAV works in 2 ways. Amoxicillin interferes with bacterial cell wall growth leading to bacterial death. AMOXI-CLAV interferes with bacterial enzymes which destroy antibiotics allowing antibiotics to continue killing bacteria.

**When it should not be used:**

Do not use AMOXI-CLAV if:

- If you or your child currently have or have had a history of an allergy to amoxicillin or beta-lactam antibiotics (such as penicillins and cephalosporins) or any of the other ingredients of AMOXI-CLAV.
- If you or your child currently have or have had a history of jaundice (yellowing of the skin and/or eyes) or liver disease while taking AMOXI-CLAV.
- You have or your doctor believes you have glandular fever (mononucleosis).

**What the medicinal ingredient is:**

AMOXI-CLAV tablets contain the medicinal ingredients amoxicillin trihydrate and clavulanate potassium.

**What the important nonmedicinal ingredients are:**

AMOXI-CLAV contains the following non medicinal ingredients magnesium stearate, croscarmellose sodium, colloidal silicon dioxide, hydroxypropyl cellulose, polyethylene glycol, and titanium dioxide (tablets).

**What dosage forms it comes in:****Tablets of:**

250/125 mg Amoxicillin/Clavulanic Acid  
500/125 mg Amoxicillin/Clavulanic Acid  
875/125 mg Amoxicillin/Clavulanic Acid.

**WARNINGS AND PRECAUTIONS**

BEFORE you use AMOXI-CLAV talk to your doctor or pharmacist if you or your child:

- are allergic to amoxicillin or beta-lactam antibiotics (such as penicillins and cephalosporins) or any of the other ingredients of AMOXI-CLAV. If you or your child have had an allergic reaction (such as a rash) when taking an antibiotic, you should talk to your doctor before taking AMOXI-CLAV.
- develop a skin rash while taking AMOXI-CLAV. Stop taking AMOXI-CLAV and immediately tell your doctor.
- have glandular fever (mononucleosis) and are prescribed AMOXI-CLAV. Please talk to your doctor before taking AMOXI-CLAV.
- have liver or kidney problems.
- suffer from a condition called phenylketonuria (PKU). This is because AMOXI-CLAV contains aspartame.
- are pregnant or planning to become pregnant.
- are breastfeeding or planning to breastfeed. Penicillins including amoxicillin are excreted in human breast milk. Discuss with your doctor.
- are taking a contraceptive pill as AMOXI-CLAV may reduce the effectiveness of the contraceptive.

**INTERACTIONS WITH THIS MEDICATION**

Some medicines may cause unwanted effects if they are taken at the same time AMOXI-CLAV. Please tell your doctor or pharmacist if you or your child are taking or have recently taken any other medicines or supplements, even those that can be bought without a prescription.

Tell your doctor especially if you or your child are taking or using any of the following medicines:

- allopurinol or probenecid (for treatment of gout)
- anticoagulants (used to prevent blood clots) such as warfarin
- mycophenolate mofetil (suppressed the immune system)

**PROPER USE OF THIS MEDICATION**

**Adults:**

The usual adult dose is 1 AMOXI-CLAV 500mg tablet every 12 hours. For more severe infections and infections of the lower respiratory tract, your doctor may prescribe 1 AMOXI-CLAV 875mg tablet every 12 hours or 1 AMOXI-CLAV 500mg tablet every 8 hours.

**Children:**

For children aged 12 weeks (3 months) and older as directed by a doctor:

Infection	Severity	Dosing Regimen	
		Twice a day*	Three times a day
Urinary Tract	Mild to moderate	25 mg per kg per day in divided doses every 12 hours	20 mg per kg per day in divided doses every 8 hours
Skin and Soft Tissue	Severe	45 mg per kg per day in divided doses every 12 hours	40 mg per kg per day in divided doses every 8 hours
Lower Respiratory Tract Sinusitis		45 mg per kg per day in divided doses every 12 hours	40 mg per kg per day in divided doses every 8 hours
Otitis Media (inner ear infection)**			40 mg per kg per day in divided doses every 8 hours

\*The twice a day regimen is recommended as it is associated with significantly less diarrhea.

\*\*Duration of therapy studied and recommended for acute otitis media is 10 day.

The normal duration of treatment is 7 to 10 days. Your doctor may continue this treatment for an additional 48 to 72 hours depending on your response to AMOXI-CLAV

**Infants and children less than 12 weeks (3 months):**

The recommended dose of AMOXI-CLAV is 30mg per kg per day in divided doses every 12 hours as directed by a doctor.

The children's dosage should not exceed that recommended for adults. Children weighing more than 38 kg should be dosed according to the adult recommendations.

You must follow the doctor's advice and use the medicine as instructed. Your doctor will decide how much medicine you or your child need each day, and how many days you should take it for.

It is better to take AMOXI-CLAV at the same time as a meal, but AMOXI-CLAV still works if it is given without food.

If there is anything you do not understand please ask your doctor or pharmacist.

**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you or your child miss a dose of AMOXI-CLAV, take it as soon as you remember. However, if it is almost time for the next dose, do not take the missed dose. Instead, continue with your next scheduled dose. Do not try to make up for the missed dose by taking double the dose next time.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The following are very rare side-effects that may happen in people taking AMOXI-CLAV:

- the tongue may change colour to yellow, brown or black, and it may have a hairy appearance.
- teeth discolouration while using AMOXI-CLAV. This is less likely to happen if teeth are cleaned thoroughly, and any discolouration can usually be removed by brushing. If the discolouration does not disappear, ask your doctor or dentist for advice.

*These are common side-effects that may happen in people taking AMOXI-CLAV:*

- a yeast infection of the nails, skin, mouth, vagina, stomach, urinary tract (mucocutaneous candidiasis)
- nausea (feeling sick) and vomiting (being sick) in adults and children
- diarrhoea (loose, or watery bowel movements) in children

*These are uncommon side-effects that may happen in people taking AMOXI-CLAV:*

- indigestion
- headache

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have Clostridium difficile colitis (bowel inflammation). If this occurs, stop taking AMOXI-CLAV and contact your healthcare professional immediately.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
<b>Uncommon</b>	<b>Allergic reactions</b> with symptoms such as mild rash, itching or hives (itchy lumps)		✓	
<b>Rare</b>	<b>Allergic reactions</b> with symptoms such as a skin reaction which results in itchy reddish purple patches especially on the palms of the hands or soles of the feet <b>Blood problems</b> , with symptoms such as bleeding, or bruising, more easily than usual			✓
<b>Very rare</b>	<b>Allergic reactions</b> with symptoms such as skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties, mouth ulcers, or a rash with blisters that may cause the skin to peel, flake, or bleed <b>Central Nervous System problems</b> such as convulsions (fits or seizures) <b>Liver problems</b> with symptoms such as yellowing of the skin and/or eyes, or dark coloured urine, nausea, vomiting,			✓

	abdominal pain, fever or unusual tiredness <b>Kidney problems</b> with symptoms such as blood in the urine which may be associated with a rash, fever, joint pain, or a reduction in passing water (urination) <b>Digestive system problems</b> with symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			✓
				✓
				✓

**Reporting Suspected Side Effects**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

Fax toll-free to 1-866-678-6789, or

Mail to:

Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

*This is not a complete list of side effects. For any unexpected effects while taking AMOXI-CLAV, contact your doctor or pharmacist.*

#### **HOW TO STORE IT**

Store all medicines out of the reach of children, preferably in a locked cupboard.

#### **Tablets:**

Store at room temperature (15°C -30°C), protected from light and moisture.

#### **MORE INFORMATION**

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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