

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CLAMOXIN 1000 mg Tablets

(Amoxicillin Trihydrate 875 mg and Potassium Clavulanate BP 125mg)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What CLAMOXIN 1000 Tablets is and what it is used for

Clamoxin is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called "penicillins" that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Clamoxin 1000 is used in adults and children to treat the following bacterial infections caused by organisms sensitive to Amoxicillin:

- Infection of the upper and lower respiratory tract
 - Otitis media (inflammation of middle ear)
 - Acute sinusitis
 - Acute exacerbation of chronic bronchitis
 - Pneumonia
- Infections of the kidneys and lower urinary tract

- Infections of the skin and soft tissues

2. Before you take CLAMOXIN 1000 Tablets

Do not take CLAMOXIN 1000 Tablets

if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillins or any of the other ingredients of the tablets.

if you have ever had liver problems or jaundice (yellowing of the skin), gastrointestinal disorder with vomiting and diarrhoea, asthma when taking an antibiotic.

Take special care with CLAMOXIN 1000 Tablets

If you are elderly (aged 60 years and above), liver function should be monitored. In case of prolonged therapy, kidney, liver and blood parameters should be monitored regularly.

Taking other medicines

Please tell your doctor or your pharmacist if you are taking or have recently taken any other medicines such as tetracyclines, macrolides, sulphonamides or chloramphenicol antibiotics, probenecid, allopurinol, diuretics, hormonal contraceptives, digoxin, disulfiram and coumarin. This includes medicines that can be bought without a prescription and herbal medicines.

Pregnancy and breast-feeding

Clamoxin 1000 tablets should be used during pregnancy only if potential benefits outweigh the risk. Since Amoxicillin is eliminated in breast milk, Breast fed babies may therefore have diarrhoea and colonization of the mucous membranes by yeast, possibly resulting in a need to discontinue breast feeding. The possibility of sensitization should also be taken into consideration.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur such as dizziness and convulsions, which may influence the ability to drive and use machines.

3. How to take CLAMOXIN 1000 Tablets

The dose of Clamoxin 1000 that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents

- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below

Adults and Children > 40 Kg:

Usual dose:

One Clamoxin 1000 tablet two times a day;

For otitis media, sinusitis, lower respiratory tract infections and urinary tract infections:

One Clamoxin 1000 tablet three times a day.

Children < 40 Kg:

Children may be treated with formulation found appropriate for the age of the child and severity of the disease.

Usual Dose:

Clamoxin 1000 Tablets: 25 mg/3.6 mg/kg/day to 45 mg/6.4 mg/kg/day given as two divided doses;

For Otitis media, sinusitis and lower respiratory tract infections:

Clamoxin 1000 Tablets: Up to 70 mg/10 mg/kg/day given as two divided doses may be considered.

As the tablets cannot be divided children weighing less than 25 kg must not be treated with Clamoxin tablets.

Clamoxin 1000 Tablets are for Oral use.

Administer at the start of meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/ Clavulanic acid.

The table below presents the received dose (mg/kg body weight) in children weighing 25 kg to 40 kg upon administering a single 875 mg/125 mg tablet.

Body weight [kg]	40	35	30	25	Single dose recommended [mg/kg body weight] (see above)
Amoxicillin [mg/kg body weight] per single dose (1 film-coated tablet)	21.9	25.0	29.2	35.0	12.5 – 22.5 (up to 35)

Clavulanic acid [mg/kg body weight] per single dose (1 film-coated tablet)	3.1	3.6	4.2	5.0	1.8 – 3.2 (up to 5)
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Elderly

No dose adjustment is considered necessary.

Renal impairment

No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.

In patients with creatinine clearance less than 30 ml/min, the use of amoxicillin to clavulanic acid ratio of 7:1 is not recommended, as no recommendations for dose adjustments are available.

Hepatic impairment

Dose with caution and monitor hepatic function at regular intervals.

How to take Clamoxin 1000

Clamoxin 1000 is for oral use.

Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid.

If you take more Clamoxin 1000 than you should

Symptoms such as gastrointestinal disturbance of fluid, electrolyte balances, renal failure and convulsions may occur in patients those receiving high doses. Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin/clavulanic acid can be removed from the circulation by haemodialysis

If you forget to take Clamoxin 1000

If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 4 hours before taking the next dose.

4. Possible side effects

Hypersensitivity Reactions

Skin reaction in the form of exanthemous rash and itching have been reported with some frequency. The typical measles-like rash occurs 5 to 11 days after the start of treatment. An immediate skin reaction in the form of nettle rash usually indicates a real penicillin allergy in which case treatment must be discontinued. Inflammation of the mucous membranes, particularly in the mouth, can occur occasionally. Black tongue has been observed in very rare instances. Dryness of the mouth and changes in the taste can occur.

Severe allergic reaction e.g. threatening shock, drug fever, increase in certain blood cell (eosinophilia), painful swelling of the skin and mucous membranes swelling of the larynx with constriction of the respiratory passages and difficulty in breathing, serum sickness, haemolytic anemia, allergic vasculitis or nephritis and skin reaction with life threatening general reaction such as Stevens -Johnson; Lyeil syndrome and exfoliative dermatitis (blister of skin) have been observed. Immediate medical assistance is required if these symptoms occur. In patient who have or had a cutaneous fungal infection, hypersensitivity reactions cannot be ruled out even if the patients are receiving penicillin for the first time.

If you get side effects

Tell your doctor or pharmacist if any of the side effects become severe or troublesome, or if you notice any side effects not listed in this leaflet.

5. How to store CLAMOXIN 1000 Tablets

Keep out of the reach and sight of children.

Do not use Clamoxin 1000 tablets after the expiry date printed on the box after 'EXP'. The expiry date refers to the last day of that month.

Store in dry place below above 25°C. Protect from light and moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What CLAMOXIN 1000 Tablets contain

What Co-amoxiclav tablets contains

Each film coated tablet contains

Amoxicillin Trihydrate BP equivalent to Amoxicillin 875 mg

Clavulanate Potassium BP equivalent to clavulanic acid 125 mg

The other ingredients are:

Microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, sodium starch glycollate, propylene glycol, hypromellose, Simethicone, Titanium Dioxide.

What CLAMOXIN 1000 Tablets looks like and contents of the pack:

White to off white oval shaped, film coated tablets.

1 blisters of alu/alu pack containing 6 tablets each are packed in a tropical blister in a carton along with a leaflet.

1 blisters of alu/alu pack containing 10 tablets each are packed in a tropical blister in a carton along with a leaflet.

2 blisters of alu/alu pack containing 10 tablets each are packed in a tropical blister in a carton along with a leaflet

Marketing Authorisation holder

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