

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CLAMOXIN 375 mg Tablets

(Amoxicillin Trihydrate 250 mg and Potassium Clavulanate BP 125 mg).

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 375 mg 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 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
 - i. Otitis media (inflammation of middle ear)
 - ii. Acute sinusitis
 - iii. Acute exacerbation of chronic bronchitis
 - iv. Pneumonia

Infections of the kidneys and lower urinary tract

- Infections of the skin and soft tissues

2. Before you take CLAMOXIN 375 mg Tablets

Do not take CLAMOXIN 375 mg 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 375 mg 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 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 375 mg Tablets

The dose of Clamoxin 375 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 375 tablet three times a day;

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

Clamoxin 375 Tablets are for Oral use.

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

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 375 mg Tablet

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Clamoxin for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Clamoxin 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

- 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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Clamoxin

Keep taking Clamoxin until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 375 mg Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

- Store in dry place below above 25°C. Protect from light and moisture.
- Tablets supplied in pouches should be used within 30 days of opening the pouch.
- Store in the original pack in order to protect from moisture.
- Do not use if the tablets are chipped or damaged.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Further information

What CLAMOXIN 375 Tablets contain

What Co-amoxiclav tablets contains

Each film coated tablet contains

Amoxicillin Trihydrate BP equivalent to Amoxicillin 250 mg

Clavulanate Potassium BP equivalent to clavulanic acid 125 mg

The other ingredients are:

Microcrystalline Cellulose, Magnesium Stearate, Colloidal Anhydrous Silica, Sodium Starch Glycollate, Opaspray K-IR 7000, Ethyl Cellulose, Propylene Glycol, Hypromellose, Simethicone, Methylene Chloride and Isopropyl Alcohol.

What CLAMOXIN 375 mg Tablets looks like and contents of the pack:

White to off white oval shaped, film coated tablets.

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

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

Marketing Authorisation holder

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