

**Patient Information Leaflet**  
**CLAMOXIN 1000 Tablets**

**Read this entire leaflet carefully before you start taking this medicine.**

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Is CLAMOXIN 1000 And What It Is Used For
2. Before You Take CLAMOXIN 1000
3. How To Use CLAMOXIN 1000
4. Possible Side Effects
5. How To Store CLAMOXIN 1000 Tablets
6. Further Information

**1. What Is CLAMOXIN 1000 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**

Do not take CLAMOXIN 1000

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**

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**

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 Co-amoxiclav tablets.

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)

### **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**

Commonly reported adverse drug reactions are diarrhoea, nausea and vomiting, also uncommon reactions such as mucocutaneous candidosis, dizziness, headache, indigestion, rise in AST/ALT, skin rash, pruritis and urticarial.

Rarely reactions such as overgrowth of non-susceptible organisms, reversible leucopenia, thrombocytopenia, reversible agranulocytosis, haemolytic anemia, prolongation of bleeding time and prothrombin time, angioneurotic oedema, anaphylaxis, serum sickness like syndrome, reversible hyperactivity, convulsions, antibiotic associated colitis, hepatitis, chloestatic jaundice, erythema multiforme, stevens Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative dermatitis, interstitial nephritis and crystalluria.

#### **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 the original package in cool and dry place, below 25°C

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 Co-amoxiclav tablets contains

Each film coated tablet contains

Amoxicillin Trihydrate BP equivalent to Amoxicillin 875 mg

Diluted Potassium Clavulanate BP equivalent to clavulanic acid 125 mg

#### **The other ingredients are**

Microcrystalline Cellulose, Magnesium Stearate, Colloidal anhydrous silica, Sodium Starch Glycolate, Hydroxypropyl Methyl Cellulose E-5 (HPMC E5), Hydroxypropyl Methyl Cellulose E15 (HPMC E15), Titanium Dioxide, Polyethylene Glycol 6000, Simeticone and Purified water.

#### **What CLAMOXIN 1000 tablets look like and contents of the pack**

White or off white capsule shape film coated tablets scored in the middle on both sides.

2 Tropical blister of 7 tablets packed in a carton along with leaflet.

#### **Marketing Authorisation Holder:**

**BLISS GVS PHARMA LTD.**

102, Hyde Park, Saki Vihar Road, Andheri (East),

Mumbai - 400 072, INDIA