

**PATIENT INFORMATION LEAFLET**  
**CLAMOXIN 457 SUSPENSION**  
**(Amoxicillin and Clavulanate Potassium for Oral Suspension USP 457 mg)**

**Read all of this leaflet carefully before you start taking this CLAMOXIN**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please consult your doctor, health care provider or your pharmacist.
- This medicine is exclusively used in hospitals and clinics, and should only be administered by qualified medical personnel.

**In this leaflet:**

1. What CLAMOXIN is and what it is used for
2. What you need to know before you give CLAMOXIN
3. How to give CLAMOXIN
4. Possible side effects
5. How to store CLAMOXIN
6. Contents of the pack and other information

**1. What is CLAMOXIN 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 babies and children to treat the following infections:

- Middle ear and sinus infections
- Respiratory tract infections
- Urinary tract infections
- Skin and soft tissue infections including dental infections
- Bone and joint infections.

## **2. What you need to know before use of CLAMOXIN**

### **Do not give your child CLAMOXIN:**

- if they are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6)
- if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

**Do not give CLAMOXIN to your child if any of the above apply to your child.**

If you are not sure, talk to their doctor or pharmacist before giving CLAMOXIN.

### **Take special care with CLAMOXIN**

- Check with their doctor, pharmacist or nurse before giving your child this medicine if they:
- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

### **Taking other medicines**

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

If your child is taking allopurinol (used for gout) with CLAMOXIN, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of CLAMOXIN.

If medicines to help stop blood clots (such as warfarin) are taken with CLAMOXIN then extra blood tests may be needed.

CLAMOXIN can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

**Pregnancy and Lactation:**

If your child who is about to take this medicine is breast-feeding, thinks they may be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine.

**Pregnancy:**

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Limited data on the use of amoxicillin/clavulanic acid during pregnancy in humans do not indicate an increased risk of congenital malformations. Use should be avoided during pregnancy, unless considered essential by the physician.

**Lactation:**

Both substances are excreted into breast milk. Consequently, diarrhoea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued. Amoxicillin/clavulanic acid should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

**Driving and using machines**

CLAMOXIN can have side effects and the symptoms may make you unfit to drive.

Do not drive or operate machinery unless you are feeling well.

**3. How to give CLAMOXIN suspension**

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adults and children weighing 40 kg or over**

This suspension is not usually recommended for adults and children weighing 40 kg and over.

Ask your doctor or pharmacist for advice.

All doses are worked out depending on the child's bodyweight in kilograms.

Your doctor will advise you how much CLAMOXIN you should give to your baby or child. You may be provided with a measuring spoon or cup. You should use this to give the correct dose to your baby or child.

Recommended dose - 20 mg/5 mg to 60 mg/15 mg for each kilogram of body weight a day, given in three divided doses.

### **Patients with kidney and liver problems**

If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.

If your child has liver problems they may have more frequent blood tests to see how their liver is working.

### **How to give CLAMOXIN**

Always shake the bottle well before each dose

Give 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 give your child CLAMOXIN for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

### **If you give more CLAMOXIN than you should**

If you give your child too much CLAMOXIN, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

### **If you forget to give CLAMOXIN**

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

### **If your child stops taking CLAMOXIN**

Keep giving your child CLAMOXIN until the treatment is finished, even if they feel better. Your child needs 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, pharmacist or nurse.

#### **4. Possible side effects of CLAMOXIN suspension**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

##### **Conditions you need to look out for**

##### **Allergic reactions:**

skin rash, inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body fever, joint pain, swollen glands in the neck, armpit or groin swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing collapse.

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

#### **5. How to store CLAMOXIN suspension**

- Keep this medicine out of the sight and reach of children.
- **Dry powder**
  - Store in the original package in order to protect from moisture.
  - Do not store above 25°C.
  - 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.
- **Liquid suspension**
  - Store in a refrigerator (2°C - 8°C). Do not freeze.
  - Once made up, the suspension should be used within 7 days.
  - 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 you to protect the environment.

## **6. FURTHER INFORMATION**

### **What CLAMOXIN contains:**

#### **Clamoxin 457**

The active substances are amoxicillin and clavulanic acid. Each ml of suspension contains amoxicillin trihydrate equivalent to 80 mg amoxicillin and potassium clavulanate equivalent to 11.40 mg of clavulanic acid.

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

Colloidal Silicon Dioxide, Methocel-E5 Premium, Aspartame, Succinic acid, Xanthan gum, Orange dry powder, Golden Caramel, Pineapple dry powder.

#### **What CLAMOXIN looks like and content of the pack:**

CLAMOXIN 457 Suspension is a white to almost white powder supplied in a HDPE bottle. Once made up, the bottle contains 70 ml of a white or almost white liquid mixture called a suspension.

#### **Marketing Authorisation Holder & Manufacturer:**

Bliss GVS Pharma Ltd.

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