

## **CLAMOXYL 125 mg / 5 ml powder for oral suspension**

### **Amoxicillin**

#### **Framed**

**Read all of this leaflet carefully before taking this medicine because it contains important information for you.**

- Keep this leaflet. You might need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you or your child. Do not give this to anyone else. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. See section 4.

#### **What does this booklet contain ?**

1. What is CLAMOXYL powder for oral suspension and in which cases is it used?
2. What should I know before taking CLAMOXYL powder for oral suspension?
3. How to take CLAMOXYL, powder for oral suspension?
4. What are the possible side effects?
5. How to store CLAMOXYL, powder for oral suspension?
6. Contents of the pack and other information.

#### **1. WHAT IS CLAMOXYL 125 mg / 5 ml, powder for oral suspension AND WHAT IT IS USED FOR?**

Pharmacotherapeutic group: broad spectrum penicillins - ATC code: J01CA04

##### **What is Clamoxyl?**

CLAMOXYL is an antibiotic. The active substance is amoxicillin. This belongs to a group of medicines called 'penicillins'.

##### **What is Clamoxyl used for?**

CLAMOXYL is used to treat infections caused by bacteria in different parts of the body. CLAMOXYL can also be used in combination with other medicines to treat stomach ulcers.

#### **2. BEFORE YOU TAKE CLAMOXYL 125 mg / 5 ml, powder for oral suspension?**

##### **Do not take CLAMOXYL 125 mg / 5 ml powder for oral suspension:**

- If you are allergic to amoxicillin, penicillin or any of the other ingredients of this medicine (listed in section 6).
- If you have had an allergic reaction to an antibiotic. This can include a rash or swelling of the face or throat.

Do not take CLAMOXYL if you are in any of the situations mentioned above. If in doubt, ask your doctor or pharmacist for advice before taking CLAMOXYL.

### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking CLAMOXYL 125 mg / 5 ml powder for oral suspension if you:

- Suffer from infectious mononucleosis (fever, sore throat, swollen glands and extreme fatigue)
- Have kidney problems
- Do not urinate regularly

If in doubt, ask your doctor or pharmacist for advice before taking CLAMOXYL.

### **Blood and urine tests**

If you need to do:

- Urinalysis (glucose determination) or blood tests to explore the function of your liver,
- A estriol dosage (used during pregnancy to check the baby is developing normally).

Tell your doctor or pharmacist that you are taking CLAMOXYL. This is because CLAMOXYL can influence the results of these tests.

### **Children**

Not applicable.

### **Other medicines and CLAMOXYL 125 mg / 5 ml powder for oral suspension**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- If you are taking allopurinol (used to treat gout) with CLAMOXYL, the risk of allergic skin reaction is higher.
- If you are taking probenecid (used to treat gout), your doctor may decide to adjust your dose of CLAMOXYL.
- If you are taking medicines to prevent blood clotting (such as warfarin), you may need to perform additional blood tests.
- If you are taking other antibiotics (such as tetracyclines) CLAMOXYL may be less effective.
- If you take methotrexate (used in the treatment of cancer and severe psoriasis) CLAMOXYL may cause an increase in adverse effects.

### **CLAMOXYL 125 mg / 5 ml powder for oral suspension with food and drink**

Not applicable.

### **Pregnancy and breast feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

CLAMOXYL may cause side effects (such as allergic reactions, dizziness and seizures) which may reduce your ability to drive.

Don't drive or use machines unless you are feeling well.

### **CLAMOXYL 125 mg / 5 ml powder for oral suspension contains aspartame, maltodextrin, sodium and sodium benzoate**

- Aspartame (E951) is a source of phenylalanine. This can be harmful to patients with a condition called 'phenylketonuria'.
- Maltodextrin is absorbed as glucose. If your doctor has told you that you have an intolerance to some sugars, contact them before taking this medicine.

- Due to the presence of sodium benzoate (E211), this medicine may cause irritation to skin, eyes and mucous membranes and may increase the risk of jaundice in the newborn.
- This medication contains 1.3 mg (0.06 mmol) of sodium per ml. This should be taken into account in patients controlling their dietary sodium intake.

### **3. HOW TO TAKE CLAMOXYL 125 mg / 5 ml powder for oral suspension?**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if in doubt.

- Shake the bottle well before each use.
- Use the measuring spoon supplied with the bottle.
- Distribute the catches evenly throughout the day; they must be spaced at least 4 hours apart.

#### **Usual dosage:**

##### **Children weighing less than 40 kg**

All dosages are determined based on the child's weight in kilograms.

- Your doctor will tell you the amount of CLAMOXYL you need to administer your baby or child.
- The usual dose is 40 mg to 90 mg per kilogram of body weight per day, administered in two or three doses.
- The maximum recommended dose is 100 mg per kilogram of body weight per day.

##### **Adults, elderly patients and children weighing 40 kg or more**

This suspension is not usually prescribed for adults and children weighing more than 40 kg. Ask your doctor or pharmacist for advice.

##### **Kidney problems**

If you suffer from kidney problems, the dosage may be reduced from the usual dosage.

##### **How long should you take CLAMOXYL?**

- You must continue to take CLAMOXYL as long as your doctor prescribes is, even if you feel better. All doses are important for fighting infection. If certain bacteria were to survive, they could be the cause of a recurrence of the infection.
- After you have finished your treatment, if your symptoms persist, see your doctor again.

Yeast infections (yeast infections that appear on moist areas of the body which can cause pain, itching and white discharge) may develop if CLAMOXYL is used for a long time. If this is your case, tell your doctor.

If you take CLAMOXYL for a long time, your doctor may do additional tests to monitor that your kidneys, liver and blood are working normally.

##### **If you take more CLAMOXYL 125 mg / 5 ml, powder for oral suspension than you should:**

If you take too much CLAMOXYL it may cause stomach pain (nausea, vomiting or diarrhea) or crystals to form in the urine making it cloudy or painful when passing urine. See your doctor as soon as possible. Bring the medicine to show your doctor.

##### **If you forget to take CLAMOXYL 125 mg / 5 ml powder for oral suspension:**

- If you forget to take a dose, take it as soon as you remember.
- Do not take the next dose too soon; wait about 4 hours before taking the next dose.
- Do not take a double dose to make up the dose you missed.

**If you stop taking CLAMOXYL 125 mg / 5 ml powder for oral suspension:**

Not applicable.

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

**4. WHAT ARE THE POSSIBLE SIDE EFFECTS?**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking CLAMOXYL and see a doctor straight away if you experience any of the serious side effects listed below, as you may need urgent medical treatment.**

The following side effects are very rare (may affect up to 1 in 10,000 people):

- Allergic reactions; signs may include: itching or rash, swelling of the face, lips, tongue, body, or difficulty breathing. These reactions can be serious and sometimes fatal.
- Skin rashes or red spots shaped pinhead under the skin, bruising. This is caused by the inflammation of the lining of the blood vessels due to an allergic reaction. These symptoms may be accompanied by joint pain (arthritis) and kidney problems.
- A delayed allergic reaction can occur usually 7 to 12 days after taking CLAMOXYL; signs include: rash, fever, joint pain and swelling of the lymph nodes, especially in the armpits
- Skin reaction known as erythema name polymorph, manifested by the following symptoms: reddish purple plates or on the skin with itching, especially the palms and soles, concentric raised lesions on the skin , tenderness in the mouth, eyes and genital mucosa. This reaction can lead to fever and severe fatigue.
- Other severe skin reactions including: change in skin color, lump under the skin, blisters, pustules, peeling skin, redness, pain, itching, peeling. These symptoms may be accompanied by fever, headache and body aches.
- Flu-like symptoms accompanied by a rash, fever, swollen glands, and abnormal blood test results [including increased white blood cells (eosinophilia) and liver enzymes] [dress syndrome (DRESS) ]
- Fever, chills, sore throat or other signs of infection, frequent bruising. These side effects could be a sign of a problem with your blood cells.
- *Jarisch-Herxheimer* which may appear during treatment with CLAMOXYL Lyme disease causes fever, chills, headache, muscle pain and rash
- Inflammation of the large intestine (colon), accompanied by diarrhea (sometimes with blood), pain and fever
- Serious side effects in the liver may occur. They are mainly seen in people treated for a long time, in men and in elderly patients. You must consult your doctor urgently in the following cases:
  - severe diarrhea with the presence of blood;
  - appearance of blisters, redness or bruises on the skin;
  - dark urine or discolored stools;
  - yellowing of the skin or the whites of the eyes (jaundice). Also see the information below on anemia, which can lead to jaundice.

These reactions may appear when taking the medicine or for several weeks after stopping it.

**If you experience any of the above reactions, stop taking this medicine and see your doctor immediately.**

**Skin reactions can sometimes be less severe:**

- Skin rashes (round color stains pink or red) with moderate itching, concentric raised lesions on the forearms, legs, palms and soles. These events are uncommon (may affect up to 1 in 100 people).

**If any of these symptoms appear, see your doctor as you will need to stop taking CLAMOXYL.**

Other possible side effects are:

**Common** (may affect up to 1 in 10 people)

- Rash
- Nausea
- Diarrhea

**Uncommon** (may affect up to 1 in 100 people)

- Vomiting

**Very rare** (may affect up to 1 in 10,000 people)

- Fungus (yeast infection that develops in the vagina, mouth or skin folds); you can ask your doctor or pharmacist for treatment against yeast infection
- Kidney Problems
- Convulsions, especially in patients taking high doses or with kidney problems
- Dizziness
- Hyperactivity
- Crystals in the urine, making these disorders or causing discomfort or difficulty urinating. Make sure you drink plenty of fluids to reduce these risks
- The teeth may appear smeared This is usually reversible brushing (reported in children)
- Language can take a yellow color, brown or black and may appear hairy
- Excessive degradation of red blood cells causing a type of anemia. The signs include: fatigue, headache, shortness of breath, dizziness, pallor, yellowing of the skin and whites of the eyes
- Low white blood cells
- Low number of cells involved in blood clotting
- Blood clotting may be slowed down. You may notice this if there is a nosebleed or cut

**Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centers - Website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE CLAMOXYL 125 mg / 5 ml powder for oral suspension?**

Keep this medication out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after {EXP}. The expiration date refers to the last day of that month.

**Dry powder**

Store at a temperature below 25 ° C.

**Liquid suspension**

Store at a temperature below 25 ° C.

After reconstitution, the suspension should be used within 14 days.

Do not use if there are visible signs of deterioration.

Do not throw away any medicine 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. CONTENTS OF THE PACKAGE AND OTHER INFORMATION**

### **What CLAMOXYL 125 mg / 5 ml contains, powder for oral suspension**

- The active substance is amoxicillin. Each suspension contains 125 mg of amoxicillin.
- The other ingredients are: carmellose sodium 12, lemon aroma-fishing strawberry, crospovidone, aspartame (E951), sodium benzoate (E211), xanthan gum (E415), hydrophobic colloidal silica, magnesium stearate.

### **What is CLAMOXYL 125 mg / 5 ml powder for oral suspension and contents of the pack**

Clamoxyl 125 mg / 5 ml powder for oral suspension is presented as a white powder with yellowish grains, contained in a glass vial with a nominal volume of 107 ml (for the presentation of 60 ml) or 147 ml ( for the presentation of 100 ml) closed with a cap fitted with a child safety device. The vials are packaged with a measuring spoon graduated to 2.5 ml and 5 ml.

Not all presentations may be marketed.

### **Marketing authorization holder**

#### **GLAXOSMITHKLINE LABORATORY**

23 RUE FRANCOIS JACOB  
92500 RUEIL-MALMAISON

### **Marketing authorization operator**

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### **Maker**

#### **GLAXO WELLCOME PRODUCTION**

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#### **ATHLONE LABORATORIES LTD**

BALLYMURRAY  
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