

## ANNEX IIIB

### PACKAGE LEAFLET: INFORMATION FOR THE USER

#### Name of the medicinal product

**CLAMOXYL 1 g, dispersible tablet**

**Amoxicillin**

#### Box

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

- 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 or your child only. Do not pass it on to others. 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 includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Clamoxyl 1 g, dispersible tablet is and what it is used for
2. What you need to know before you take Clamoxyl 1 g, dispersible tablet
3. How to take Clamoxyl 1 g, dispersible tablet
4. Possible side effects
5. How to store Clamoxyl 1 g, dispersible tablet
6. Contents of the pack and other information.

### 1. WHAT CLAMOXYL 1 g, dispersible tablet IS AND WHAT IT IS USED FOR

**Pharmacotherapeutic group – ATC code: J01CA04.**

#### What CLAMOXYL is

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

#### What CLAMOXYL is used for

CLAMOXYL is used to treat infections caused by bacteria in different parts of the body.

CLAMOXYL may also be used in combination with other medicines to treat stomach ulcers.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLAMOXYL 1 g, dispersible tablet

#### Do not take CLAMOXYL 1 g, dispersible tablet:

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

Do not take CLAMOXYL if any of the above apply. If you are not sure, talk to your doctor or pharmacist before taking CLAMOXYL.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking CLAMOXYL 1 g, dispersible tablet if you:

- have glandular fever (fever, sore throat, swollen glands and extreme tiredness)
- have kidney problems
- are not urinating regularly.

If you are not sure, talk to your doctor or pharmacist before taking CLAMOXYL.

## **Blood and urine tests**

If you have to have:

- urine tests (glucose) or blood tests for liver function
- oestriol tests (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 affect the results of these tests.

## **Children**

Not applicable.

## **Other medicines and CLAMOXYL 1 g, dispersible tablet**

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

- If you are taking allopurinol (used for the treatment of gout) with CLAMOXYL, the risk of an allergic skin reaction is higher.
- If you are taking probenecid (used for the treatment of gout), your doctor may decide to adjust your dose of CLAMOXYL.
- If you are taking medicines to stop blood coagulation (such as warfarin), you may need to have extra blood tests.
- If you are taking other antibiotics (such as tetracycline) CLAMOXYL may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) CLAMOXYL may cause an increase in side effects.

## **CLAMOXYL 1 g, dispersible tablet 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 can have side effects (such as allergic reactions, dizziness and convulsions) likely to reduce your capacity to drive.

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

## **CLAMOXYL 1 g, dispersible tablet contains aspartame**

This medicine contains 20 mg aspartame in each tablet. Aspartame (E951) is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

## **3. HOW TO TAKE CLAMOXYL 1 g, dispersible tablet**

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

- Completely dissolve each tablet in a glass of water and stir the mixture well until evenly mixed. Swallow the mixture immediately
- Space the doses evenly during the day, at least 4 hours apart.

### **Usual dosage:**

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

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

- Your doctor will advise you how much CLAMOXYL you should give to your baby or child.
- The usual dose is 40 mg to 90 mg for each kilogram of body weight a day, given in two or three divided doses.
- The maximum dose is 100 mg for each kilogram of body weight a day.

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

The usual dose of CLAMOXYL is 250 mg to 500 mg three times a day or 750 mg to 1 g every 12 hours, depending on the severity and type of infection.

- **Severe infections:** 750 mg to 1 g three times a day.
- **Urinary tract infection:** 3 g twice daily for one day.
- **Lyme disease (an infection spread by parasites called ticks):** isolated erythema migrans (early stage – red or pink circular rash): 4 g a day, systemic manifestations (late stage – for more serious symptoms or when the disease spreads around your body): up to 6 g a day.
- **Stomach ulcer:** 750 mg or 1 g twice a day for 7 days with other antibiotics and medicines to treat stomach ulcers.
- **To prevent heart infection during surgery.** the dose varies according to the type of surgery. Other medicines may also be given at the same time. Your doctor, pharmacist or nurse will be able to give you more details.
- The maximum recommended dose is 6 g per day.

## Kidney problems

If you have kidney problems the dose might be lower than the usual dose.

## How long should you take CLAMOXYL for?

- You should keep taking CLAMOXYL for as long as your doctor has prescribed it, even if you feel better. Every dose is important to fight the infection. If some bacteria survive, they might cause the infection to come back.
- Once you finish treatment, if your symptoms persist, go back to see the doctor.

Thrush (a yeast infection of moist areas of the body which causes soreness, itching and white discharge) may develop if CLAMOXYL is used for a long time. If this occurs tell your doctor.

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

## If you take more CLAMOXYL 1 g, dispersible tablet than you should

If you have taken too much CLAMOXYL, it may cause an upset stomach (nausea, vomiting or diarrhoea) or the formation of crystals in the urine, making urine cloudy or causing pain while urinating. Talk to your doctor as soon as possible. Take the medicine to show the doctor.

## If you forget to take CLAMOXYL 1 g, dispersible tablet

- 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 for a forgotten dose.

## If you stop taking CLAMOXYL 1 g, dispersible tablet

Not applicable.

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

## 4. POSSIBLE SIDE EFFECTS

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

**Stop taking CLAMOXYL and see a doctor straight away if you notice any of the following serious side effects, 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; the signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties. These can be serious and occasionally fatal
- rash or pinpoint flat red round spots under the skin surface, bruising. This is due to inflammation of blood vessel walls due to an allergic reaction. These symptoms can be accompanied by joint pain (arthritis) and kidney problems
- a delayed allergic reaction can occur usually 7 to 12 days after taking CLAMOXYL; the signs include: rash, fever, joint pains and enlargement of the lymph nodes, especially in the armpits

- a skin reaction known as erythema multiforme, occurring with the following symptoms: itchy reddish or purple patches on the skin, especially on the palms of the hands or soles of the feet, raised concentric lesions on the skin, sensitivity in the mouth, eyes and genital mucosa. This reaction may involve fever and significant fatigue
- other severe skin reactions include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These symptoms may be accompanied by fever, headaches and body aches
- flu-like symptoms accompanied by a rash, fever, swollen lymph nodes and abnormal blood test results (including increased white blood cells (*eosinophilia*) and liver enzymes) (*drug-induced hypersensitivity syndrome (DRESS)*)
- fever, chills, sore throat or other signs of infection, frequent bruises. These side effects may be a sign of a problem with your blood cells
- *Jarisch-Herxheimer* reaction, which may occur during treatment with CLAMOXYL for Lyme disease and causes fever, chills, headaches, muscle pain and skin rash
- inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever
- serious liver side effects may occur. They are mainly observed in people having treatment over a long period, males and the elderly. You must tell your doctor urgently if you get:
  - severe diarrhoea with bleeding;
  - blisters, redness or bruising of the skin
  - dark urine or paler stools
  - yellowing of the skin or the whites of the eyes (jaundice). See also information below about anaemia, which might result in jaundice.

These can happen when taking the medicine or for up to several weeks after.

**If you get any of the above reactions, stop taking the medicine and see your doctor straight away.**

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

- a moderately itchy rash (round, pink or red patches), raised concentric lesions on forearms, legs, palms of hands and soles of feet. These symptoms are uncommon (may affect up to 1 in 100 people).

**If any of these symptoms occurs, talk to your doctor as you will have to stop taking CLAMOXYL.**

Other possible side effects are:

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

- skin rash
- nausea
- diarrhoea

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

- vomiting

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

- thrush (a yeast infection of the vagina, mouth or skin folds); you can get treatment for thrush from your doctor or pharmacist
- kidney problems
- convulsions, particularly in patients taking high doses or with kidney problems
- dizziness
- hyperactivity
- crystals in the urine, making urine cloudy or causing discomfort or difficulty in passing urine. Make sure you drink plenty of fluids to reduce these risks
- teeth may appear stained, usually returning to normal with brushing (reported in children)
- the tongue may change to yellow, brown or black and it may seem to be covered in hair
- excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, paleness and yellowing of the skin and the whites of the eyes
- low number of white blood cells
- low number of cells involved with blood clotting
- blood clotting may be slowed. You may notice this if you have a nosebleed or cut yourself
- Inflammation of the protective membrane around the brain (aseptic meningitis).

## Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: French National Agency for Medicines and Health Products Safety (ANSM) and the network of Regional Pharmacovigilance Centres – Website: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr)

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

## 5. HOW TO STORE CLAMOXYL 1 g, dispersible tablet

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 box after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use if there are visible signs of deterioration.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

### What CLAMOXYL 1 g, dispersible tablet contains

- The active substance is amoxicillin. Each tablet contains 1 g amoxicillin.
- The other ingredients are: crospovidone, aspartame (E951), min flavour, magnesium stearate.

### What Clamoxyl 1 g, dispersible tablet looks like and contents of the pack

CLAMOXYL, 1 g dispersible tablets are white to off-white, oval tablets with a score line, engraved with “1g”. The score line is only to facilitate taking the tablet and not to not divide into equal doses.

They are packaged in blister packs enclosed in a carton and are available in packs of 3, 6, 8, 10, 12, 14, 16, 18, 20, 24, 30, 32 tablets and a hospital pack of 100 tablets.

Not all pack sizes may be marketed.

### Marketing authorisation holder

**LABORATOIRE GLAXOSMITHKLINE**  
23 RUE FRANCOIS JACOB  
92500 RUEIL MALMAISON

### Marketing authorisation local representative

**LABORATOIRE GLAXOSMITHKLINE**  
23 RUE FRANCOIS JACOB  
92500 RUEIL MALMAISON

### Manufacturer

**GLAXO WELLCOME PRODUCTION**  
ZI DE LA PEYENNIERE  
53100 MAYENNE

### Names of the medicinal product in the Member States of the European Economic Area

**This medicinal product is authorised in the Member States of the European Economic Area under the following names: In compliance with the regulation in force.**

[To be completed subsequently by the holder]

### This leaflet was last revised in:

[To be completed subsequently by the holder]

## Other

Detailed information on this medicine is available on the website of ANSM (France).

### **ADVICE/HEALTH EDUCATION**

Antibiotics are effective against infections caused by bacteria. They are not effective against infections caused by viruses.

Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons is because the bacteria causing the infection are resistant to the antibiotic that has been taken. This means that the bacteria can survive and even multiply despite the antibiotic.

Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.

When your doctor prescribes a course of an antibiotic, it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.

- 1. It is very important that you take the antibiotic at the right dose, at the right times and for the right length of treatment. Read the instructions on the leaflet and if you do not understand anything ask your doctor or pharmacist to explain.**
- 2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.**
- 3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.**
- 4. You should not give antibiotics that were prescribed for you to other people.**
- 5. If you have any antibiotic left over when you have taken the course as directed by your doctor, you should take the remainder to your pharmacist for appropriate disposal.**