

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Germentin 250 mg/125 mg Film-coated Tablets**

(amoxicillin/clavulanic acid)

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

#### **1. What Germentin is and what it is used for**

Germentin 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). Clavulanic acid stops this from happening.

Germentin is used in adults and children to treat the following infections:

- sinus infections
- urinary tract infections
- skin infections
- infections from animal bites
- dental infections.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

#### **2. What you need to know before you take Germentin**

##### **Do not take Germentin:**

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

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Germentin if you:

- have glandular fever
- are being treated for liver or kidney problems
- are not passing water regularly.

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

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Germentin or a different medicine.

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

Germentin can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking Germentin, to reduce the risk of any problems. (see **section 4**).

### **Blood and urine tests**

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Germentin. This is because Germentin can affect the results of these types of tests.

### **Other medicines and Germentin**

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

If you are taking allopurinol (used for gout) with Germentin, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used to treat gout), your doctor may decide to adjust your dose of Germentin. Concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended.

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

Germentin can affect how methotrexate (a medicine used to treat cancer, severe psoriasis or rheumatic diseases) works. Penicillin's may reduce the excretion of methotrexate causing a potential increase in side effects.

Germentin can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

**Pregnancy, breast-feeding and fertility**

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.

Amoxicillin and clavulanic acid can pass into breast milk. If you breast-feed while taking this medicine, your baby may be more likely to get diarrhoea or an infection. If this happens, you may need to stop breast-feeding. You should only use Germentin whilst breast-feeding if your doctor tells you to.

**Driving and using machines**

Germentin can have side effects such as allergic reactions, dizziness or fits that may make you unfit to drive or use machinery.

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

**Germentin contains potassium**

This medicine contains 24 mg potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Germentin**

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

**Use in adults and children weighing 40 kg and over**

The recommended dose is 1 tablet three times a day

**Use in children weighing less than 40 kg**

Germentin tablets should not be taken by children less than 40 kg.

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

**Patients with kidney and liver problems**

- If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

**How to take Germentin**

- Take with a meal
- Swallow the tablets whole with a glass of water.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.

- Do not take Germentin for more than 2 weeks. If you still feel unwell you should go back to see your doctor.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

### **If you take more Germentin than you should**

If you take too much Germentin, signs might include an upset stomach (feeling sick, being sick or diarrhoea which can cause a change in the amount of salt and fluid in the body) or convulsions (fits). Talk to your doctor as soon as possible. Take the medicine carton to show the doctor.

### **If you forget to take Germentin**

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 tablet.

### **If you stop taking Germentin**

Keep taking Germentin 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**

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

**Stop taking Germentin and tell your doctor immediately or go to your nearest hospital emergency department if you notice any of the following:**

**Rare** (may affect up to 1 in 1,000 people)

- frequent infections causing fever, severe chills, sore throat or mouth ulcers (these may be signs you have a low number of white blood cells) (leucopenia)

**Not known** (cannot be estimated from the available data)

- tiredness, headaches, shortness of breath when exercising, dizziness, pale or yellowing of the skin or eyes (haemolytic anaemia)
- sudden itching, red skin rash or swelling of the face, lips, tongue, throat or neck, difficulty breathing or swallowing. These are signs of an allergic reaction
- sensitivity to light, stiff neck, body aches, sore throat, severe headache, flu-like symptoms (these may indicate you have a type of meningitis that can't be passed on to others)
- diarrhoea with blood or mucus, stomach pain or fever
- acute inflammation of the pancreas (acute pancreatitis): if you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.
- drug-induced enterocolitis syndrome (DIES): DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with

the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

- yellowing of the skin or whites of the eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness and abdominal pain, with blood test results showing abnormal liver function. These are signs of serious problems with your liver
- serious skin reactions such as a widespread rash with blisters, bleeding and peeling skin, particularly around the mouth, nose, eyes or genitals with fever
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- 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
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- pain passing urine, lower back pain or fever. These may be signs of inflammation of the tubes in the kidney (interstitial nephritis)
- fits (especially if you take high doses of Germentin or if you have kidney problems)

**Contact your doctor as soon as possible for advice if you get the following symptom:**

**Very common side effects** (may affect more than 1 in 10 people)

- diarrhoea. This may possibly suggest you have a more serious condition

Other side effects include:

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

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially if you take high doses
- vomiting (being sick)

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

- indigestion
- dizziness
- headache
- increase in some substances (enzymes) produced by the liver (detected by a blood test)

**Rare** (may affect up to 1 in 1,000 people)

- bruising or bleeding more easily or for longer than normal. This may be signs of a low number of cells involved in blood clotting in the body

**Not known** (cannot be estimated from the available data)

- hyperactivity
- black tongue which looks hairy
- Other infections that are difficult to treat (over-growth of non-susceptible organisms)
- Shortness of breath
- crystals in urine (seen as cloudy urine or in a urine test) leading to acute renal injury
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

- inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis)

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Germentin**

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

Do not store tablets above 25°C. Store in the original package in order to protect from moisture.

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

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 Germentin tablets contain**

- The active substances are 250 mg of amoxicillin (as the trihydrate) and 125 mg of clavulanic acid (as the potassium salt) (see section 2 'Germentin contains potassium').
- The other ingredients are magnesium stearate, talc, povidone, croscarmellose sodium, microcrystalline cellulose. The tablet coating includes triethyl citrate, ethylcellulose (containing sodium laurilsulfate, cetyl alcohol), hypromellose, talc and titanium dioxide (E171).

#### **What Germentin tablets look like and contents of the pack**

The coated tablets are off-white, capsule-shaped and marked 'AXC 375' on one side and 'G' twice on the other side. Both sides have a score line. Germentin is available in blister packs of 3, 15, 16, 21, 30, 50, 90, 100 and 500 tablets. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Viartis Limited, Damastown Industrial Park, Mulhuddart Dublin 15, DUBLIN Ireland.

#### **Manufacturer**

McDermott Laboratories Limited, t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13.

Sandoz GmbH, Biochemiestr 10, A-6250 Kundl, Austria

**This leaflet was last revised in March 2024.**

## Other sources of information

### Advice/medical education

Antibiotics are used to treat infections caused by bacteria. They have no effect 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 for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they 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 number of days. Read the instructions on the label 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 a pharmacy for appropriate disposal.