

Package leaflet: Information for the patient

Germentin 500 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 (or for 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 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 active substances 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.

Germentin is used in adults 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 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 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 this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine 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 or have recently taken or might take any other medicines. This includes medicines that can be bought without a prescription and herbal medicines.

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

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

If you are taking probenecid (used for 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.

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

Germentin can have possible side effects such as dizziness and convulsions (fits) and the symptoms may make you unfit to drive. Don't drive or operate machinery unless you are feeling well.

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

3. How to take Germentin

Always take this medicine exactly as your doctor 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

Children aged 6 years or less should preferably be treated with Germentin oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Germentin tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

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 with a glass of water. The tablets can be broken along the score line to make them easier to swallow. You must take both pieces of the tablet at the same time.

- 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 the doctor.

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) 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.

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.

- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

Contact a doctor immediately if you get any of these symptoms. **Stop taking Germentin.**

Serious skin reactions:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*)
- widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
- a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).
- 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))
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)).
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – *erythema multiforme*).

Contact a doctor immediately if you get any of these symptoms.

Inflammation of large intestine:

- Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/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.

Contact your doctor as soon as possible for advice if you get these symptoms.

Other possible serious side effects

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- inflammation of the protective membrane surrounding the brain and spinal cord (*aseptic meningitis*)
- convulsions (in people taking high doses of Amoxicillin/Clavulanic Acid or who have kidney problems)
- severe reduction in the number of white blood cells (*agranulocytosis*) which may cause an increase in infections, such as sore throat, mouth ulcers, fever etc.
- low number of red blood cells (*haemolytic anaemia*) which may cause you to feel tired, breathless and have unusually pale skin.

Contact your doctor as soon as possible for advice if you get these symptoms.

Other possible side effects

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

- diarrhoea (in adults).

Common side effects (may affect up to 1 in 10 people):

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses (if affected take Germentin with a meal)
- vomiting
- diarrhoea (in children).

Uncommon side effects (may affect up to 1 in 100 people):

- skin rash
- itching
- raised itchy rash (*hives*)

- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in your blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects (may affect up to 1 in 1,000 people) that may show up in your blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells.

Not known (frequency cannot be estimated from the available data):

These side effects have occurred in a very small number of people but their exact frequency is unknown.

- blood takes longer to clot
- hyperactivity
- black tongue which looks hairy
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

Side effects that may show up in your blood or urine tests:

- crystals in urine leading to acute renal injury.

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 HPRA Pharmacovigilance. Website: 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 out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

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 contains

The active substances are amoxicillin and clavulanic acid. Each tablet contains 500 mg of amoxicillin (equivalent to 574 mg of amoxicillin trihydrate) and 125 mg clavulanic acid (equivalent to 148.9 mg of potassium clavulanate).

The other ingredients are magnesium stearate, talc, povidone, microcrystalline cellulose, croscarmellose sodium, triethyl citrate, hypromellose, ethylcellulose, sodium laurilsulfate, cetyl alcohol, titanium dioxide (E171).

What Germentin looks like and contents of the pack

The film-coated tablets of Germentin are off-white, oval, and biconvex with a score line on both sides.

Packs of 3, 10, 12, 14, 15, 16, 20, 21, 24, 30 and 50 tablets.

Hospital packs 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatrix Limited,

Damastown Industrial Park,

Mulhuddart Dublin 15,

DUBLIN Ireland

Manufacturer

Sandoz GmbH, Kundl, Austria

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Invented Name
Germany	amoxidura plus 500/125mg
Belgium	Amoxiclavmylan 500mg filmomhulde tabletten
Greece	Co-Amoxiclav/Mylan επικαλυμμένα με λεπτό υμένιο δισκία (500+125)mg/TAB
Ireland	Germentin 500 mg/125 mg film coated tablets
Spain	Amoxicillin/acido clavulanico Viartis 500/125mg comprimidos recubiertos con película EFG
Netherlands	Amoxicilline/Clavulaanzuur Viartis 500/125mg, tabletten 500mg + 125mg

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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.