

Package leaflet: Information for the patient

Germentin 125 mg/31.25 mg per 5 ml Powder for Oral Suspension (amoxicillin and clavulanic acid)

Read all of this leaflet carefully before you start giving your child this medicine because it contains important information for you. If you are an adult who has been given this medicine, this information applies to you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for a baby or child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. 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 give Germentin
3. How to give 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). The other active component (clavulanic acid) stops this from happening.

Germentin is used in adults, 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.

You must talk to a doctor if your child does not feel better or if your child feels worse after 14 days.

2. What you need to know before you give Germentin

Do not give your child Germentin:

- 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, lips, tongue, throat or neck
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Do not give Germentin 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 Germentin.

Warnings and precautions

Check with their doctor, pharmacist or nurse before giving your child Germentin if they:

- 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 your child, talk to their doctor or pharmacist before giving Germentin.

In some cases, your doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child 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 your child is taking Germentin, to reduce the risk of any problems (see section 4).

Blood and urine tests

If your child is 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 they 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 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 Germentin, it may be more likely that they will have an allergic skin reaction.

If your child is taking probenecid (used to treat gout), your doctor may decide to adjust the 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 your child who is about to take this medicine is pregnant or breast-feeding, thinks they might be pregnant or are planning to have a baby, ask their doctor or pharmacist for advice before taking this medicine.

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

Driving and using machines

Germentin can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

Germentin contains aspartame (E951)

This medicine contains 8.5 mg aspartame (E951) in each 5 ml dose which is equivalent to 1.7 mg/ml. Aspartame is a source of phenylalanine. This may be harmful if you or your child has 'phenylketonuria' (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Germentin contains glucose and sorbitol

If you have been told by your doctor that you or your child has an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 0.15 mg sorbitol in each 5 ml dose.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml suspension, that is to say essentially 'sodium-free'.

3. How to give Germentin

Always give 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 or over

This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

Use in children weighing less than 40 kg

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

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

- Always shake the bottle well before each dose
- Give with a meal
- 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 Germentin for more than 2 weeks. If your child still feels unwell they should go back to see the doctor.

If you give more Germentin than you should

If you give your child 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 their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Germentin

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.

Do not take a double dose to make up for a forgotten dose.

If your child stops taking Germentin

Keep giving your child Germentin 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

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

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

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 throat (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 your child gets any of these symptoms. **Stop taking Germentin.**

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 your child gets these symptoms.

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)
- 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)

→ if you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in blood tests

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

Not known (cannot be estimated from the available data)

- allergic reactions (see above)
- inflammation of the large intestine (see above)
- inflammation of the protective membrane surrounding the brain and spinal cord (aseptic meningitis)
- serious skin reactions:
 - a widespread rash with blisters, bleeding 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))

→ **Contact a doctor immediately if your child gets any of these symptoms.**

- inflammation of the liver (hepatitis)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may cause yellowing of the skin and 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
- pain passing urine, lower back pain or fever. These may be signs of inflammation of the tubes in the kidney
- blood takes longer to clot
- hyperactivity
- fits/convulsions (especially if your child takes high doses of Germentin or if your child has kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing.
- tiredness, headaches, shortness of breath when exercising, dizziness, pale or yellowing of the skin or eyes
- 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)

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

- severe reduction in the number of white blood cells
- low number of red blood cells (haemolytic anaemia)
- crystals in urine

Other side effects include:

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

- diarrhoea (in adults)

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 your child takes high doses

→ if affected take Germentin with a meal

- being sick (vomiting)
- diarrhoea (in children)

Uncommon (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 blood tests:

- increase in some substances (enzymes) produced by the liver which can be seen 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
- stained teeth (in children), usually removed by brushing
- shortness of breath
- other infections that are difficult to treat (over-growth of non-susceptible organisms)
- 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)
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)).

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 this medicine out of the sight and reach of children.

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

Reconstituted suspension: To be stored in a refrigerator (2 to 8°C) and used within 7 days. Do not freeze. Do not use this medicine if lumps of powder are visible in the bottle before reconstitution.

Store in the original package with the bottle tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date 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 125 mg/5 ml amoxicillin (as the trihydrate) and 31.25 mg/5 ml clavulanic acid (as the potassium salt).

The other ingredients are citric acid, sodium citrate, aspartame (E951) (see section 2 ‘Germentin contains aspartame’), talc, guar, silicon dioxide, flavouring agents: lemon (containing glucose and sorbitol E420) (see section 2 ‘Germentin contains glucose and sorbitol’), peach-apricot (containing sorbitol E420) (see section 2 ‘Germentin contains glucose and sorbitol’) and orange (containing essence of bergamot).

What Germentin looks like and contents of the pack

Germentin powder for oral suspension comes in a bottle. The powder is off-white in colour with a fruity flavour. The pharmacist mixes the powder with water to make a suspension. Germentin is available in bottles of 60ml or 100ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Sandoz GmbH, Biochemiestr 10, A-6250 Kundl, Austria
McDermott Laboratories Limited, t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13.

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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.

Instructions for reconstitution

After opening of the screw cap, ensure that the bottle cap seal is intact and tightly attached to the bottle rim. Do not use if not intact.

Shake bottle to loosen powder. Do not use this medicine if lumps of powder are visible in the bottle before reconstitution. Add volume of water (as indicated below) invert and shake well.

<u>Strength</u>	<u>Volume of water to be added at reconstitution (ml)</u>	<u>Final volume of reconstituted oral suspension (ml)</u>
125 mg/31.25 mg/5 ml	Make up to mark	60
	95	100

Do not use the reconstituted suspension if the colour is not off-white.

Shake the bottle well before each dose.

The suspension may be diluted with an equal quantity of water to provide a half strength suspension.