

Package leaflet: Information for the patient

Clavamel Forte 500 mg/125 mg Film-coated Tablets

Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start using 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 Clavamel Forte is and what it is used for
2. What you need to know before you take Clavamel Forte
3. How to take Clavamel Forte
4. Possible side effects
5. How to store Clavamel Forte
6. Contents of the pack and other information

1. What Clavamel Forte is and what it is used for

Clavamel Forte 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.

Clavamel Forte 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 Clavamel Forte

DO NOT take Clavamel Forte:

- 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 (hypersensitive) 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 Clavamel Forte if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Clavamel Forte.

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 Clavamel Forte.

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 Clavamel Forte or a different medicine.

Conditions you need to look out for

Clavamel Forte 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 Clavamel Forte, to reduce the risk of any problems. See '*Conditions you need to look out for*' in 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 Clavamel Forte. This is because Clavamel Forte can affect the results of these types of tests.

Other medicines and Clavamel Forte

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 Clavamel Forte, 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 Clavamel Forte.

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

Clavamel Forte can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

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

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

Clavamel Forte can have side effects and the symptoms may make you unfit to drive. Don't drive or operate machinery unless you are feeling well.

Clavamel Forte contains sodium

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

3. How to take Clavamel Forte

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

Adults and children weighing 40 kg and over

The recommended dose is:

- 1 tablet three times a day

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Amoxicillin/clavulanic acid oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Clavamel Forte tablets to children weighing less than 40 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 Clavamel Forte

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Clavamel Forte for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Clavamel Forte than you should

If you take too much Clavamel Forte, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

If you forget to take Clavamel Forte

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.

If you stop taking Clavamel Forte

Keep taking Clavamel Forte 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 Clavamel Forte.**

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.

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 Clavamel Forte before food
- 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)

- 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 your blood tests:

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

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is not known (frequency cannot be estimated from the available data).

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the membranes that surround the brain and spinal cord (*aseptic meningitis*)
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- 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 (*exanthematous 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 you get 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 make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Clavamel Forte or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing

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

- severe reduction in the number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine leading to acute kidney 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 the national reporting system:

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 Clavamel Forte

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 carton and the strip. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

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 Clavamel Forte contains

The active substances are amoxicillin and clavulanic acid.

Each tablet contains 500 mg amoxicillin and 125 mg clavulanic acid.

The other ingredients are:

Core

Colloidal anhydrous silica, Magnesium Stearate, Sodium Starch Glycolate (Type A), Microcrystalline Cellulose

Coating

Triethyl Citrate, Hypromellose, Talc, Ethylcellulose, Cetyl alcohol, Sodium lauryl sulphate, Titanium Dioxide (E171)

What Clavamel Forte looks like and contents of the pack

Clavamel Forte film-coated tablets are oblong, white to slightly yellowish film-coated tablets (10 mm x 21 mm), embossed on one side (GG N6).

Clavamel Forte are supplied in Al/Al strips containing 10, 12, 20, 21, 24 or 30 film-coated tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria

STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Germany: Amoxicillin/Clavulansäure AL 500mg/125mg Filmtabletten

Spain: Amoxicilina/Acido clavulánico STADA 500mg/125mg comprimidos recubiertos con película EFG

Ireland: Clavamel Forte 500mg/125mg film-coated tablets

This leaflet was last revised in November 2022.