

PACKAGE LEAFLET: INFORMATION FOR THE USER

Clavamel Forte 500/125mg Tablets

Active substance: amoxicillin and clavulanic acid

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Clavamel Forte 500/125 mg tablets are and what they are used for
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1. What Clavamel Forte 500/125 mg tablets are and what they are used for

Co-amoxiclav 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 500/125 mg tablets are 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. Before you give Clavamel Forte 500/125 mg tablets

Do not take Clavamel Forte 500/125 mg tablets:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid or any of the other ingredients of Clavamel Forte 500/125 mg tablets (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 500/125 mg tablets if any of the above apply to you. If you are not sure, talk to their doctor or pharmacist before giving Clavamel Forte 500/125 mg tablets.

Take special care with Clavamel Forte 500/125 mg tablets

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 applies 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 Co-amoxiclav or a different medicine.

Conditions you need to look out for

Clavamel Forte 500/125 mg tablets 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 or 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 500/125 mg tablets. This is because Clavamel Forte 500/125 mg tablets can affect the results of these types of tests.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 500/125 mg tablets, it may be more likely that they will have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust the dose of Clavamel Forte 500/125 mg tablets.

If medicines to help stop blood clots (such as warfarin) are taken with Clavamel Forte 500/125 mg tablets then extra blood tests may be needed.

Clavamel Forte 500/125 mg tablets can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Pregnancy and breast-feeding

If you are pregnant, you think you might be pregnant or if you are breast-feeding, please tell your doctor or pharmacist.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Clavamel Forte 500/125 mg tablets can have side effects and the symptoms may make you unfit to drive. Don't drive or operate machinery unless you are feeling well.

3. How to give Clavamel Forte 500/125 mg tablets

Always take Clavamel Forte 500/125 mg tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg or over

The usual 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 Co-amoxiclav powder for oral suspension

Ask your doctor or pharmacist for advice when giving Clavamel Forte 500/125 mg 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 they may have more frequent blood tests to see how your liver is working.

How to take Clavamel Forte 500/125 mg tablets

- 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 500/125 mg tablets for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Clavamel Forte 500/125 mg tablets than you should

If you take too much Clavamel Forte 500/125 mg tablets, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to take Clavamel Forte 500/125 mg tablets

If you forget to take a dose, give 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 500/125 mg tablets

Keep taking Clavamel Forte 500/125 mg tablets 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Clavamel Forte 500/125 mg tablets can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

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.

Contact a doctor immediately if you get any of these symptoms. **Stop taking Clavamel Forte 500/125 mg tablets.**

Inflammation of large intestine

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

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

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These 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 500/125 mg tablets before food
- vomiting
- diarrhoea (in children).

Uncommon side effects

These 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.

Rare side effects

These may affect up to 1 in 1000 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 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 unknown.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- 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*).
- 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 child's 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 500/125 mg tablets 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 blood or urine tests:

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

If you get side effects

- Tell your doctor or pharmacist** if any of the side effects become **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5. How to store Clavamel Forte 500/125 mg tablets

Keep out of the reach and sight of children.

Store in the original package.

Strip: Do not store above 30°C.

Glass bottle: Keep the container tightly closed.

Do not take Clavamel Forte 500/125 mg tablets after the expiry date which is stated on the blister after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Clavamel Forte 500/125 mg tablets contains

The active substances are amoxicillin and clavulanic acid.

Each Clavamel Forte 500/125 mg tablet contains 500 mg of amoxicillin (as amoxicillin trihydrate) and 125 mg of clavulanic acid (as potassium clavulanate).

The other ingredients are:

- Cellulose, microcrystalline
- Quinoline yellow (E104)
- Titanium dioxide (E171)
- Crospovidone
- Povidone
- Silica, colloidal anhydrous
- Stearic acid
- Macrogol 6000
- Hypromellose
- Saccharine sodium
- Vanilla flavour
- Magnesium stearate

What Clavamel Forte 500/125 mg tablets look like and contents of the pack:

Clavamel Forte 500/125 mg tablets are yellowish white to light yellow, oblong tablets with an embossment “625” on one side.

Clavamel Forte 500/125 mg tablets are available as 10, 14, 20 tablets in a brown glass bottle (type III), with aluminium screw cap with desiccant (white gel and molecular sieve) or 10, 12, 14, 16, 20, 30, 32, 50, 100 or 500 tablets in Al/Al-blister.

Marketing Authorisation Holder and Manufacturer

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

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

NL: Amoxicilline/Clavulaanzuur STADA 500/125 tabletten 500 en 125 mg
AT: Amoxistad plus 625 mg Tabletten
BE/LU: Amoclane 500/125 mg tabletten
DE: Amoxi-Clavulan AL 500/125 mg Tabletten
IE: Clavamel Forte 500/125 mg tablets

This leaflet was last approved in March 2013.

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.
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