

PACKAGE LEAFLET: INFORMATION FOR THE USER

Klavox Film-Coated Tablets 1 g 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 (or for your child). 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.

In this leaflet:

1. What Klavox is and what it is used for
2. Before you take Klavox
3. How to take Klavox
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1. What Klavox is and what it is used for

What Klavox is

Klavox 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. Klavox 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. Before you take Klavox

Do not take Klavox:

- If you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Klavox (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 Klavox if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Klavox.

Take special care with Klavox

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

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

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

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 Klavox or a different medicine.

Conditions you need to look out for Klavox 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 Klavox, 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 Klavox. This is because Klavox can affect the results of these type of tests.

Using other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that can be bought without a prescription.

- If you are taking allopurinol (used for gout) with Klavox, 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 Klavox.
- If medicines to help stop blood clots (such as warfarin) are taken with Klavox then extra blood tests may be needed.
- In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin (see 2. Before you take Klavox).
- Klavox can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Klavox can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) 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

Klavox 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 take Klavox

Always take Klavox 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 and over

The usual doses are:

- 1 tablet of Klavox 1 g twice daily.

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Klavox suspension.

Ask your doctor or pharmacist for advice when giving Klavox 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 see how your liver is working.

How to take Klavox

- Swallow the tablet whole with a glass of water at the start of a meal or slightly before.
- 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.
- Do not take Klavox for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Klavox than you should

If you have too much Klavox, 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 to show the doctor.

If you forget to take Klavox

- 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 dose.

If you stop taking Klavox

Keep taking Klavox 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, Klavox 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

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

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 Klavox 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 your 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 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 unknown.

- Allergic reactions
- Inflammation of the large intestine
- Prolongation of bleeding time and prothrombin time (see 2. Before you take Klavox)

- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)

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).

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 the kidney
- Blood takes longer to clot
- Hyperactivity
- Convulsions (in people taking high doses of Klavox or who have kidney problems)
- Black tongue which looks hairy

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.

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

5. How to store Klavox

- Keep out of the reach and sight of children.
- Do not use Klavox after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a dry place below 25°C.
- 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 Klavox contains

Klavox contains two medicines amoxicillin and clavulanic acid.

Each Klavox 1 g tablet contains 875 mg amoxicillin and 125 mg clavulanic acid.

Other ingredients:

Excipients
Magnesium Stearate, Colloidal Silicon Dioxide, Sodium Starch Glycolate, and Avicel PH 112.
Coating Material
Opadry OY-S-7300 and Silicon Oil.

What Klavox looks like and contents of the pack

Klavox 1 g tablet is a white to off-white oblong shaped film-coated tablet with breakline on one side and other side with numbers "167".

Each pack of Klavox 1 g tablets contains 14 tablets.

Marketing Authorisation Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant
Saudi Arabia

This leaflet is approved in September 2019.

'Klavox' trade mark
34KL821

To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2340.
- Hotline: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
 - The doctor and the pharmacists are experts in medicine, its benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children**
Council of Arab Health Ministers
Union of Arab Pharmacists