

PACKAGE LEAFLET: INFORMATION FOR THE USER

Klavox
457mg/5ml
Powder for oral suspension
Amoxicillin and Clavulanic acid

Read all of this leaflet carefully before you start giving your child 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 is usually prescribed for a baby or child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- 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:

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1. WHAT **Klavox** IS AND WHAT IT IS USED FOR

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 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.

2. BEFORE YOU GIVE **Klavox**

Do not give your child **Klavox**:

- If they are allergic (hypersensitive) to amoxicillin, clavulanic acid or any of the other ingredients of **Klavox** (listed in section 6)
- If they have ever had an allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
- If they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic

Do not give **Klavox** to your child if any of the above apply to your child.

If you are not sure, talk to your doctor or pharmacist before giving **Klavox**.

Take special care with **Klavox**

Check with your doctor or pharmacist before giving your child this medicine if they:

- 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 your child, talk to your doctor or pharmacist before giving **Klavox**.

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 **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 your child is taking **Klavox**, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

Blood or urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests, let the doctor or nurse know that they are taking **Klavox**. This is because **Klavox** can affect the results of these types of tests.

Using other medicines

Please tell your doctor or pharmacist if your child is taking or has recently taken 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 **Klavox**, it may be more likely that they will have an allergic skin reaction.
- If your child is taking probenecid (used for gout), your doctor may decide to adjust the 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 your patient who is about to take this medicine is pregnant or breast-feeding, please tell your doctor or pharmacist.

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

Important information about some of the ingredients of **Klavox**

- **Klavox** does not contain sugar.
- **Klavox** contains aspartame (NF) which is a source of phenylalanine. This may be harmful for children born with a condition called 'phenylketonuria'.

3. HOW TO GIVE **Klavox**

Always give **Klavox** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

To make up to 70ml: first shake bottle to loosen powder. Then add 62ml of water and shake well or add water to 2/3 of fill line level on label, shake well and fill up to the line. Shake well before taking each dose.

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.

Children weighing less than 40 kg:

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

- Your doctor will advise you how much **Klavox** you should give to your baby or child.
- You may be provided with a plastic measuring spoon or plastic measuring cup or dosing syringe. Instructions on how to use the dosing syringe are provided at the end of this leaflet. You should use this to give the correct dose to your baby or child.
- Recommended dose - 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose - up to 70 mg/10 mg for each kilogram of body weight a day, given in two 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 **Klavox**

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

If you give more **Klavox** than you should

If you give your child too much **Klavox**, 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 give **Klavox**

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.

If your child stops taking **Klavox**

Keep giving your child **Klavox** until the treatment is finished, even if he feels 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Klavox** 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 your child gets any of these symptoms. Stop giving **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 your child gets 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 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
- Inflammation of the large intestine
- Prolongation of bleeding time and prothrombin time (see 2. Before you take **Klavox**)
- 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 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 make your child's skin and whites of the eyes appear yellow
- Inflammation of tubes in the kidney
- Blood takes longer to clot
- Hydractivity
- Convulsions (in people taking high doses of **Klavox** 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 your child gets 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 **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.
- The expiry date which is stated on the bottle label is for the pharmacist's use.
- Once reconstituted the suspension must be stored in a refrigerator and used within 7 days.
- Keep tightly closed and 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 457mg/5ml Powder for oral suspension: When reconstituted each 5 ml contains 400 mg amoxicillin and 57 mg clavulanic acid.

The amoxicillin is present as amoxicillin trihydrate and the clavulanic acid is present as potassium clavulanate.

- The other ingredients are Xanthan Gum, Hydroxypropyl Methyl cellulose, Aspartame NF, Colloidal Silicon Dioxide, Succinic Acid, Silicon Dioxide NF 18 Silica Gel, Raspberry Dry Flavour NN07943, Orange Dry Flavour 61027 1 E, Orange Dry Flavour 9/027108, Orange Dry Flavour 653970, Golden Syrup Dry Flavour 52.927.
- **Klavox** does not contain sugar.

What **Klavox** looks like and contents of the pack

Klavox 457mg/5ml Powder for oral suspension: 100 ml/pack

Clear bottle with white child-resistant cap.

Marketing Authorisation Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant

Saudi Arabia

This leaflet was last revised in September 2019.

¹ **Klavox**® trade mark
34KL818

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