

Patient Information Leaflet (PIL)

CoAmox 1000 mg film coated tablets

Amoxicillin/clavulanic acid

Read all of this leaflet carefully before you start taking 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 (or for your child) 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 CoAmox is and what it is used for
2. Before you take CoAmox
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1. What CoAmox is and what it is used for

CoAmox 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.

CoAmox 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 CoAmox

a. Do not take CoAmox:

- 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 reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

→ **Do not take CoAmox if any of the above apply to you.** If you are not sure, talk to your doctor or pharmacist before taking CoAmox.

b. Take special care with CoAmox

Talk to your doctor or pharmacist before taking CoAmox 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 CoAmox.

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 CoAmox or a different medicine.

Conditions you need to look out for

CoAmox 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 CoAmox, 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 CoAmox. This is because CoAmox can affect the results of these types of tests.

c. Taking other medicines and CoAmox

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

If you are taking allopurinol (used for gout) with CoAmox, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of CoAmox.

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

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

CoAmox can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

d. Pregnancy, breast-feeding and fertility

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.

e. Driving and using machines

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

3. How to take CoAmox

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

Adults and children weighing 40 kg and over

- Usual dose – 1 tablet two times a day
- Higher dose – 1 tablet three times a day

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with CoAmox oral suspension or sachets. Ask your doctor or pharmacist for advice when giving CoAmox 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 check how your liver is working.

How to take CoAmox

- Swallow the tablets whole with a glass of water with a meal.

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.

- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take CoAmox for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

a. If you take more CoAmox than you should

If you take too much CoAmox, 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.

b. If you forget to take CoAmox

If you forget to take a dose, take it as soon as you remember, but wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

c. If you stop taking CoAmox

Keep taking CoAmox 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. 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 throat (*angioedema*), causing difficulty in breathing collapse.

→ **Contact a doctor immediately** if you get any of these symptoms. **Stop taking CoAmox.**

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 CoAmox with a meal

- 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.

Frequency not known

Frequency 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 (*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*).

- 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 CoAmox 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.

5. How to store CoAmox

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

Do not store above 30°C.

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

Do not use if the tablets are chipped or damaged.

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. Further information

a. What CoAmox contains

The active substances are amoxicillin and clavulanic acid. Each tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin and potassium clavulanate equivalent to 125 mg of clavulanic acid.

- The other ingredients are: Tablet core – Colloidal silicon dioxide, Crospovidone, dried, Crosslinked carboxymethylcellulose sodium dried, Magnesium stearate & Microcrystalline Cellulose, dried.

Film-coat – Hydropropoxycellulose, Ethylcellulose, Polysorbate, Triethylcitrate, Titanium dioxide, Talc.

b. What CoAmox looks like and contents of the pack

CoAmox 1000 mg film coated tablets are white to off-white, oblong film coated tablet with beveled edges, scored and debossed with 875/125 on one side and debossed with AMC on the other side.

They are packaged in blister packs, enclosed in a carton. Each pack contains 12 tablets.

c. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Acino Pharma AG, Liesberg, Switzerland.

Manufacturer:

Lek, Prevalje, Slovenia

d. This leaflet was last revised in June 2018.

e. 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,

Ext: 2317-2356-2353-2354-2334-2340.

- Toll free phone: 8002490000
- E-mail: npc.drug@sdfa.gov.sa
- Website: www.sdfa.gov.sa/npc

f. Council of Arab Health Ministers

This is a Medicament

- 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 pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacist

Product	PIL CoAmox Acino 1000mg film tab SA	Order No.	4500047062	1. proof	08.10.2018
Material	40894	Dimension	130 x 810 mm	2. proof	11.10.2018
Text-Code	3918	Pages	2	3. proof	
Pharmacode		Colour	black	4. proof	
	Müller-Druck + Grafik AG, CH-4147 Aesch	Customer	Acino Pharma AG		