

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CILAMOX.

It does not contain all the available information.

It does not take place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of using CILAMOX against the benefits this medicine is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What is CILAMOX

The name of your medicine is CILAMOX.

CILAMOX is an antibiotic that belongs to the group of medicines called penicillins.

CILAMOX contains an active ingredient called amoxicillin trihydrate.

CILAMOX is available as:

- ◆ capsules: 250mg and 500mg
- ◆ sugar free syrup: 250 mg/5 mL

What is CILAMOX used for

CILAMOX is used to treat infections in different parts of the body caused by bacteria.

CILAMOX works by killing the bacteria that are causing the infection. CILAMOX can also be used to prevent infection.

CILAMOX will not work against infections caused by viruses such as colds or flu.

Your doctor however, may have prescribed CILAMOX for another purpose.

Ask your doctor (or pharmacist) if you have any questions about why CILAMOX has been prescribed for you.

Before you take CILAMOX

When you must not take it

Do not take CILAMOX if you have ever had an allergic reaction to:

- ◆ medicines containing amoxicillin
- ◆ penicillin or any other similar antibiotics such as cephalosporins
- ◆ any of the other ingredients in CILAMOX listed at the end of this leaflet.

Some symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips, mouth or throat which may cause difficulty swallowing or breathing; wheezing or shortness of breath.

Tell your doctor if you have suffered from any of the allergic conditions in the past due to the use of penicillin.

Do not use CILAMOX if the packaging is torn or shows signs of tampering.

Do not use CILAMOX if the expiry date printed on the pack has passed.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- ◆ You are allergic to any other medicines, foods, dyes or preservatives.
- ◆ You have ever had an allergic reaction to any antibiotics in the past.
- ◆ You have glandular fever (mononucleosis) or a blood disorder.
- ◆ You are pregnant or intend to become pregnant. *CILAMOX may be used during pregnancy (Australian Use in Pregnancy Category A). However, your doctor will discuss with you the risks and benefits of taking CILAMOX during pregnancy.*
- ◆ You are breastfeeding or plan to breastfeed. CILAMOX can pass to your baby from breast milk.
- ◆ You have liver or kidney problems. The dosage of CILAMOX may need to be changed or you may need to be given an alternative medicine.

If you have not told your doctor about any of the above, tell them before you start taking CILAMOX.

Taking other medicines

Tell your doctor (or pharmacist) if you are taking any other medicines. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way other's work. These include:

- ◆ Medicines used to treat gout, eg probenecid or allopurinol.
- ◆ Oral contraceptive pills. You may need to use other birth control methods while you are taking CILAMOX.

- ◆ Other antibiotics. These may interfere with the actions of CILAMOX.

If you are not sure whether you are taking any of these medicines, check with your doctor or your pharmacist.

How to take CILAMOX

Follow the instructions given by your doctor and Pharmacist and read the label carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist.

How much to take

The dose varies from person to person.

The usual dose is:

Adults: CILAMOX capsule 250 mg – 500 mg every eight hours or CILAMOX capsule 3 g as a single dose.

Children (under 20 kg): CILAMOX sugar free syrup 25 - 50 mg/kg/day in equally divided doses every eight hours.

The dose will depend on the type of treatment required for a patient. Your doctor will decide the number of doses needed each day and how long you will need to take CILAMOX. These doses may differ from the usual doses shown in this leaflet.

How to take it

CILAMOX can be taken with or without food.

Capsules: Swallow the whole capsule with a glass of water.

Syrup: Shake the bottle well before administer the required dose of syrup as instructed by your doctor or pharmacist.

How long to take it

Your doctor or pharmacist will tell you how long to use CILAMOX.

Take the whole course of CILAMOX until it is finished. Do not stop taking CILAMOX even if you feel better. Your infection and symptoms may return.

If you forget to take it

If you forget to take CILAMOX, take it as soon as you remember and then go back to your normal dose times. Do not take two doses within 3 - 4 hours of each other.

If it is almost time for your next dose, skip the dose you missed and take your next dose at the time it is due.

Do not take double dose to make up for the dose you missed. If you not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Telephone your doctor or the Poisons Information Centre (phone 13 11 26) or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CILAMOX. Do this even if there are no signs of discomfort or poisoning.

While you are using CILAMOX

Things you must do

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking CILAMOX.

Tell all your doctor(s), dentist and pharmacist(s) who are treating you that you are taking CILAMOX.

If your symptoms do not improve within a few days, or if they become worse, tell your doctor immediately.

If you develop any form of skin rash and/or itching, swelling or difficulty in breathing while taking CILAMOX, do not take

CILAMOX any more. Contact your doctor immediately.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped using CILAMOX. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

Tell your doctor if you get a sore mouth or tongue, vaginal itching or discharge while taking or after you have stopped taking CILAMOX. This could be due to a fungal infection called Thrush. This may also result in fever and irritation in the stomach. Sometimes the use of this medicine allows fungi to grow, as CILAMOX is ineffective against fungi.

If you have to get any blood or urine tests done tell your doctor and nurse that you are taking CILAMOX. CILAMOX may affect the results of some tests.

Tell your doctor if, for any reason, you have not used CILAMOX exactly as prescribed. Otherwise, your doctor may think that the medicine was not effective and change your treatment unnecessarily.

Things you must not do

Do not give CILAMOX to anyone else even if their symptoms seem similar to yours.

Do not use CILAMOX to treat other conditions unless your doctor tells you.

Things to be careful of

Take care while driving or operating machinery until you know how CILAMOX affects you.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CILAMOX.

CILAMOX treats most people with infections, but it may have some unwanted side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Mild Side Effects:

Tell your doctor if you notice any of the following and they worry you:

- ◆ nausea & vomiting
- ◆ diarrhoea
- ◆ oral thrush (white, furry sore tongue and mouth)
- ◆ vaginal thrush (sore, itchy vagina)

Serious Side Effects:

Tell your doctor immediately if you notice any of the following:

- ◆ rash or itching
- ◆ bleeding or bruising more easily than normal
- ◆ yellowing of the skin and eyes
- ◆ dark urine or pale stools
- ◆ difficulty in passing urine
- ◆ fits or seizures
- ◆ severe diarrhoea

Stop taking CILAMOX and contact your doctor immediately or go to Accident and Emergency at the nearest hospital, if any of the following happens:

- ◆ lumpy rash (hives), itching, blistering or peeling of the skin.
- ◆ swelling of the face, lips, mouth or throat
- ◆ Wheezing, shortness of breath or difficulty breathing.

CILAMOX may cause other side effects not listed above. If you have any other side effects, tell your doctor.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using CILAMOX

Storage

Keep CILAMOX where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep CILAMOX capsules in a cool dry place where the temperature stays below 25°C.

Store the prepared CILAMOX sugar free syrup in a refrigerator preferably between 4 - 8°C.

DO NOT FREEZE. DISCARD UNUSED PRODUCT 14 DAYS AFTER PREPARATION.

Do not leave CILAMOX in the car or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using CILAMOX or it has passed its expiry date, ask your pharmacist what to do with any CILAMOX left over.

Further Information

This is not all the information that is available on CILAMOX. If you need more information, ask a doctor or pharmacist.

Product Description

What it looks like

Both CILAMOX 250 mg and 500 mg are opaque white body and opaque white cap capsules.

CILAMOX sugar free syrup 250 mg/5 mL is white in colour.

Active Ingredients

The active ingredient in Cilamox capsule and syrup is Amoxicillin (as Amoxicillin trihydrate)

List of Inactive Ingredients

CILAMOX 250 mg and 500 mg capsules contain the following:

- Magnesium stearate
- Gelatin
- Titanium dioxide

CILAMOX 250 mg/5 mL sugar free syrup also contains the following:

- Sorbitol
- Sodium benzoate
- Disodium edetate
- Silicon dioxide
- Silica-colloidal anhydrous
- Xanthan gum
- Saccharin sodium
- Trusil Nature Identical Passionfruit Flavour 17-3281
- Trusil Nature Identical Vanilla Flavour 17-9522

Both CILAMOX capsules and syrups are gluten, sucrose and lactose free.

Australian Registration numbers:

CILAMOX 250 mg - AUST R 56300
CILAMOX 500 mg - AUST R 56302

CILAMOX 250 mg/5 mL Sugar free Syrup - AUST R 57377

SPONSOR

Sigma Pharmaceuticals (Australia) Pty Ltd (A.C.N. 004 118 594)
96 Merrindale Dve
Croydon Victoria 3136
Australia
Telephone: 03 - 9839 2800

This leaflet was prepared in February 1996, updated in April and December 1996, August 2001, February 2008 and January 2009.