

CILICAINE *(sil-i-kane)*

Phenoxymethylpenicillin

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about CILICAINE.

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 CILICAINE 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 CILICAINE?

The name of your medicine is CILICAINE.

CILICAINE is a type of antibiotic that belongs to the group of medicines

called penicillins (*pen-i-sil-lins*).

CILICAINE contains a penicillin as an active ingredient called phenoxymethylpenicillin (*fen-oxy-meth-ill-pen-i-sil-lin*).

CILICAINE is available as:

- Cilicaïne VK capsules: 250 mg and 500 mg

- Cilicaïne V oral suspension: 125 mg & 250 mg/5 mL

What is CILICAINE used for?

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

CILICAINE works by killing the bacteria that are causing the infection.

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

Your doctor however, may have prescribed CILICAINE for another

purpose.

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

A doctor's prescription is required for CILICAINE.

Before you take CILICAINE

When you must not take it

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

- CILICAINE or other penicillin's
- any of the other ingredients in CILICAINE listed at the end of this leaflet.

If you have had an allergic reaction to cephalosporins. You may have an increased chance of being allergic to CILICAINE if you are or have been allergic to cephalosporins.

Some symptoms of an allergic reaction may include skin rash, itching, nausea, vomiting and

diarrhoea.

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 CILICAINE if the packaging shows sign of tampering or the seal is broken.

Do not use CILICAINE after the expiry date printed on the pack has passed.

It may have no effect at all, or worse, it may give an entirely unexpected effect if you use after the expiry date.

Before you start to take it

You must tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives.
- you are pregnant or intend to become pregnant.
- you are breast-feeding or plan to breast feed.
- you have or ever had asthma, kidney or any other health problems.

Like most medicines, CILICAINE is not

recommended in pregnancy and during breast-feeding. Your doctor will discuss the possible risks and benefits of taking CILICAINE during pregnancy and breast-feeding.

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. Your doctor or pharmacist can tell you what to do when taking with other medicines.

Avoid drinking alcohol while taking CILICAINE and for several days after completing a course of treatment with CILICAINE.

Tell your doctor or pharmacist if you are taking any oral contraceptive pills. You may need to use other birth control methods while you are taking CILICAINE.

**How to take
CILICAINE**

How much to take

The usual dose is:

Adults: *One CILICAINE capsule 250 mg - 500 mg every four to six hours or 250 mg twice daily.*

Children and infants:
15-50 mg/Kg/day in three to six divided doses. If not calculated by body weight the following dosage schedule may be used:

*Up to 1 year:
62.5 mg every six hours.*

*1 - 5 years:
125 mg every six hours.*

*6 - 12 years:
125 - 250 mg every six hours.*

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

Follow the instructions given by your doctor and pharmacist and read the label carefully.

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

How to take it

Swallow the whole capsule with a glass of water.

To children, administer the required dose of suspension as instructed by your doctor or pharmacist.

When to take it

CILICAINE should be taken preferably one hour before food. It should be taken every four to six hours, as instructed by your doctor or pharmacist.

How long to take it

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

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

If you forget to take it

If you forget to take CILICAINE, 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 have trouble remembering to take or give CILICAINE, ask your pharmacist for some hints.

If you take too much (overdose)

Telephone your doctor or Poisons Information Centre (phone 131126) if you think that you or anyone else may have taken too much CILICAINE. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers of these places handy.

There are unlikely to be any serious problems from an overdose of CILICAINE. But you must consult your doctor or Poison Information centre.

While you are using CILICAINE

Things you must do

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

If you develop any form of skin rash and/or itching or difficulty in breathing while taking CILICAINE, do not take CILICAINE any more. Contact your doctor immediately.

If you get diarrhoea, nausea or vomiting, tell your doctor. Consult your pharmacist or nurse in absence of your doctor. Do this even if it occurs several weeks after you have stopped using CILICAINE.

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.

If you become pregnant while you are taking CILICAINE tell your doctor.

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

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

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

Tell your doctor if you feel that CILICAINE is not helping your condition.

Tell your doctor if, for any reason, you have not used CILICAINE 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 stop taking CILICAINE until it is finished.

Do not stop taking CILICAINE even if you feel better. Your infection and symptoms may not clear completely.

Do not give CILICAINE to anyone else even if his or her symptoms seem similar to yours.

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

Your doctor has prescribed CILICAINE is especially for you and your condition. If you use it for another condition, it may not work or make the condition worse.

Things to be careful of

Tell your doctor if you get a sore mouth or tongue, vaginal itching or discharge while taking or after you have stopped

taking CILICAINE. This could be due to a fungal infection called Thrush. This may also result in fever and irritation in stomach. The use of this medicine may sometimes allow fungi to grow, as CILICAINE is ineffective against fungi.

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

CILICAINE generally does not affect your ability to drive a car or operate machinery. However, as with many other medicines, CILICAINE may also cause dizziness, drowsiness and/or tiredness in some people.

Side Effects

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

CILICAINE helps 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.

Ask your doctor or pharmacist to answer any

questions you may have.

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

Side effects reported by some people using CILICAINE include:

- skin rash
- nausea & vomiting
- black hairy tongue
- diarrhoea
- epigastric distress
- difficulty in breathing

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

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

After using CILICAINE

Storage

Keep CILICAINE 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 CILICAINE capsules in a cool dry place where

the temperature stays below 25°C.

Store CILICAINE V oral suspension in a refrigerator preferably between 2 - 8°C. Do not freeze. Shake CILICAINE V oral suspension well before use.

Do not leave CILICAINE in the car or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

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

Further Information

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

Product Description

What it looks like

CILICAINE 250 mg is opaque dark scarlet body and cap with SIGMA 250 mg inscribed in white ink on each capsule.

CILICAINE 500 mg

capsule is opaque white body and cap with SIGMA 500 mg inscribed in black ink on each capsule.

CILICAINE V oral suspension 125 mg/5mL is cream to yellow in colour. CILICAINE V oral suspension 250 mg/5mL is white in colour.

Ingredients

* Phenoxymethylpenicillin as the potassium salt is an active ingredient in both CILICAINE VK 250 mg and 500 mg capsules.

* Phenoxymethylpenicillin as the benzathine salt is an active ingredient in both CILICAINE V 125 mg/5mL and 250 mg/5mL sugar free syrups.

List of inactive ingredients

CILICAINE VK 250 mg capsules:

Gelatin, brilliant blue FCF CI42090, sunset yellow FCF CI15985, erythrosine CI45430, titanium dioxide and magnesium stearate.

Negligible quantities of the following ingredients are present in the white ink used to write the name SIGMA: Pharmaceutical glaze USP/NF, titanium dioxide, isopropyl alcohol, ammonium hydroxide,

propylene glycol, butan-1-ol and dimethicone.

CILICAINE VK 500 mg capsules:

Gelatin, titanium dioxide and magnesium stearate.

Negligible quantities of the following ingredients are present in the black ink used to write the name SIGMA: Pharmaceutical glaze USP/NF, isopropyl alcohol, pharmaceutical shellac USP/NF, butyl alcohol USP/NF and carbon black (vegetable).

CILICAINE V 125 mg/5mL oral suspension:

Sodium cyclamate, saccharin sodium, sorbitol, quinoline yellow CI47005, carmellose sodium, sodium phosphate - monobasic, masking agent LN5346 (ARTG No.406) and natural banana flavour 01-5215 (ARTG No.1862). Sodium dehydroacetate is used as a preservative.

CILICAINE V 250 mg/5mL oral suspension:

Sodium cyclamate, sucrose, carmellose sodium, sorbitol, sodium phosphate - dibasic, masking agent LN5346 (ARTG No.406), imitation coconut milk 03-5723 (ARTG No.545) and imitation vanice flavour 10-2245 (ARTG No.543).

Sodium dehydroacetate is used as a preservative.

Both CILICAINE capsules and syrups are Gluten and lactose free.

CILICAINE VK capsules

The Australian Product Registration numbers are: AUST R 55676 and 55675 for CILICAINE VK 250 mg and 500 mg capsules respectively.

CILICAINE sugar free syrup

The Australian Product Registration numbers are AUST R 48896 and AUST R 43486 for CILICAINE V125 and V250 oral suspension, respectively.

SPONSOR

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