CILICAINE® V

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CILICAINE V?

CILICAINE V contains the active ingredient phenoxymethylpenicillin benzathine. CILICAINE V is used to treat infections in different parts of the body caused by bacteria.

For more information, see Section <u>1. Why am I using</u> CILICAINE V? in the full CMI.

2. What should I know before I use CILICAINE V?

Do not use if you have ever had an allergic reaction to CILICAINE V or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use CILICAINE V? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CILICAINE V and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CILICAINE V?

- Your doctor will tell you how much CILICAINE V you need to take.
- This will depend on the type of infection you have.

More instructions can be found in Section <u>4. How do I use CILICAINE V?</u> in the full CMI.

5. What should I know while using CILICAINE V?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using CILICAINE V.
- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

	 If you develop itching with swelling of skin rash or difficulty breathing while you are taking CILICAINE V do not take any more and contact your doctor immediately.
Things you should not do	 Do not take CILICAINE V to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you. Do not stop taking your medicine because you are feeling better, unless advised by your doctor.
Driving or using machines	 Be careful driving or operating machinery until you know how CILICAINE V affects you.
Drinking alcohol	 Be careful when drinking alcohol while you are taking this medicine.

Looking after your medicine

- Store CILICAINE V oral suspension in a refrigerator, between 2°C to 8°C. Do not freeze. Shake well before use.
- Keep your suspension in the bottle until it is time to take it.

For more information, see Section <u>5. What should I know while using CILICAINE V?</u> in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea & vomiting, black hairy tongue, diarrhoea, or pain or discomfort right below your ribs (epigastric distress). If any of the following happen, tell your doctor immediately or go the Accident and Emergency at your nearest hospital: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CILICAINE® V

Active ingredient(s): phenoxymethylpenicillin

benzathine

Consumer Medicine Information (CMI)

This leaflet provides important information about using CILICAINE V. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CILICAINE V.

Where to find information in this leaflet:

- 1. Why am I using CILICAINE V?
- 2. What should I know before I use CILICAINE V?
- 3. What if I am taking other medicines?
- 4. How do I use CILICAINE V?
- 5. What should I know while using CILICAINE V?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using CILICAINE V?

CILICAINE V contains the active ingredient phenoxymethylpenicillin benzathine. CILICAINE V belongs to a group of medicines called penicillins. It works by killing the bacteria that are causing the

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

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

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

Your doctor may have prescribed this medicine for another purpose.

This medicine is not addictive.

This medicine is only available on a doctor's prescription.

2. What should I know before I use CILICAINE V?

Warnings

Do not use CILICAINE V if:

 you are allergic to any medicine containing phenoxymethylpenicillin benzathine, other penicillins, cephalosporins as you may have an increased chance of being allergic to CILICAINE V if you are allergic to this or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- o rash, itching or hives on the skin
- o nausea, vomiting and diarrhoea

Always check the ingredients to make sure you can use this medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes
- have or have had any of the following medical conditions:
 - asthma
 - kidney problems

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Like most medicines, CILICAINE V is not recommended during pregnancy of breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and CILICAINE V may interfere with each other.

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 V.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CILICAINE V.

4. How do I use CILICAINE V?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

- Follow the instructions provided when CILICAINE V was prescribed, including the number of days it should be taken.
- Adults: 250 mg to 500 mg every four to six hours, preferable one hour before food.
- Prevention of recurrence following rheumatic fever:
 250 mg twice a day continuously.
- **Children**: the dose varies depending on their age, weight and how sick they are.
- Your doctor may adjust your dose depending on the type and severity of the infection.

When to take CILICAINE V

 CILICAINE V should be taken at about the same time each day.

- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- Your medicine is best taken on an empty stomach (one hour before meals and at bedtime), unless otherwise directed by your doctor

How to take CILICAINE V

- Shake the bottle well before each dose and accurately measure the dose with a medicine measure.
- Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

How long to take it

 Continue taking your medicine for as long as your doctor tells you.

What if I am feeling better?

- The whole course of antibiotics should be taken, even if you are feeling better. If you stop taking antibiotics too soon the infection may start up again because not all the infection has been killed.
- If your symptoms do not improve within a few days of starting CILICAINE V, or if they have become worse, check with your doctor.

If you forget to take CILICAINE V

CILICAINE V should be taken regularly at the same time each day.

If it almost time for your next dose, skip the dose you missed and take you next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking you medicine as you would normally.

Do not take double dose to make for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much CILICAINE V

If you think that you have taken too much CILICAINE V, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or

 go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CILICAINE V?

Things you should do

- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- If you develop itching with swelling of skin rash or difficulty breathing while you are taking CILICAINE V do not take any more and contact your doctor immediately.
- If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after CILICAINE V has been stopped.

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 get a sore white mouth or tongue while taking or soon after stopping CILICAINE V, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of CILICAINE V allows fungi to grow and the above symptoms to occur. CILICAINE V does not work against fungi.

- If you become pregnant while taking CILICAINE V tell your doctor.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CILICAINE V.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
 It may interfere with the results of some tests.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you should not do

- Do not take CILICAINE V to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CILICAINE V affects you.

CILICAINE V generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, this medicine may cause dizziness/drowsiness/tiredness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Keep your suspension in the bottle until it is time to take it.

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

Keep it where children cannot reach it

Getting rid of any unwanted medicine

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

6. Are there any side effects?

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

CILICAINE V helps most people with infections, but it may have some unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Less serious side effects

Less serious side effects	What to do
nausea & vomitingblack hairy tonguediarrhoea	Speak to your doctor or pharmacist if you have any of these less serious

Less serious side effects	What to do
 pain or discomfort right below your ribs in the area of your upper abdomen (epigastric distress) 	side effects and they worry you.
The above list includes the more common side effects of your medicine.	

Serious side effects

Serious side effects	What to do
 shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body rash, itching or hives on the skin The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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Serious side effects What to do Severe abdominal Tell your doctor cramps or stomach immediately if you cramps notice any of the following side effects, Watery and severe particularly if they occur diarrhoea, which may several weeks after also be bloody stopping treatment with • Fever, in combination CILICAINE V with one or both of the above These are rare but serious side effects. CILICAINE V can change bacteria, which is normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CILICAINE V contains

Active ingredient (main ingredient)	CILICAINE V contains 40.27 mg per mL of Phenoxymethylpenicillin benzathine as the active ingredient (equivalent to 30 mg per mL of phenoxymethylpenicillin).
Other ingredients (inactive ingredients)	 Apricot Flavouring Super Alpina 58% (ARTG PI No: 106680)

	 Butylated hydroxyanisole Citric acid Polysorbate 80 Potassium sorbate Purified water Sodium citrate dihydrate Sodium methyl hydroxybenzoate Sodium propyl hydroxybenzoate Sucrose Xanthan gum
Potential allergens	CILICAINE V contains hydroxybenzoates, sorbates, sugars and soya bean products.

Do not take this medicine if you are allergic to any of these ingredients.

What CILICAINE V looks like

CILICAINE V is a beige, dense, viscous creamy suspension and apricot flavoured. (AUST R 151598)

Sponsor

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This leaflet was prepared in June 2022.

CILICAINE® is a Viatris company trade mark

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