

# KALIXOCIN<sup>®</sup>

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking KALIXOCIN?

KALIXOCIN contains the active ingredient clarithromycin. KALIXOCIN is used to treat certain bacterial infections including respiratory tract infections, ear infections, skin infections and peptic ulcer. KALIXOCIN is also used to prevent a specific bacterial infection associated with HIV infection. For more information, see Section [1. Why am I taking KALIXOCIN?](#) in the full CMI.

### 2. What should I know before I take KALIXOCIN?

Do not take if you have ever had an allergic reaction to clarithromycin, other antibiotics from the macrolide family 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.**

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For more information, see Section [2. What should I know before I take KALIXOCIN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with KALIXOCIN and affect how it works or may be affected by KALIXOCIN. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take KALIXOCIN?

Your doctor will tell you how much to take and when to take it. Take KALIXOCIN exactly as directed by your doctor. More instructions can be found in Section [4. How do I take KALIXOCIN?](#) in the full CMI.

### 5. What should I know while taking KALIXOCIN?

|                             |   |
|-----------------------------|---|
| <b>Things you should do</b> | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking KALIXOCIN.</li><li>• Tell your doctor if you are taking KALIXOCIN for an infection and your symptoms do not improve within a few days, or they become worse, you</li></ul> |
|-----------------------------|---|

|   |  |
|---|--|
|   | <p>become pregnant, you get severe diarrhoea, you experience heart palpitations, changes in heartbeat, dizziness or fainting or you are having urine tests.</p>  |
| <p><b>Things you should not do</b></p>    | <ul style="list-style-type: none"> <li>● Do not take KALIXOCIN to treat any other complaints unless your doctor says so.</li> <li>● Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> </ul> |
| <p><b>Driving or using machines</b></p>   | <ul style="list-style-type: none"> <li>● Be careful driving or operating machinery until you know how KALIXOCIN affects you.</li> </ul>  |
| <p><b>Looking after your medicine</b></p> | <ul style="list-style-type: none"> <li>● Keep KALIXOCIN tablets in a cool dry place below 25°C and protected from light.</li> </ul>  |

For more information, see Section [5. What should I know while taking KALIXOCIN?](#) in the full CMI.

## 6. Are there any side effects?

**Tell your doctor if you experience any of the following:** stomach cramps and pains, nausea, vomiting and diarrhoea, oral thrush or vaginal thrush, change in taste sensation, headache, asthma, shortness of breath, muscle weakness, pain or spasms, conjunctivitis, chills, fatigue, eructation (belching), stomach distension or flatulence. **Tell your doctor immediately if you notice any of the following as you may need urgent medical care:** yellowing of the eyes or skin, feeling generally unwell and having poor appetite, hearing disturbances, chest pain, dizziness, confusion, hallucinations, convulsions, fainting, irregular heartbeat, any type of skin rash, itching, hives, severe diarrhoea, especially if bloody or severe upper stomach pain, with nausea and vomiting. **Stop taking KALIXOCIN and 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:** swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse. 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.

# KALIXOCIN<sup>®</sup>

Active ingredient: *clarithromycin*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

- [1. Why am I taking KALIXOCIN?](#)
- [2. What should I know before I take KALIXOCIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take KALIXOCIN?](#)
- [5. What should I know while taking KALIXOCIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking KALIXOCIN?

**KALIXOCIN contains the active ingredient clarithromycin**, an antibiotic that belongs to the group of medicines called macrolides. These medicines work by killing or stopping the growth of bacteria which cause infections. KALIXOCIN will not work against infections caused by viruses, such as colds or flu.

**KALIXOCIN is used to treat certain bacterial infections, including the following:**

- **respiratory tract infections (throat, airways and lungs)**
- **ear infections**
- **skin infections**
- **peptic ulcer**

**KALIXOCIN is also used to prevent a specific bacterial infection associated with HIV infection.**

Your doctor, however, may have prescribed KALIXOCIN for another purpose. Ask your doctor if you have any questions about why KALIXOCIN has been prescribed for you.

### **KALIXOCIN to treat peptic ulcer**

Peptic ulcers are associated with an infection in the intestine and stomach by a type of bacteria called *Helicobacter pylori* (*H. pylori*). Nearly all patients with peptic ulcers are infected with this bacteria.

The *H. pylori* infection can be treated with a combination of KALIXOCIN (clarithromycin) and other appropriate antibiotic and stomach acid control treatments. However, the best combination of tablets to treat *H. pylori* infection is yet to be determined. Your doctor will determine the best combination for you.

If your symptoms return, consult your doctor. It is possible that KALIXOCIN may no longer be effective in killing the *H. pylori* infection and a different antibiotic may be needed.

## 2. What should I know before I take KALIXOCIN?

### Warnings

#### Do not take KALIXOCIN if:

- you are allergic to clarithromycin, other antibiotics from the macrolide family, including erythromycin, roxithromycin or azithromycin or any of the ingredients listed at the end of this leaflet.

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

- you have severe liver problems and poor kidney function.
- you have an irregular heartbeat.
- you have ever had a heart condition called long QT syndrome (or QT prolongation).
- you have low magnesium or potassium levels.

- you are taking any of the following medicines:
  - astemizole or terfenadine (commonly used to treat allergy symptoms - these medicines may be available without a prescription)
  - cisapride (used to relieve certain stomach problems)
  - colchicine (used to treat gout)
  - domperidone (used for nausea)
  - ergotamine or dihydroergotamine (used to treat headaches)
  - lomitapide (used to treat high cholesterol)
  - lovastatin or simvastatin (used to treat high cholesterol)
  - midazolam tablets or syrup (used to treat sleeplessness and anxiety)
  - pimozide (used to treat schizophrenia)
  - ticagrelor or ranolazine (used to prevent blood clotting)

Taking KALIXOCIN with any of the above medicines may cause serious side effects.

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

Do not take KALIXOCIN after the expiry date or if the packaging is torn or shows any signs of tampering.

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

## **Check with your doctor if you have:**

- any other medical conditions or take any medicines for any other condition
- allergies to any other medicines, foods, dyes or preservatives
- heart problems, including slow heart rate
- liver problems
- poor kidney function
- myasthenia gravis, a condition which the muscles become weak and tire easily
- intolerance to sugars
- any electrolyte imbalances

Your doctor may want to take special care if you have any of these conditions. If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given KALIXOCIN.

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**

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking KALIXOCIN when pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the risks and benefits of taking KALIXOCIN when breastfeeding.

### **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 may interfere with KALIXOCIN and affect how it works or may be affected by KALIXOCIN. These include the medicines already listed under "Do not take KALIXOCIN if" (see above) and the following medicines:**

- aminoglycosides (used to treat infections)
- calcium channel blockers such as verapamil, amlodipine, diltiazem (used to treat high blood pressure)
- carbamazepine, phenytoin, phenobarbital (phenobarbitone), sodium valproate (used to treat epilepsy)
- ciclosporin, tacrolimus (medicines affecting the immune system)
- cilostazol (used to treat poor circulation)
- digoxin, quinidine, disopyramide (used to treat heart failure)
- fluconazole and itraconazole (used to treat fungal infections)
- fluoxetine (used to treat depression)

- herbal medicines such as St John's Wort
- ibrutinib (used in cancer therapy)
- insulin (used to treat diabetes)
- medicines used to treat HIV infection
- methylprednisolone (a corticosteroid)
- nateglinide, repaglinide, pioglitazone, rosiglitazone (used to treat diabetes)
- omeprazole (used to treat stomach problems)
- quetiapine (used in psychotic disorders)
- rifabutin, rifapentine, rifampicin (used to treat some infections)
- sildenafil, tadalafil, vardenafil (used to treat erectile dysfunction in adult males)
- statins such as atorvastatin, rosuvastatin (used to treat high cholesterol)
- theophylline (used to treat asthma)
- tolterodine (used to treat bladder problems)
- triazolam, alprazolam, midazolam (used to treat sleeplessness and anxiety)
- vinblastine (used to treat cancer)
- warfarin and other anticoagulants such as apixaban, dabigatran and rivaroxaban (used to prevent blood clotting)

These medicines may be affected by KALIXOCIN or may affect how well KALIXOCIN works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of

medicines to be careful with or avoid while taking KALIXOCIN.

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

## **4. How do I take KALIXOCIN?**

### **How much to take**

- Your doctor will tell you how much to take and when to take it. Take KALIXOCIN exactly as directed by your doctor. This may differ from the information contained in this leaflet.
- **The dose of KALIXOCIN will depend on the infection to be treated.**
- For respiratory tract infections and skin infections, the usual adult dose is one KALIXOCIN 250 mg tablet twice a day.
- For more severe infections, the dose can be increased to two KALIXOCIN 250 mg tablets twice a day.
- Your doctor will adjust the amount or frequency of your doses according to the infection being treated and the severity of your condition.
- **If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.**

### **How to take KALIXOCIN**

KALIXOCIN tablets should be swallowed whole with a glass of water.

## **When to take KALIXOCIN**

- KALIXOCIN should be taken at about the same time each day.
- This will allow your medicine to have the best effect and help you remember to take it.

## **How long to take it**

**Keep taking KALIXOCIN until you finish the pack or for as long as your doctor tells you.**

If you are being treated for an infection, KALIXOCIN is usually taken for one or two weeks.

Do not stop taking KALIXOCIN, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

**Check with your doctor if you are not sure how long you should be taking KALIXOCIN.**

## **If you forget to take KALIXOCIN**

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

**Otherwise, take it as soon as you remember, and then continue taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

**If you miss more than one dose, are not sure what to do, or have any questions, check with your doctor or pharmacist.**

## **If you take too much KALIXOCIN**

If you think that you have taken too much KALIXOCIN, 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.**

If you take too much KALIXOCIN, you may develop severe gastrointestinal symptoms, liver problems, or allergic reactions.

## **5. What should I know while taking KALIXOCIN?**

### **Things you should do**

**If you are taking KALIXOCIN for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.**

**Tell your doctor if you become pregnant while taking KALIXOCIN.**

### **Call your doctor straight away if you:**

- **get severe diarrhoea.** Do this even if it occurs several weeks after stopping KALIXOCIN. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicine to stop your diarrhoea without first checking with your doctor.
- **experience any heart palpitations, changes in heartbeat, dizziness or fainting while taking KALIXOCIN.**

If you are having any urine tests, tell your doctor you are taking KALIXOCIN as it may affect the results of some laboratory tests.

If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking KALIXOCIN.

Remind any doctor, dentist or pharmacist you visit that you are taking KALIXOCIN.

## **Things you should not do**

- Do not take KALIXOCIN to treat any other complaints unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how KALIXOCIN affects you.**

## **Looking after your medicine**

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they will not keep well.

Keep KALIXOCIN tablets in a cool dry place below 25°C and protected from light.

Store it in a cool dry place away from moisture, heat or sunlight. Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.** A locked cupboard at least 1.5 metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

KALIXOCIN treats infections in most people, but it may have unwanted side effects in some people.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

### Less serious side effects

| Less serious side effects   | What to do   |
|---|--|
| <ul style="list-style-type: none"><li>● stomach cramps and pains</li><li>● nausea, vomiting and diarrhoea</li><li>● oral thrush (sore white mouth or tongue) or</li></ul> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

| <b>Less serious side effects</b>   | <b>What to do</b> |
|--|-------------------|
| vaginal thrush (vaginal itching or discharge) <ul style="list-style-type: none"> <li>● change in taste sensation</li> <li>● headache</li> <li>● asthma, shortness of breath</li> <li>● muscle weakness, pain or spasms</li> <li>● conjunctivitis</li> <li>● chills</li> <li>● fatigue</li> <li>● eructation (belching)</li> <li>● stomach distension (bloating)</li> <li>● flatulence</li> </ul> |                   |

## **Serious side effects**

| <b>Serious side effects</b>   | <b>What to do</b>   |
|---|---|
| <ul style="list-style-type: none"> <li>● yellowing of the eyes or skin (jaundice)</li> <li>● feeling generally unwell and having poor appetite</li> <li>● hearing disturbances</li> <li>● chest pain</li> </ul> | <p><b>Tell your doctor straight away if you notice any of these symptoms as you may need urgent medical care.</b></p> |

| <b>Serious side effects</b>   | <b>What to do</b>  |
|---|--|
| <ul style="list-style-type: none"> <li>● dizziness, confusion, hallucinations, convulsions</li> <li>● fainting, irregular heartbeat</li> <li>● any type of skin rash, itching, hives</li> <li>● severe diarrhoea, especially if bloody</li> <li>● severe upper stomach pain, with nausea and vomiting (pancreatitis)</li> </ul> |  |
| <ul style="list-style-type: none"> <li>● swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse</li> </ul>  | <p><b>Stop taking KALIXOCIN and 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.</b></p> |

**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.

## **After you have finished taking KALIXOCIN**

**Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with KALIXOCIN:**

- severe stomach or abdominal cramps
- watery and severe diarrhoea, which may also be bloody (this may occur several weeks after you stop taking KALIXOCIN)
- fever, in combination with one or both of the above

These are rare but serious side effects. You may have a serious condition affecting your bowel and you may need urgent medical care.

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

Other side effects not listed above may also occur in some patients. Ask your doctor or pharmacist for more information about side effects, as they have a more complete list of side effects. Tell your doctor about these or any other symptoms. If the condition persists or worsens, seek medical attention.

Tell your doctor if you notice anything that is making you feel unwell while you are taking, or soon after you have finished taking KALIXOCIN, even if it is not on this list.

## **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](http://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 KALIXOCIN Tablet contains

|   |   |
|---|---|
| <b>Active ingredient<br/>(main ingredient)</b>      | 250 mg clarithromycin   |
| <b>Other ingredients<br/>(inactive ingredients)</b> | <ul style="list-style-type: none"><li>● croscarmellose sodium</li><li>● povidone</li><li>● silicon dioxide</li><li>● microcrystalline cellulose</li><li>● purified talc</li><li>● hypromellose</li><li>● hypromellose</li><li>● sorbitan mono-oleate</li><li>● stearic acid</li><li>● magnesium stearate</li><li>● propylene glycol</li></ul> |

|                            |  |
|----------------------------|--|
|                            | <ul style="list-style-type: none"> <li>• sorbic acid</li> <li>• vanillin</li> <li>• titanium dioxide</li> <li>• quinoline yellow</li> <li>• pregelatinised maize starch</li> </ul> |
| <b>Potential allergens</b> | KALIXOCIN tablets contain sorbates   |

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

## **What KALIXOCIN looks like**

KALIXOCIN 250 mg tablets are yellow, oval, film-coated tablets. Each blister pack contains 14 tablets (AUST R 99707).

## **Who distributes KALIXOCIN**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

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