

Kalixocin

contains the active ingredient clarithromycin

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Kalixocin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Kalixocin against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Kalixocin is used for

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

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

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

Kalixocin is an antibiotic that belongs to a group of medicines called macrolides. These medicines work by killing or stopping the growth of bacteria which causes infections.

Kalixocin will not work against infections caused by viruses, such as colds or flu, or infections caused by fungi.

Ask your doctor if you have any questions about why Kalixocin has been prescribed for you.

Your doctor may have prescribed Kalixocin for another reason.

Kalixocin is available only with a doctor's prescription.

There is no evidence that Kalixocin is addictive.

Before you take Kalixocin

When you must not take it

Do not take Kalixocin if you are allergic to any:

- * **medicines containing clarithromycin (eg. Klacid)**
- * **antibiotic from the macrolide family including,**
 - erythromycin (eg. EES, Erythrocin, Eryc, E-Mycin)
 - roxythromycin (eg. Rulide, Biaxig)
 - azithromycin (eg. Zithromax)
- * **ingredients listed at the end of this leaflet.**

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

Do not take Kalixocin if you are taking any of the following medicines:

- * **cisapride (Prepulsid), a medicine used to treat stomach disorders**
- * **pimozide (Orap), a medicine used to treat psychotic disorders**
- * **ergotamine (Cafergot, Cafergot S, Migral) or dihydroergotamine (Dihydergot), medicines used for migraines.**

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

Do not take Kalixocin after the expiry date 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, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Kalixocin is not recommended for use in pregnant women. Your doctor will discuss the risks and benefits of taking Kalixocin during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Like many other medicines, Kalixocin passes into breast milk.

Your doctor will discuss the risks and benefits of taking Kalixocin when breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * liver problems
- * severe kidney problems.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell him/her before you start taking Kalixocin.

Taking other medicines

Do not take Kalixocin if you are taking any of the following medicines:

- * cisapride (Prepulsid), a medicine used to treat stomach disorders
- * pimozide (Orap), a medicine used to treat psychotic disorders
- * ergotamine (Cafergot, Cafergot S, Migral) or dihydroergotamine (Dihydergot), medicines used for migraines.

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

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

Some medicines and Kalixocin may interfere with each other. These include:

- * warfarin, a medicine used to prevent blood clotting (Coumadin, Marevan)
- * some medicines used for epilepsy such as phenytoin (Dilantin), carbamazepine (eg. Tegretol, Teril), sodium valproate (Epilim, Valpro)
- * theophylline, a medicine used to treat asthma (Theo-Dur, Nuelin)
- * digoxin, a medicine commonly used to treat heart failure (eg. Lanoxin)

- * some medicines used to treat sleeplessness or insomnia such as triazolam (Halcion) or midazolam (Hypnovel)
- * some medicine used to treat HIV infection such as zidovudine (Retrovir), ritonavir (Norvir), indinavir (Crixivan), saquinavir (Fortavase, Invirase), rifabutin (Mycobutin)
- * methylprednisolone, a corticosteroid
- * vinblastine (Velbe), a medicine used to treat cancer
- * sildenafil (Viagra), used to treat erectile dysfunction in adult males
- * some medicines used to treat an irregular heart beat such as quinidine (Kinidin), disopyramide (Rythmodan)
- * alprazolam (eg. Kalma, Xanax) used to treat anxiety
- * repaglinide (NovoNorm), a medicine used to treat diabetes
- * colchicine, a medicine used to treat gout (Colgout, Lengout)
- * simvastatin (eg. Zocor, Lipex), a medicine used to lower high cholesterol levels
- * fluconazole (eg. Diflucan) for fungal infections
- * tacrolimus and cyclosporin, immunosuppressive agents.

These medicines may be affected by Kalixocin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Kalixocin.

How to take Kalixocin

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

They may differ from the information contained in this leaflet.

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

How much to take

The dose varies from person to person.

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and the type of 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.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Kalixocin can be taken with or without food.

Take your medicine at about the same time each day.

This will allow your medicine to have the best effect and also help you remember when to take it.

How long to take it

Keep taking Kalixocin until you finish the pack, or for as long as your doctor recommends.

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 or your symptoms may return if you stop taking your medicine too soon.

If you forget to take it

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Kalixocin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking Kalixocin

Things you must do

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

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking Kalixocin.

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

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

If you get a sore, white mouth or tongue while taking or soon after stopping Kalixocin, 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 Kalixocin allows fungi to grow and the above symptoms to occur. Kalixocin does not work against fungi.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Kalixocin.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Kalixocin.

If you become pregnant while taking Kalixocin, tell your doctor.

If you need to have any urine tests, tell your doctor that you are taking Kalixocin.

Kalixocin may affect the results of some tests.

Things you must not do

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

If you stop taking Kalixocin too soon, the infection may not clear completely or your symptoms may return.

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

Do not give Kalixocin to anyone else, even if they have the same condition as you.

Side effects

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

Kalixocin helps most people with their infections, but it may have unwanted side effects in some people.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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:

- * stomach pains
- * nausea, vomiting
- * diarrhoea or constipation
- * change in taste sensation
- * headache
- * unusual tiredness or weakness.

The above list includes the milder side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- * oral thrush (sore white mouth or tongue) or vaginal thrush (vaginal itching or discharge)
- * yellowing of the eyes or skin
- * feeling generally unwell and having poor appetite
- * uncomfortable sensitivity to light
- * dizziness, confusion, hallucinations
- * severe upper stomach pain with nausea and vomiting
- * signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal.

The above list includes serious side effects which may require urgent medical attention.

Stop taking Kalixocin and tell your doctor immediately or go to Accident and Emergency at the nearest hospital if any of the following occur:

- * chest pain
- * convulsions
- * any type of skin rash, itching, blistering, peeling of the skin or hives
- * swelling of the face, lips, tongue or other parts of the body
- * shortness of breath, wheezing, troubled breathing
- * severe stomach or abdominal cramps, watery and severe diarrhoea, which may also be bloody (this may occur several weeks after you stop taking Kalixocin).

Do not take any medicine to stop the diarrhoea unless advised by your doctor.

The side effects listed above are serious and require urgent medical attention or hospitalisation.

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.

This is not a complete list of all possible side effects.

Other side effects not listed above may also occur in some people.

After taking Kalixocin

Storage

Keep Kalixocin where 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 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 your tablets in a cool dry place, protected from light, where the temperature stays below 25 degrees C.

Do not store Kalixocin or any other medicine in the bathroom or near a sink.

Do not leave Kalixocin in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Kalixocin, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Kalixocin 250 mg tablets are yellow, oval shaped, film-coated tablets.

Each pack contains 14 tablets.

Ingredients

The active ingredient in Kalixocin is clarithromycin.

Each Kalixocin tablet contains 250 mg of clarithromycin.

The tablets also contain the following inactive ingredients:

- * microcrystalline cellulose
- * croscarmellose
- * hydroxypropylcellulose
- * hypromellose
- * magnesium stearate
- * povidone
- * propylene glycol
- * quinoline yellow CI47005 (E104)

- * silicon dioxide
- * sorbitan mono-oleate
- * pregelatinised maize starch
- * stearic acid
- * purified talc
- * titanium dioxide CI77891 (E171)
- * vanillin.

The tablets do not contain lactose or gluten.

Supplier

Kalixocin is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

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