

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about this medicine.

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 Klacid against the benefits they expect it will have on 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 Klacid is used for

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

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

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

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

Klacid is 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.

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

Klacid is available only with a doctor's prescription.

There is no evidence that Klacid is addictive.

Klacid 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 Klacid (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 Klacid may no longer be effective in killing the *H. pylori* infection and a different antibiotic may be needed.

Before you take Klacid

When you must not take it

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

- medicines containing clarithromycin
- other antibiotics from the macrolide family, including erythromycin, roxithromycin or azithromycin

- any of the ingredients listed at the end of this leaflet

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

Do not take Klacid if you have severe liver problems and poor kidney function.

Do not take Klacid if you have an irregular heartbeat.

Do not take Klacid if you have ever had a heart condition called long QT syndrome (or QT prolongation).

Do not take Klacid if you have low potassium levels.

Do not take Klacid 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.

Do not take Klacid if 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)
- domperidone (used for nausea)
- pimozide (used to treat schizophrenia)
- ergotamine or dihydroergotamine (used to treat headaches)
- lovastatin or simvastatin (used to treat high cholesterol)
- ticagrelor or ranolazine (used to prevent blood clotting)
- colchicine (used to treat gout)
- midazolam tablets or syrup (used to treat sleeplessness and anxiety)

Taking Klacid 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.

Before you start to take or are given Klacid:

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.

Your doctor will discuss the risks and benefits of taking Klacid when pregnant.

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

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

Tell your doctor if you have, or have ever had, any other health problems or medical conditions, including:

- 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
- low magnesium or any other 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 Klacid.

Taking other medicines

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

Some medicines may affect the way Klacid works or may be affected by Klacid. These include the medicines already listed under "When you must not take Klacid" (see above) and the following medicines:

- digoxin, quinidine, disopyramide (used to treat heart failure)
- warfarin and other anticoagulants (used to prevent blood clotting)
- phenytoin, carbamazepine, phenobarbital (phenobarbitone), sodium valproate (used to treat epilepsy)
- theophylline (used to treat asthma)
- triazolam, alprazolam, midazolam (used to treat sleeplessness and anxiety)
- cilostazol (used to treat poor circulation)
- statins such as rosuvastatin, atorvastatin (used to treat high cholesterol)
- methylprednisolone (a corticosteroid)
- vinblastine (used to treat cancer)
- sildenafil, tadalafil, vardenafil (used to treat erectile dysfunction in adult males)
- ciclosporin, tacrolimus (medicines affecting the immune system)
- medicines used to treat HIV infection
- rifabutin, rifapentine, rifampicin (used to treat some infections)
- repaglinide, nateglinide, pioglitazone, rosiglitazone (used to treat diabetes)
- insulin (used to treat diabetes)
- calcium channel blockers such as verapamil, amlodipine, diltiazem (used to treat high blood pressure)
- fluoxetine (used to treat depression)
- omeprazole (used to treat stomach problems)
- aminoglycosides (used to treat infections)
- fluconazole and itraconazole (used to treat fungal infections)
- tolterodine (used to treat bladder problems)
- herbal medicines such as St John's Wort
- quetiapine (used in psychotic disorders)
- ibrutinib (used in cancer therapy)

These medicines may be affected by Klacid or may affect how well Klacid 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 Klacid.

How to take Klacid

Your doctor will tell you how much to take and when to take it. Take Klacid exactly as directed by your doctor.

This may differ from the information contained in this leaflet.

How much to take

The dose of Klacid will depend on the infection to be treated.

For respiratory tract infections and skin infections, the usual adult dose is one Klacid 250 mg tablet twice a day.

For more severe infections, the dose can be increased to one Klacid 500 mg tablet twice a day.

For respiratory tract infections the usual dose for children is 7.5 mg/kg twice a day or as directed by your doctor. For children under 12 years of age, Klacid Powder for Oral Liquid should be used.

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 Klacid

Klacid Tablets

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

Klacid Powder for Oral Liquid

Shake the bottle well and accurately measure the dose with a medicine measure.

Shaking the bottle before use and using a medicine measure will make sure that you get the correct dose. The measuring syringe that is provided with the bottle can be used to measure the correct volume of medicine.

When to take Klacid

Take your medicine 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 Klacid for

Keep taking Klacid until you finish the pack or bottle, or for as long as your doctor tells you.

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

Do not stop taking Klacid, 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 Klacid.

If you forget to take it

If it is almost time for you to take 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 that 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Klacid. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places/services handy.

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

While you are taking Klacid

Things you must do

If you are taking Klacid 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 Klacid.

If you get severe diarrhoea, tell your doctor or pharmacist immediately.

Do this even if it occurs several weeks after stopping Klacid. 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.

Tell your doctor immediately if you experience any heart palpitations, changes in heartbeat, dizziness or fainting while taking Klacid.

If you have to have any urine tests, tell your doctor you are taking Klacid 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 Klacid.

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

Things you must not do

Do not use Klacid 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.

Things to be careful of

Be careful driving or operating machinery until you know how Klacid affects you.

Side effects

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

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

All medicines can 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.

While you are taking Klacid

Tell your doctor if you experience any of the following:

- stomach cramps and pains
- nausea, vomiting and severe diarrhoea
- oral thrush (sore white mouth or tongue) or vaginal thrush (vaginal itching or discharge)
- change in taste sensation
- headache
- asthma, shortness of breath
- muscle weakness, pain or spasms
- conjunctivitis
- chills
- fatigue
- eructation
- stomach distension
- 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 (jaundice)
- feeling generally unwell and having poor appetite
- hearing disturbances
- chest pain
- dizziness, confusion, hallucinations, convulsions
- fainting, irregular heart beat
- any type of skin rash, itching, hives
- severe diarrhoea, especially if bloody
- severe upper stomach pain, with nausea and vomiting (pancreatitis)

Stop taking Klacid and tell your doctor immediately or go to casualty at your nearest hospital if any of the following happen:

- swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse

After you have finished taking Klacid

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

- severe stomach or abdominal cramps
- watery and severe diarrhoea, which may also be bloody (this may occur several weeks after you stop taking Klacid)
- 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. Inform your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

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

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

After using Klacid

Storage:

Keep your medicine where children cannot reach them.

A locked cupboard at least 1.5 metres above the ground is a good place to store medicines.

Klacid Tablets:

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 Klacid tablets in a cool dry place, protected from light, where the temperature stays below 25°C.

Powder for Oral Liquid:

Klacid Powder for Oral Liquid should be kept in a cool dry place, protected from light, where the temperature stays below 30°C.

The reconstituted suspension can be used for up to 14 days when stored below 30°C. DO NOT REFRIGERATE.

Do not keep Klacid or any other medicine in the bathroom or near a sink. Do not leave Klacid in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal:

If your doctor tells you to stop taking Klacid, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Klacid 250 mg tablets are yellow, oval, film-coated tablets. Each blister pack contains 14 tablets.

Klacid 500 mg tablets are pale yellow, oval, film-coated tablets.

Klacid Powder for Oral Liquid 250mg/5 mL has a white to pale yellow colour with a fruit punch aroma. The reconstituted suspension has a tendency towards grittiness.

Ingredients

The active ingredient in Klacid is clarithromycin.

Klacid Tablets:

Each Klacid 250 mg tablet contains 250 mg of clarithromycin.

Each Klacid 500 mg tablet contains 500 mg of clarithromycin.

The tablets also contain the following inactive ingredients:

- croscarmellose sodium
- povidone
- silicon dioxide
- microcrystalline cellulose
- purified talc
- hypromellose
- hypromellose
- sorbitan mono-oleate

- stearic acid
- magnesium stearate
- propylene glycol
- sorbic acid
- vanillin
- titanium dioxide
- quinoline yellow
- pregelatinised maize starch (in the 250 mg tablets only)

Klacid tablets also contain sorbates.

Klacid tablets do not contain lactose or gluten.

Klacid Powder for Oral Liquid 250 mg/5 mL:

Each 5 mL of Klacid Powder for Oral Liquid contains 250 mg of clarithromycin.

It also contains the following inactive ingredients:

- povidone
- castor oil
- silicon dioxide
- xanthan gum
- potassium sorbate
- citric acid
- titanium dioxide
- maltodextrin
- sucrose
- fruit punch flavour

Klacid powder for oral liquid also contains sugars, sorbates and sulfites.

Supplier

Klacid 250 mg and 500 mg tablets and Klacid Powder for Oral Liquid are supplied in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point, NSW 2000
www.mylan.com.au
Phone: 1800 314 527

Australian registration numbers:

Klacid 250 mg Tablets: AUST R 79564 (blister)

Klacid 500 mg Tablets: AUST R 52473 (blister)

Klacid Powder for Oral Liquid 250 mg/5 mL: AUST R 56729

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