

NEW ZEALAND CONSUMER MEDICINE INFORMATION

KLACID

**Clarithromycin Powder for Oral Liquid 250 mg/5 mL
250 mg and 500 mg Film Coated Tablets**



What is in this leaflet

Please read this leaflet carefully before you start taking Klacid.

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
- skin infections
- ear infections
- peptic ulcer
- certain types of bacterial infections

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

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.

Klacid to treat peptic ulcer

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

The *H. pylori* infection can be treated with a combination of Klacid (clarithromycin) and other appropriate antibiotic and stomach acid control treatments. 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.

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.

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

Before you take Klacid

When you must not take it

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

- any medicines containing clarithromycin
- other antibiotics from the macrolide family – these include:
erythromycin,
roxithromycin, 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 or kidney problems.

Do not take Klacid if you have an irregular heartbeat.

Do not take Klacid if you have low potassium, low magnesium or other electrolyte abnormalities in your blood.

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

- astemizole or terfenadine, used to treat allergy symptoms
- cisapride, used to relieve certain stomach problems
- domperidone, used to treat nausea.
- pimozide, used to treat schizophrenia
- ergot alkaloids e.g. ergotamine or dihydroergotamine, used to treat migraines
- certain statins e.g. lovastatin or simvastatin, used to treat high cholesterol
- ticagrelor, used to prevent blood clotting
- ranolazine, used to treat angina

- colchicine, used to treat gout
- oral midazolam, used in sleep disorders and as a sedative
- lomitapide, a medication use to treat high cholesterol

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

Do not take Klacid if the packaging is torn or shows any signs of tampering.

Do not take Klacid if the use by date (Exp.) printed on the pack has passed.

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

Before you start to take it

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

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

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
- liver problems
- kidney problems
- diabetes, there is an increase risk of low blood sugar (hypoglycaemia) when taking Klacid with medicines to treat diabetes.
- low magnesium or potassium levels other electrolyte abnormalities in your blood.
- history of diarrhoea with antibiotic use
- myasthenia gravis, a condition in which the muscles become weak and tire easily

Tell your doctor if you take any of the following groups of medications:

- benzodiazepines - used in sleep disorders and as a sedative
- statins - medication to lower cholesterol
- medication that thins the blood
- medication to treat diabetes

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

Ask your doctor if it is necessary (or required to) to monitor your sugar intake as Klacid Powder for Oral Liquid contains sugar.

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 get without a prescription from your pharmacy, supermarket or health food shop.

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

- digoxin, quinidine, disopyramide (used to treat heart failure)
- warfarin, rivaroxaban, apixaban and other anticoagulants (used to prevent blood clotting)
- phenytoin, carbamazepine, phenobarbital, sodium valproate (used to treat epilepsy)
- theophylline (used to treat asthma)
- triazolam, alprazolam (used to treat sleeplessness and anxiety)
- intravenous (IV) midazolam which is used in anaesthesia or for conscious sedation in surgical and diagnostic procedures
- cilostazol (used to treat poor circulation)

- rosuvastatin, atorvastatin (used to treat high cholesterol)
- methylprednisolone (a corticosteroid)
- vinblastine, ibrutinib (used to treat cancer)
- sildenafil, tadalafil, vardenafil (used to treat erectile dysfunction in adult males)
- cyclosporin, tacrolimus (medicines affecting the immune system)
- rifabutin, rifampicin (used to treat some infections)
- ritonavir, zidovudine, nevirapine, efavirenz, atazanavir, etravirine, saquinavir (used to treat HIV)
- repaglinide, nateglinide, pioglitazone and rosiglitazone (used to treat diabetes)
- insulin (used to treat diabetes)
- calcium channel blockers such as verapamil, amlodipine, diltiazem (used to treat high blood pressure)
- omeprazole (used to treat stomach problems)
- aminoglycosides (used to treat infections)
- fluconazole, itraconazole (used to treat fungal infections)
- tolterodine (used to treat bladder problems)
- herbal medicines such as St John's Wort
- medicines used to treat psychosis (e.g. quetiapine)
- rifapentine (a medicine used in the treatment of tuberculosis)

These medicines may be affected by Klacid 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 or pharmacist can tell you what to do if you are taking any of these medicines.

How to take Klacid

Follow all directions given to you by your doctor or pharmacist carefully. 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 250 mg twice a day.

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

For respiratory tract infections, the usual dose for children is 7.5mg per kg twice a day or as directed by your doctor.

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 bottle, ask your doctor or pharmacist for help.

How to take it

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 and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

When to take it

Take Klacid at about the same time(s) 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.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking Klacid until you finish the bottle or box, 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, or are not sure what to do, check with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the 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.

While you are taking Klacid

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.

If you need 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 tells you to.

Do not give your 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.

Children should be careful when riding bicycles or climbing trees.

Side effects

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 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 and they worry you:

- stomach cramps and pains
- nausea, vomiting and diarrhoea
- oral thrush or vaginal thrush
- change in sense of taste
- headache
- increased sweating
- difficulty sleeping
- asthma, shortness of breath

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
- palpitations, fast heart rate
- dizziness, confusion, hallucinations, convulsions,
- mood changes
- any type of skin rash, itching, hives
- severe diarrhoea, especially if bloody
- swelling of feet or ankles
- experiencing symptoms of low blood sugar (glucose) such as sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat
- abnormal bleeding

Stop taking Klacid and tell your doctor immediately or go to Accident and Emergency 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

- skin rash with severe blistering,
- severe skin rash with fever
- muscle pain or sore muscles
- severe upper stomach pain, with nausea and vomiting (pancreatitis).

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

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.

After 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
- 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.

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 Powder for Oral Liquid should be kept in a cool dry place, 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.

Keep Klacid tablets in a cool dry place where the temperature stays below 25°C.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Klacid Powder for Oral Liquid 250 mg/5 mL

A white to off white colour with a fruit punch aroma. The reconstituted suspension has a tendency towards grittiness.

Klacid Tablets

250 mg – yellow, oval, film coated tablets.

500 mg – pale yellow, oval, film coated tablets.

Ingredients

Klacid Powder for Oral Liquid 250 mg/5 mL

Active ingredient(s):

Each 5 mL of reconstituted Klacid Powder for Oral Liquid contains 250 mg of clarithromycin as the active ingredient.

Inactive ingredient(s):

Klacid Powder for Oral Liquid also contains:

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

Date of Information

08 July 2021

(Based on datasheet dated 08 July 2021)

Klacid Tablets

Active ingredient(s):

Each Klacid tablet contains either 250 mg or 500 mg of clarithromycin as the active ingredient.

Inactive ingredient(s):

- croscarmellose sodium
- pregelatinized starch (250 mg tablet only)
- microcrystalline cellulose
- povidone
- silicon dioxide
- hydroxypropylcellulose
- talc
- hypromellose
- sorbitan monooleate
- stearic acid
- magnesium stearate
- propylene glycol
- sorbic acid
- vanillin flavour
- Colours are titanium dioxide (171) and quinoline yellow (104)

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
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Auckland.

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