KLACID(R) Powder for Oral Liquid 250mg/5mL

CONSUMER MEDICINE INFORMATION

PLEASE READ THIS INFORMATION CAREFULLY

What is in this leaflet

This leaflet answers some common questions about this medicine.

It does not contain all of 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
- * peptic ulcers

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.

KLACID to treat peptic ulcer

Peptic ulcers are associated with an infection in the intestine and stomach by a 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), another antibiotic (amoxycillin) and another medicine called omeprazole (used to control the acidity of the stomach).

However, the best combination of medicines 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

Do not take KLACID if:

- * you have ever had an allergic reaction to medicines containing clarithromycin or to other antibiotics from the macrolide family. These may include:
 - erythromycin (EES, Erythrocin, Eryc, E-mycin, EMU-V)
 - * roxithromycin (Rulide, Biaxsig)
 - * azithromycin (Zithromax)

Some of the symptoms of an allergic reaction may include rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing.

- * you are allergic to any of the ingredients listed at the end of this leaflet.
- * you have severe liver problems or poor kidney function.
- * the packaging is torn or shows any signs of tampering
- * the use by date (Exp.) printed on the pack has passed.

Before you start to take or are given KLACID you must 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.
- * you are breastfeeding or wish to breastfeed. Your doctor will discuss the risks and benefits of taking KLACID when breastfeeding.
- * you have, or have ever had, any other health problems or medical conditions, including liver problems or poor kidney function.
- you are allergic to any other medicines, foods, dyes or preservatives.

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

When you must not take KLACID:

Do not take KLACID if you are taking 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) used for migraines

Some medicines may affect the way KLACID works. These include:

- medicines used to prevent blood clotting - warfarin (Coumadin, Marevan)
- some medicines used for epilepsy
 phenytoin (Dilantin) or carbamazepine (Tegretol) and hexobarbital
- * medicine used to treat asthma theophylline (Theo-Dur, Nuelin)
- medicine used to treat heart failure - digoxin (Lanoxin),
- * medicines used to treat sleeplessness - triazolam (Halcion) or midazolam

- (Hypnovel)
- * medicine used to treat HIV infection zidovudine (Retrovir), ritonavir (Norvir), indinavir (Crixivan), saquinavir (Fortavase, Invirase)
- * methylprednisolone, a corticosteroid
- * vinblastine, a medicine used to treat cancer.
- * sildenafil, used to treat erectile dysfunction in adult males.
- * quinidine (Kinidin) for heart arrythmias
- disopyramide (Norpace, Rythmodan) for heart arrhythmias
- * alprazolam (Kalma, Xanax) used to treat anxiety
- * sodium valproate (Epilim, Valpro) for control of epilepsy
- * repaglinide (NovoNorm) for treatment of diabetes
- * cochicine for the treatment of gout

These medicines may be affected by KLACID or may affect how well KLACID works. 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 the usual dose for children is 7.5mg/kg twice a day or as directed by your

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 box/bottle, ask your doctor or pharmacist for help.

How long to take KLACID for:

Keep taking KLACID until you finish the 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 KLACID

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 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 KLACID (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty 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.

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 any one else, even if their symptoms seem similar to yours.

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 or vaginal thrush
- * change in taste sensation
- * headache

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
- * 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
- * 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.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

The reconstituted suspension can be used for up to 14 days when stored

below 30 degrees 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.

Phone: 1800 225 311

Australian registration numbers:

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

Date of information:

10 March 2005.

Product Description

What it looks like

KLACID Powder for Oral Liquid 250mg/5mL has a white to pale yellow colour with a fruit punch aroma.

Ingredients:

KLACID Powder for Oral Liquid 250mg/5mL:

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

It also contains povidone, carbomer 934P, hypromellose phthalate, castor oil, silicon dioxide, xanthan gum, potassium sorbate, citric acid, titanium dioxide, maltodextrin, sucrose and fruit punch flavour.

Manufacturer:

KLACID Powder(s) for Oral Liquid are distributed by:

ABBOTT AUSTRALASIA PTY LTD 32-34 Lord Street Botany NSW 2019 (ABN 95 000 180 389)