

NOUMED CLARITHROMYCIN

clarithromycin tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED CLARITHROMYCIN.

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 risks and benefits. Your doctor has weighed the risks of taking this medicine against the benefits it is expected to have for you or your child.

If your child is being treated with NOUMED CLARITHROMYCIN, follow the same instructions in this leaflet as you would as the patient.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NOUMED CLARITHROMYCIN is used for

NOUMED CLARITHROMYCIN tablets contain the active ingredient clarithromycin.

Clarithromycin is an antibiotic that belongs to the group of medicines called macrolides. These work by killing or stopping the growth of the bacteria that cause infections.

It does not work against infections caused by viruses, such as colds or 'flu.

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

- respiratory tract infections
- ear infections
- skin infections
- peptic ulcer

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

The *H. pylori* infection can be treated with a combination of clarithromycin, another antibiotic and a medicine used to control the acidity of the stomach. 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 clarithromycin may no longer be effective in treating the *H. pylori* infection and a different antibiotic may be needed.

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

This medicine is available only with a doctor's prescription. Your doctor may have prescribed NOUMED CLARITHROMYCIN for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

This medicine is not addictive.

Before you take it

When you must not take it

Do not take this medicine if you have an allergy to:

- medicines containing clarithromycin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- other macrolide antibiotics such as erythromycin, roxithromycin or azithromycin.

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

Do not take this medicine if you have any of the following medical conditions:

- severe liver problems and poor kidney function
- cardiac arrhythmia (irregular heartbeat)
- heart condition called long QT syndrome (or QT prolongation)
- hypokalaemia (low potassium levels in blood).

Do not take NOUMED CLARITHROMYCIN if you are also currently taking any of the following medicines:

- domperidone (used for nausea)
- lovastatin or simvastatin (statins used to lower cholesterol)
- ticagrelor or ranolazine (medicines for heart attacks or chest pain)
- colchicine (used to treat gout)

- midazolam oral syrup or tablets (for sedation)
- cisapride (used to relieve certain stomach disorders)
- ergotamine or dihydroergotamine (used for migraine headaches)
- pimozide (used to treat psychotic disorders)
- astemizole or terfenadine (antihistamines)

Taking NOUMED CLARITHROMYCIN with any of these medicines may cause serious side effects.

If you are not sure whether you should take this medicine, talk to your doctor or pharmacist.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines (especially macrolide antibiotics like clarithromycin), foods, preservatives or dyes.

Tell your doctor what other medicines you are taking.

NOUMED CLARITHROMYCIN should be avoided if you are taking certain other medicines, or their doses may need to be changed (see Taking other medicines below).

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

Your doctor will discuss the risks and benefits involved.

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

- heart problems, including slow heartbeat

- liver problems
- kidney problems
- myasthenia gravis (a condition in which the muscles become weak and you tire easily)
- intolerance to sugar
- low magnesium or other electrolyte imbalances.

Your doctor may recommend another medicine or monitor your condition more carefully if you have had any of these conditions.

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

Taking other medicines

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

Other than those medicines that must not be taken with clarithromycin, some medicines and NOUMED CLARITHROMYCIN may interfere with each other. These include:

- digoxin, disopyramide or quinidine (for heart disorders)
- warfarin or other anticoagulants (prevent blood clotting)
- phenytoin, carbamazepine, phenobarbital (phenobarbitone) or sodium valproate (for epilepsy)
- theophylline (for asthma)
- triazolam or alprazolam (for sleeplessness and anxiety)
- cilostazol (for poor circulation)
- other statins such as rosuvastatin, atorvastatin (to lower cholesterol)
- methylprednisolone (a corticosteroid)
- vinblastine or ibrutinib (cancer therapies)
- sildenafil, tadalafil, vardenafil or avanafil (for erectile dysfunction in adult males)

- cyclosporin, tacrolimus (medicines affecting the immune system)
- antiviral medicines to treat HIV infection such as zidovudine, ritonavir, saquinavir, efavirenz, nevirapine, atazanavir, indinavir
- rifampicin, rifabutin, rifapentine (antibiotics)
- pioglitazone or other oral diabetic medicines belonging to the meglitinide and glitazone groups
- insulin (for diabetes)
- calcium channel blockers (for high blood pressure) such as verapamil, amlodipine, diltiazem
- fluoxetine (for depression)
- omeprazole (for stomach ulcers, acid reflux)
- aminoglycoside antibiotics
- fluconazole or itraconazole (for fungal infections)
- tolterodine (for overactive bladder symptoms)
- quetiapine (an antipsychotic medication)
- herbal medicines, such as St John's Wort (*Hypericum perforatum*).

These medicines may be affected by NOUMED CLARITHROMYCIN or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will be able to tell you what to do if you are taking these medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NOUMED CLARITHROMYCIN.

How to take NOUMED CLARITHROMYCIN

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

They may differ from the information contained in this leaflet.

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

How much to take

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

For respiratory tract infections and skin infections, the usual adult dose is one 250 mg tablet twice a day. The dose for children 12 years or older is based on their weight.

For more severe infections, the dose can be increased to two 250 mg tablets twice a day.

Your doctor may adjust the amount or frequency of your doses according to the infection being treated and the severity of your condition.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

If you take the wrong dose, NOUMED CLARITHROMYCIN may not work as well.

How to take it

Swallow the tablets whole with a glass of water.

If you need to break a tablet, hold it with both hands and snap along break line.

When to take it

Take your medicine at about the same times each day.

Taking it at the same times each day will have the best effect and help you remember to take it.

How long to take it

Continue taking your medicine until you finish the entire pack, or for as long as your doctor tells you.

NOUMED CLARITHROMYCIN is usually taken for one or two weeks to get rid of the infection.

Do not stop taking NOUMED CLARITHROMYCIN, even if you feel better after a few days, until you have finished the pack or been told to stop by your doctor.

The infection may not clear completely and clarithromycin may become ineffective against the bacteria causing the infection if you stop taking this 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 your dose as soon as you remember, then continue to take it as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you miss more than one dose or are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) 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 NOUMED CLARITHROMYCIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep this telephone number handy.

If you take too much NOUMED CLARITHROMYCIN, you may develop severe gastrointestinal upset, allergic reactions or liver problems.

While you are taking it

Things you must do

If your symptoms do not improve, or become worse, within a few days after taking NOUMED CLARITHROMYCIN, 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 the medicine.

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

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

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOUMED CLARITHROMYCIN.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are asked to have a urine test, tell your doctor or pathologist that you are taking NOUMED CLARITHROMYCIN.

It may affect the results of some laboratory tests.

If you become pregnant while taking this medicine, tell your doctor.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take NOUMED CLARITHROMYCIN to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition or symptoms as yours.

Things to be careful of

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

Side effects

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

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 the following list of potential side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

While taking the medicine

Tell your doctor or pharmacist 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/tiredness
- belching (eructation), 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 (jaundice)
- feeling generally unwell and having poor appetite
- hearing problems
- chest pain
- dizziness, confusion, hallucinations, convulsions
- fainting, irregular heartbeat
- any type of skin rash, itching, hives
- severe diarrhoea, especially if bloody
- severe upper stomach pain, with nausea and vomiting (pancreatitis).

If any of the following happen, stop taking NOUMED CLARITHROMYCIN, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

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

After you have stopped taking the medicine

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

- severe stomach or abdominal cramps
- watery and severe diarrhoea, which may also be bloody
- fever, together with either or both cramps and diarrhoea.

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

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

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

Tell your doctor if you notice anything that is making you feel unwell while, or soon after, taking this medicine even if the side effect is not on the above lists.

After taking it

Storage

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

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

Keep your medicine in a cool, dry place, where the temperature stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car especially on hot days. Heat and dampness can destroy some medicines.

Keep this medicine 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.

Disposal

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

Product description

What it looks like

NOUMED CLARITHROMYCIN is a white, oblong, convex, coated tablet scored on both sides. The tablets are packaged in blister packs of 14 tablets each.

Ingredients

Active ingredient

Each NOUMED
CLARITHROMYCIN tablet contains
250 mg of clarithromycin.

Inactive ingredients

- lactose monohydrate
- microcrystalline cellulose
- powdered cellulose
- croscarmellose sodium
- hypromellose
- colloidal anhydrous silica
- macrogol 4000
- magnesium stearate
- titanium dioxide.

NOUMED CLARITHROMYCIN
tablets do not contain sucrose, gluten,
tartrazine or any other azo dyes.

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Telephone 1800 930 999

Australian registration number

AUST R 298270

This leaflet was revised in March
2021.