

PART III: CONSUMER INFORMATION

Pr CLARITHROMYCIN
Clarithromycin tablets, film-coated

This leaflet is Part III of a three-part "Product Monograph" published when CLARITHROMYCIN was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about CLARITHROMYCIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CLARITHROMYCIN is used to treat certain infections caused by bacteria such as pneumonia, bronchitis, infections of the sinuses, skin and throat.

When used with other medications, it can treat infection caused by a bacterium called *Helicobacter pylori* (*H. pylori*) and reduce the risk of duodenal ulcer recurrence. A duodenal ulcer is a sore on the lining of the duodenum, which is the beginning of the small intestine.

It can also be prescribed to prevent and combat MAC disease in patients with HIV. MAC is a short word for *Mycobacterium avium* complex, the germs that cause MAC disease.

What it does:

CLARITHROMYCIN is an antibiotic that kills bacteria in your body.

When it should not be used:

Do not take CLARITHROMYCIN if you

- have ever had an allergic reaction (rash, difficulty breathing) to this product, or if you are sensitive to clarithromycin, erythromycin, other antibacterial agents of the same family, or to any ingredient in this product (see What the nonmedicinal ingredients are).
- are taking astemizole*, cisapride*, colchicine, pimozone, terfenadine*, ergotamine, dihydroergotamine, lovastatin, **oral** midazolam, ranolazine*, saquinavir, simvastatin, or ticagrelor.

Astemizole*, cisapride*, pimozone, terfenadine*, ergotamine, dihydroergotamine and colchicine can interact with CLARITHROMYCIN, possibly leading to an irregular heartbeat pattern; deaths have occurred.

* not marketed in Canada

- have ever developed liver problems after using CLARITHROMYCIN.
- suffer from severe liver failure in combination with kidney impairment.
- have a history of heart disturbance or irregular heartbeat (arrhythmias, QT prolongation, torsades de pointes).

- have hypokalaemia (low potassium levels in the blood).

What the medicinal ingredient is:

Clarithromycin

What the nonmedicinal ingredients are:

Colloidal silica hydrated, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, opadry yellow (D&C Yellow #10 aluminum lake, hydroxypropyl methylcellulose, lactose monohydrate, polyethylene glycol 4000, titanium dioxide) and powdered cellulose.

What dosage forms it comes in:

Tablets of 250 mg and 500 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

CLARITHROMYCIN should not be used in pregnancy unless advised by your doctor due to potential hazards to the fetus. Do not take CLARITHROMYCIN without first talking to your doctor if you are breast feeding a baby.

Before taking CLARITHROMYCIN, tell your doctor if you have liver or kidney disease. You may not be able to take clarithromycin, or you may require a lower dose and special monitoring during therapy. Talk to your doctor if CLARITHROMYCIN gives you prolonged and severe diarrhea.

The development of antibiotic resistance has been seen in patients with HIV receiving clarithromycin. To avoid failure of the treatment with a potential for developing antimicrobial resistance and a risk of failure with subsequent therapy, you/your child should follow closely the prescribed regimen.

Antibacterial drugs like CLARITHROMYCIN treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, CLARITHROMYCIN should be taken exactly as directed. Misuse or overuse of CLARITHROMYCIN could lead to the growth of bacteria that will not be killed by CLARITHROMYCIN (resistance). This means that CLARITHROMYCIN may not work for you in the future. Do not share your medicine.

Treatments with antibiotics such as clarithromycin have resulted in heart problems such as irregular heartbeat, torsades de pointes and QT prolongation sometimes leading to death. Talk to your doctor if you are elderly and/or have risk factors such as:

- heart disease, heart problems, low heartbeat.
- are taking other medicines which are known to cause serious disturbances in heart rhythm.
- have disturbances in the levels of salts (electrolytes) in your blood, such as hypomagnesemia

BEFORE you use CLARITHROMYCIN talk to your doctor or pharmacist:

- about all health problems you have now or have had in the past;
- about all other medicines you are taking, including non-prescription medicines, nutritional supplements, or herbal products (see INTERACTIONS WITH THIS MEDICATION);
- if you have or develop severe diarrhea as this may be a sign of a more serious condition;
- if you have kidney problems;
- if you have liver problems;
- if you are taking digoxin, atorvastatin, pravastatin, midazolam;
- if you are taking quetiapine. Serious and life-threatening reactions have occurred in those taking clarithromycin and quetiapine, including malignant neuroleptic syndrome. Your doctor will decide if you should take this medication;
- if you are allergic to other medicines, foods, dyes, or preservatives;
- if you are pregnant, trying to get pregnant, breastfeeding or planning to breastfeed because clarithromycin has been detected in human breast milk.

WHILE taking CLARITHROMYCIN, contact your doctor if:

- You develop symptoms of myasthenia gravis or the symptoms of your existing myasthenia gravis worsen. These symptoms could include muscle weakness that gets worse with activity and gets better with rest, drooping eyelid, blurred or double vision, difficulty chewing and swallowing, or trouble breathing.
- You develop symptoms of hepatitis (liver inflammation) such as abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine etc. Stop taking the drug immediately.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CLARITHROMYCIN include:

Alfentanil, alprazolam, amlodipine, aripiprazole, astemizole*/terfenadine*, atazanavir, atorvastatin, bromocriptine, carbamazepine, cilostazol, cisapride*/pimozide, colchicine, cyclosporine, digoxin, diltiazem, disopyramide/quinidine, efavirenz, ergotamine/dihydroergotamine, etravirine, fluconazole, hexobarbital, insulin, itraconazole, lansoprazole/omeprazole, lovastatin/pravastatin/simvastatin, methylprednisolone, midazolam/triazolam, nateglinide, nevirapine, phenobarbital, phenytoin, pioglitazone, quetiapine, ranolazine*, repaglinide, rifabutin/rifampin, rifapentine*, risperidone, ritonavir/indinavir, rosiglitazone, rosuvastatin, saquinavir, sildenafil, St. John’s Wort (*Hypericum perforatum*), tacrolimus, tadalafil, ticagrelor, theophylline, tolterodine, valproic acid, vardenafil, verapamil,

vinblastine, warfarin/acenocoumarol, zidovudine and drugs metabolized by cytochrome P450 system.

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PROPER USE OF THIS MEDICATION

Usual Adult Dose:

CLARITHROMYCIN may be taken with or without meals.

Respiratory Tract or Skin Infections:

The usual dosage of CLARITHROMYCIN is 250 mg to 500 mg every 12 hours for 7 to 14 days.

Infections with *H. Pylori*:

Triple Therapy: CLARITHROMYCIN + Omeprazole + Amoxicillin

The recommended dose is the following for 10 days:

- CLARITHROMYCIN: 500 mg every 12 hours
- Omeprazole: 20 mg once daily
- Amoxicillin: 1 g every 12 hours

MAC disease:

The recommended dose of CLARITHROMYCIN for prevention and treatment of MAC disease is 500 mg every 12 hours.

Treatment of disseminated MAC infection (MAC infection spread through your whole body) in patients with HIV should continue for life if improvement of symptoms is observed.

Overdose:

In case of overdose, contact your healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms. Symptoms of CLARITHROMYCIN overdose are abdominal pain, vomiting, nausea, and diarrhea.

Missed Dose:

If you miss a dose, take it as soon as you remember unless it is almost time for the next dose. In that case, skip the missed dose and take the next one as directed. Do not take double or extra doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CLARITHROMYCIN can cause side effects. The majority of side effects observed in clinical trials with CLARITHROMYCIN were of a mild and transient nature.

The following adverse reactions were reported during the clinical studies with clarithromycin, the medicinal ingredient (occurring between 1% and 10% in clinical trials) or during post-marketing surveillance: abdominal pain, abnormal taste, diarrhea, ear disorder, flatulence, indigestion, headache, nausea, rash, vomiting. Talk to your doctor or pharmacist if any of these side effects persist or become bothersome.

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have Clostridium difficile colitis (bowel inflammation). If this occurs, stop taking CLARITHROMYCIN and contact your healthcare professional immediately.

Serious side effects from CLARITHROMYCIN are not common.

If dizziness, confusion or disorientation occur while taking CLARITHROMYCIN, do not drive or operate machinery.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Uncommon	Allergic reactions*			✓
	Severe diarrhea		✓	
	Severe abdominal cramps		✓	
	Irregular heartbeat			✓

*Allergic reactions, with symptoms such as itching, skin eruptions, rash, sore throat, fever, swelling, skin rash, itchiness, difficulty breathing, lightheadedness/dizziness.

This is not a complete list of side effects. For any unexpected effects while taking CLARITHROMYCIN, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CLARITHROMYCIN and all other medicines out of reach and sight of children.

Store at controlled room temperature between 15 and 30°C in a tightly closed container. Protect from light. Do not use beyond the expiration date.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada,
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting:

Sanis Health Inc., at:
1-866-236-4076
or quality@sanis.com

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