

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some common questions about CLARITHRO.

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 using CLARITHRO against the benefits they expect it will have for 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 CLARITHRO is used for

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

- respiratory tract infections
- skin infections
- peptic ulcer.

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

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

CLARITHRO 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.

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

CLARITHRO is available only with a doctor's prescription.

### CLARITHRO to treat peptic ulcer

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

The *H. pylori* infection can be treated with a combination of CLARITHRO (clarithromycin), another antibiotic (amoxicillin) and another medicine called omeprazole (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 CLARITHRO may no longer be effective in killing the *H. pylori* infection and a different antibiotic may be needed.

### Before you take CLARITHRO

#### *When you must not take it*

**Do not take CLARITHRO if you are allergic to medicines containing clarithromycin or any other macrolide antibiotic (such as erythromycin, roxithromycin and azithromycin) or any of the ingredients listed at the end of this leaflet.**

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.

### Do not take CLARITHRO if you are taking these medicines:

- cisapride (Prepulsid), a medicine used to treat stomach disorders
- pimozone (Orap), a medicine used to treat psychotic disorders
- ergotamine (Cafergot) or dihydroergotamine (Dihydergot), medicines for migraines.

### Do not take CLARITHRO if you have:

- severe liver problems
- poor kidney function.

**Do not take CLARITHRO if the expiry date (Exp.) printed on the pack has passed.**

**Do not take CLARITHRO if the packaging shows signs of tampering or the tablets do not look quite right.**

### *Before you start to take it*

**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 CLARITHRO during pregnancy.

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

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

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

- liver problems

- kidney problems.

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 CLARITHRO.

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may be affected by clarithromycin, or may affect how well it works. These include:

- medicines used to prevent blood clotting - warfarin (Coumadin, Marevan)
- some medicines used for epilepsy such as phenytoin (Dilantin) and carbamazepine (Tegretol)
- theophylline (Nuelin), a medicine used to treat asthma
- digoxin (Lanoxin), a medicine used to treat heart failure
- triazolam (Halcion), medicine used to treat sleeping problems
- midazolam (Hypnovel), medicine used to produce sleep before operation and to relief anxiety
- medicines 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 for treatment of erectile dysfunction in adult males
- quinidine (Kinidin) for heart arrhythmias
- disopyramide (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
- colchicine for treatment of gout
- simvastatin and atorvastatin for treatment of high cholesterol levels.

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CLARITHRO.

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## How to take CLARITHRO

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### *How much to take*

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

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

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

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

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

### *How to take CLARITHRO*

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

### *If you forget to take CLARITHRO*

**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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

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

**If you are not sure what to do, ask your doctor or pharmacist.**

### *How long to take CLARITHRO for*

Keep taking CLARITHRO until you finish the pack or for as long as your doctor tells you.

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

Do not stop taking CLARITHRO, 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 CLARITHRO.

### *If you take too much CLARITHRO (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CLARITHRO. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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

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## While you are taking CLARITHRO

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### *Things you must do*

**If you are taking CLARITHRO 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 CLARITHRO.**

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

Do this even if it occurs several weeks after stopping CLARITHRO. 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 CLARITHRO as it may affect the results of some laboratory tests.**

**Before starting any new medicine, tell your doctor or pharmacist that you are taking CLARITHRO.**

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

### *Things you must not do*

**Do not use CLARITHRO to treat any other conditions unless your doctor tells you to.**

**Do not give CLARITHRO to anyone else, even if they have the same condition as you.**

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## Side effects

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

CLARITHRO 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.**

**Tell your doctor if you notice any of the following and they worry you:**

- 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:**

- 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).

These are serious side effects. You may need urgent medical treatment.

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

- symptoms of an allergic reaction such as swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, shortness of breath or sudden collapse.

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## After using CLARITHRO

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**Tell your doctor immediately if you notice any of the following**

**side effects, even if they occur several weeks after stopping treatment with CLARITHRO:**

- 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.**

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

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## After using CLARITHRO

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### *Storage*

**Keep CLARITHRO 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.

**Keep CLARITHRO in a cool dry place, protected from light, where the temperature stays below 25°C.**

**Do not store CLARITHRO or any other medicine in the bathroom or near a sink.**

**Do not leave CLARITHRO in the car or on window sills.**

Heat and dampness can destroy some medicines.

### *Disposal*

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

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## Product description

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### *What it looks like*

CLARITHRO is a yellow, oval film-coated tablet.

Each blister pack contains 14 tablets.

### *Ingredients*

The active ingredient in CLARITHRO is Clarithromycin. Each CLARITHRO 250 tablet contains 250 mg of Clarithromycin.

CLARITHRO tablets also contain:

- microcrystalline cellulose
- croscarmellose sodium
- pregelatinised maize starch
- povidone
- purified talc
- magnesium stearate
- colloidal anhydrous silica
- Opadry II 40L22445 yellow.

### *Sponsor*

Sigma Pharmaceuticals (Australia)  
Pty Ltd  
96 Merrindale Drive  
Croydon Vic 3136  
Tel: 03 - 9839 2800

Australian registration numbers:  
CLARITHRO 250 - AUST R 117197

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