**APPROVED PATIENT INFORMATION LEAFLET**

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**KLARIBIN TABLETS 250 mg** (Tablet)

**KLARIBIN TABLETS 500 mg** (Tablet)

Clarithromycin

**Read all of this leaflet carefully before you start taking KLARIBIN.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **KLARIBIN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## 1. WHAT KLARIBIN CONTAINS

The active substance is clarithromycin.

**KLARIBIN TABLETS 250 mg:** Each film-coated tablet contains 250 mg clarithromycin.

**KLARIBIN TABLETS 500 mg:** Each film-coated tablet contains 500 mg clarithromycin.

The other ingredients are cellulose, microcrystalline; croscarmellose sodium; magnesium stearate; Opadry yellow (hypromellose, propylene glycol, titanium dioxide, hydroxypropyl cellulose, vanillin, sorbic acid and iron oxide yellow); povidone; and silica, colloidal anhydrous.

## 2. WHAT KLARIBIN IS USED FOR

**KLARIBIN** is indicated for the symptomatic treatment of:

- Chest infections such as bronchitis and pneumonia.
- Throat and sinus infections such as pharyngitis and sinusitis.
- Mild to moderately severe acute otitis media (infection of your middle ear).
- Skin and soft tissue infections.

- Eradication of *Helicobacter pylori* (the bacteria responsible for causing gastric or duodenal ulcers) when used in combination with a proton pump inhibitor and another antibiotic to decrease recurrence of duodenal ulcer.

## 3. BEFORE YOU TAKE KLARIBIN

**Do not take KLARIBIN:**

- If you have a hypersensitivity to clarithromycin or any macrolide antibiotics or to any component of the formulation.
- If you are taking astemizole, cisapride or pimozide.
- If you suffer from porphyria.
- If you are pregnant.
- If you are taking ergotamine or dihydroergotamine commonly used to treat migraine as the combination with **KLARIBIN** may cause constriction of blood vessels resulting in a decrease of oxygen supply to the brain and hands and feet ultimately causing tissue damage.
- If you are taking statins e.g. simvastatin and lovastatin, medicines used to treat high cholesterol, as it may increase the risk of rhabdomyolysis which is the breakdown of damaged muscle.
- If you are taking colchicine, a medicine used to treat gout.

**Take special care with KLARIBIN:**

- If you suffer from liver problems. If you experience yellowing of skin and white of the eyes, abdominal pain and tenderness, dark urine and severe itchy skin you should stop taking **KLARIBIN** immediately.
- If you suffer from kidney problems - the elimination of **KLARIBIN** is reduced in patients with renal function impairment, especially those with a creatinine clearance of <30 ml/min.
- If you are taking rifabutin and/or rifampicin as the combination will cause a decrease of **KLARIBIN** in your blood. Co-administration has been reported to cause a higher incidence of uveitis, an inflammation of part of the eye compared to when rifabutin is taken alone.
- If you are taking theophylline, a medicine used to open your airways to help you breath better.
- If you experience severe diarrhoea, you may be suffering from pseudomembranous colitis due

to **KLARIBIN**.

- If you are taking benzodiazepines e.g. midazolam, triazolam or triazolam, medicines used as muscle relaxants and to treat anxiety.
- If you are taking blood glucose lowering medicines such as insulin as it may cause hypoglycaemia, where your glucose level drops too much.

**Taking KLARIBIN with food and drink:**

You may take **KLARIBIN** with or without food.

**Pregnancy and Breast-feeding:**

If you are pregnant or breast-feeding, you should not take **KLARIBIN** as safety and efficacy in pregnancy and breast-feeding have not been established. **KLARIBIN** is excreted in the breast milk.

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| If you are pregnant or breast-feeding, please consult your doctor, pharmacist or other health care professional for advice before taking **KLARIBIN**. |

**Driving and operating machines:**

Do not drive or operate machine before you know how **KLARIBIN** will affect you.

**Taking other medicines with KLARIBIN:**

- You should not take **KLARIBIN** with colchicine (gout medicines), statins (high cholesterol medicines) or migraine medications.
- Taking **KLARIBIN** with astemizole, cisapride or pimozide may cause irregular heart rhythms and can be fatal.
- Medicines such as such as rifampicin, phenytoin, carbamazepine, phenobarbital, efavirenz, etravirine and St John's Wort may increase the metabolism of **KLARIBIN** and therefore reduce its efficacy.
- Antifungals such as fluconazole and itraconzole and antiretrovirals such as atazanavir and saquinavir may increase the blood concentration of **KLARIBIN**.
- Other medicines which may be affected by **KLARIBIN** include ciclosporin, disopyramide,

carbamazepine, methylprednisolone, omeprazole, quinidine, sildenafil, tacrolimus, triazolam, vinblastine, digoxin, zidovudine, phenytoin, and valproate.

- If you are taking warfarin or any other blood thinning medicines.
- If you are immunocompromised and treated with higher doses of **KLARIBIN** for a long period you may experience the following: nausea, vomiting, taste perversion, abdominal pain, diarrhoea, rash, flatulence, headache, and hearing disturbance.

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)

## 4. HOW TO TAKE KLARIBIN

Always take **KLARIBIN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **KLARIBIN** is too strong or too weak, talk to your doctor or pharmacist.

**Children**

Safety and efficacy in infants under 6 months of age has not been established. **KLARIBIN** is not suitable for use in children under the age of 12 years.

**Adults and children older than 12 years:** 250 mg twice daily.

In more severe infections, the dosage may be increased to 500 mg twice daily.

**KLARIBIN** may be taken with or without food.

Your doctor will prescribe an appropriate dose according to your condition.

**If you take more KLARIBIN than you should:**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

**If you forget to take KLARIBIN:**

Do not take a double dose to make up for forgotten individual doses.

## 5. POSSIBLE SIDE EFFECTS

**KLARIBIN** can have side effects.

If you experience any of the following, stop taking **KLARIBIN** and tell your doctor immediately:

- An allergic reaction where you have difficulty breathing
- Dizziness, blurred vision or fainting as you may have low blood glucose levels.
- Irregular heartbeats for example too fast or too slow.
- A severe peeling rash which may spread to your mouth or eyes.
- Yellowing of your skin and white of the eyes, dark urine or a painful, tender abdomen as you may have jaundice.

If you experience any of the following symptoms, tell your doctor as soon as possible:

- Abdominal cramps or pain, tenderness, severe, watery diarrhoea which may also be bloody, fever
- Convulsions
- Disorientation
- Muscle pain

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Oral thrush, or a vaginal infection
- Decreased appetite
- Anxiety
- Insomnia
- Hallucinations
- Bad dreams
- Depersonalisation
- Depression
- Dizziness

- Vertigo
- Confusion
- Tremor
- Hearing loss
- Vertigo
- Tinnitus (ringing in your ears)
- Nausea,
- Vomiting
- Muscle pain

Not all side effects reported for **KLARIBIN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

## 6. STORING AND DISPOSING OF KLARIBIN

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

Keep HDPE containers tightly closed.

Keep the blisters in the carton until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 7. PRESENTATION OF KLARIBIN

**KLARIBIN TABLETS 250 mg:**

**1. <u>PVC / PVdC Blister Pack:</u>**

Tablets are packed in clear 250 micron PVC film coated with 60 gsm PVdC and printed aluminium foil with 6-8 gsm Heat seal Lacquer.

<u>Pack size:</u> 10's – Each carton contains 1 blister of 10 tablets.

14's - Each carton contains 1 blister of 14 tablets.

**2. HDPE Container Pack:**

Tablets are packed in 100 ml white HDPE container of 38 mm neck finish (OFC 113 ml) with 38mm-400RS white closure with induction seal wad.

Pack size: 100's: One HDPE container of 100 tablets.

**KLARIBIN TABLETS 500 mg:**

**1) PVC / PVdC Blister Pack:**

Tablets are packed in clear 250 micron PVC film coated with 60 gsm PVdC and printed aluminium foil with 6-8 gsm Heat seal Lacquer.

Pack size: 10's – Each carton contains 1 blister of 10 tablets.

14's - Each carton contains 1 blister of 14 tablets.

**2) HDPE Container Pack:**

Tablets are packed in 120 ml white HDPE container of 38 mm neck finish (OFC 138 ml) with 38mm-400RS white closure with induction seal wad. Each container contains 100 tablets.

Pack size: 100's: One HDPE container of 100 tablets.

## 8. IDENTIFICATION OF KLARIBIN

**KLARIBIN TABLETS 250 mg:** Light yellow coloured, oval shaped, biconvex film-coated tablets, with 'D' debossed on one side and '62' on the other side.

**KLARIBIN TABLETS 500 mg:** Light yellow coloured, oval shaped, biconvex film-coated tablets, with 'D' debossed on one side and '63' on the other side.

## 9. REGISTRATION NUMBER/REFERENCE NUMBER

**KLARIBIN TABLETS 250 mg:** 42/20.1.1/0852

**KLARIBIN TABLETS 500 mg:** 42/20.1.1/0853

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12

Johannesburg

South Africa

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