PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CLARIHEXAL 125 P (Granules for oral suspension)

CLARIHEXAL 250 P (Granules for oral suspension)

Clarithromycin

Contains sugar (sucrose 2,4 g per 5 ml).

Preservative: Potassium sorbate 0,615 % *m/m*

Read all of this leaflet carefully before you start taking CLARIHEXAL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CLARIHEXAL 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.

What is in this leaflet

1. What CLARIHEXAL is and what it is used for

2. What you need to know before you take CLARIHEXAL

3. How to take CLARIHEXAL

4. Possible side effects

5. How to store CLARIHEXAL

6. Contents of the pack and other information

1. What CLARIHEXAL is and what it is used for

CLARIHEXAL belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) that cause infections. CLARIHEXAL contains the active ingredient, clarithromycin. Clarithromycin is used to treat bacterial infections in many different parts of the body.

Your doctor will prescribe CLARIHEXAL to treat the following infections such as:

- Lower respiratory tract such as bronchitis and pneumonia (chest infections).
- Upper respiratory tract infections such as pharyngitis (throat) and sinusitis (sinus) infections.
- Mild to moderately severe acute otitis media (ear infections, particularly inflammation of the middle ear).
- Skin and soft tissue infections such as folliculitis, cellulitis or erysipelas.
- CLARIHEXAL may also be used to treat gastrointestinal ulcers caused by an organism called *Helicobacter pylori*. Together with CLARIHEXAL, your doctor will also prescribe other medication that you must use at the same time, to prevent the ulcer from coming back.

2. What you need to know before you take CLARIHEXAL

Do not take CLARIHEXAL:

- If you are hypersensitive (allergic) to clarithromycin, any macrolide antibiotics (erythromycin or azithromycin) or any of the other ingredients of CLARIHEXAL (listed in section 6).
- If you are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.
- If you are taking oral midazolam (a sedative).
- If you are taking lomitapide, lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).
- If you are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies), domperidone or cisapride (for stomach problems) or pimozide (for mental

health problems), as combining these medicines can sometimes cause serious disturbances in heart rhythm.

- Have a history of QT prolongation (an abnormality if the electrocardiogram (ECG)) or an irregular heart beat (ventricular cardiac dysrhythmia).
- If you are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina).
- If you are taking colchicine (usually taken for gout).
- If you have hypokalaemia (a condition characterized by low levels of potassium in the blood).
- If you have severe liver disease with kidney disease.
- If you suffer from porphyria.

Warnings and precautions

Take special care with CLARIHEXAL:

- If you have kidney and severe liver disease. You may have an increased chance of side effects.
- If you experience Rhabdomyolysis is a condition in which skeletal muscle tissue dies, releasing substances into the blood that cause kidney failure.
- If you develop severe or prolonged diarrhoea (pseudomembranous colitis), which may have blood or mucus in it, during or after taking CLARIHEXAL, contact your doctor immediately.
- If you have, or have had, heart problems (e.g. heart disease, heart failure, an unusually slow heart rate) or abnormally low levels of magnesium in the blood (hypomagnesaemia).
- If you have pneumonia (serious lung infection with fever, chills, shortness of breath, cough, phlegm or coughing blood).

- In the event of severe acute hypersensitivity reactions, such as anaphylaxis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, CLARIHEXAL therapy should be discontinued immediately and appropriate treatment should be urgently initiated.
- If you suffer from blood clots or currently using blood thinning medicine.
- If you have a weak immune system (immunocompromised) you may experience nausea, vomiting, irregular taste, stomach pain, runny stomach, rash, flatulence (gas), headache, hearing disturbance, irregular liver test results and irregular low white blood cell and platelet counts or difficulty breathing, restlessness and dry mouth.

Other medicines and CLARIHEXAL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- Terfenadine or astemizole (used to treat hay fever or allergies), cisapride or domperidone (used to treat stomach disorders) or pimozide (used to treat certain mental disorders) as combining these medicines can sometimes cause serious disturbances in heart rhythm.
- Ergot alkaloids, e.g. ergotamine or dihydroergotamine used to treat migraines.
- Alprazolam, midazolam, temazepam, nitrazepam, lorazepam or triazolam used to treat anxiety disorders or insomnia (difficulty sleeping).
- Atorvastatin, rosuvastatin, lovastatin or simvastatin commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood. Statins can cause Rhabdomyolosis (a condition that causes the breakdown of muscle tissue, which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- Carbamazepine, valproate, phenobarbital or phenytoin used to treat epilepsy (fits).
- Rifabutin, rifampicin, rifapentine, fluconazole or itraconazole used to treat bacterial infections.

- Etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir or saquinavir used to treat HIV.
- Warfarin, rivaroxaban or apixaban also known as blood thinners used to treat blood clots.
- Quetiapine used to treat certain mental/mood disorders.
- Sildenafil, tadalafil or vardenafil used to treat erectile dysfunction.
- Tacrolimus used to treat eczema.
- Sirolimus used to prevent rejection of kidney transplant.
- Vinblastine used to treat certain types of cancer.
- Theophylline used to treat asthma.
- Nateglinide or repaglinide used to treat Type 2 diabetes.
- Omeprazole used to treat heartburn or stomach ulcers.
- Tolterodine used to treat overactive bladder.
- Colchicine used to treatment of gout.
- Digoxin, quinidine, disopyramide, calcium channel blockers (verapamil, amlodipine, diltiazem) used to treat irregular heartbeat.
- Itraconazole used to treat fungal infections.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CLARIHEXAL.

Driving and using machines

It is not always possible to predict to what extent CLARIHEXAL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CLARIHEXAL affects them. CLARIHEXAL may make you dizzy, drowsy, confused or disorientated.

CLARIHEXAL contains sugar

CLARIHEXAL contains sucrose, which is a type of sugar. Patients with the rare hereditary condition of galactose intolerance e.g. galactosaemia or glucose-galactose malabsorption should not take CLARIHEXAL.

3. How to take CLARIHEXAL

Do not share medicines prescribed for you with any other person.

Always take CLARIHEXAL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual duration of treatment is 5 to 10 days and will depend on the type of infection and its seriousness.

Children who weigh less than 8 kg will usually be given a dose of approximately 7,5 mg/kg twice a day.

SHAKE THE BOTTLE BEFORE EACH DOSE

The usual dosage for children is as follows:

Weight	**Approximate age**	**Dose in ml of 125 mg/5 ml suspension**	**Dose in ml of 250 mg/5 ml suspension**
8 to 11 kg	1 to 2 years	2,5 ml twice daily	---
12 to 19 kg	2 to 4 years	5 ml twice daily	2,5 ml twice daily
20 to 29 kg	4 to 8 years	7,5 ml twice daily	3,75 ml twice daily
30 to 40 kg	8 to 12 years	10 ml twice daily	5 ml twice daily

The usual dose in adults is 250 mg twice a day, which could be increased to 500 mg twice a day for more severe infections.

If you suffer from severe renal impairment, your doctor will reduce the dosage of CLARIHEXAL by half.

Reconstitution instructions:

CLARIHEXAL is provided to your pharmacist as granules. Your pharmacist will dissolve the granules in distilled water before giving the medicine to you.

CLARIHEXAL 125 P:

Add 29,5 ml of distilled water to reconstitute to 50 ml. Shake the bottle.

Add 59 ml of distilled water to reconstitute to 100 ml. Shake the bottle.

Add 70,8 ml of distilled water to reconstitute to 120 ml. Shake the bottle.

CLARIHEXAL 250 P:

Add 28,5 ml of distilled water to reconstitute to 50 ml. Shake the bottle.

Add 57 ml of distilled water to reconstitute to 100 ml. Shake the bottle.

If you take more CLARIHEXAL than you should

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

If you forget to take CLARIHEXAL

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

4. Possible side effects

CLARIHEXAL can have side effects.

Not all side effects reported for CLARIHEXAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLARIHEXAL, please consult your health care provider for advice.

If any of the following happens, stop taking CLARIHEXAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe skin reactions such as painful blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- A red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis).
- A rare allergic skin reactions which cause severe illness with ulceration of the mouth, lips and skin which causes severe illness with rash, fever and inflammation of internal organs (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to CLARIHEXAL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Changes in the way your heart beats for example if you notice it beating faster.
- Muscle pain or weakness known as rhabdomyolysis (a condition that causes the breakdown of muscle tissue, which can result in kidney damage).
- Fits.
- Yellowing of the skin and eyes, dark urine, and tiredness, which may be symptoms of liver problems.
- Watery and severe diarrhoea, which may be bloody.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Difficulty sleeping.

- Headache or irregular taste.
- Nausea.
- Vomiting.
- Stomach pain.
- Diarrhoea.
- Indigestion.
- Irregular liver function test.
- Rash.
- Excessive sweating.

Less frequent side effects:

- Thrush.
- Mild to severe nausea, vomiting, cramps and diarrhoea, usually caused by a virus.
- Infection.
- Irregular blood cells that may cause fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal.
- Weight loss.
- Lack of appetite.
- Anxiety.
- Nervousness.
- Dizziness.
- Sleepiness.
- Shaking.
- Ringing in the ear or hearing loss.
- Vertigo.
- Nosebleed.
- Inflammation of the lining of the oesophagus and lining of the stomach.
- Anal pain.

- Bloating, constipation, wind, burping.
- Dry mouth.
- Situation where the bile (fluid made by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis).
- Itching or itchy rash.
- Muscle spasms or muscle pain.
- Aching muscles, muscle tenderness or weakness, not caused by exercise.

Frequency unknown:

- Bacterial infection of the skin.
- Confusion.
- Depression.
- Seeing things (hallucinations).
- Abnormal dreams or nightmares.
- Mood of excitement, over activity and uninhibited behaviour.
- Loss of taste or smell.
- Tingling feeling in hands and feet also known as “pins and needles”.
- Deafness.
- Bleeding.
- Teeth or mouth discolouration.
- Acne.
- Generally feeling unwell.
- Fever.
- Chest pain.
- Chills.
- Fatigue.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CLARIHEXAL.

Suspected adverse reactions can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store CLARIHEXAL

- Store at or below 25 °C. The reconstituted suspension should not be placed in the fridge but should be stored at temperatures at or below 25 °C for not more than 14 days.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use this medicine after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLARIHEXAL contains

Active ingredient: Clarithromycin.

Inactive ingredients: Fruit punch flavouring, glycerol monostearate, hypromellose, macrogol 6000, maltodextrin, methacrylic acid-ethyl acrylate copolymer, poloxamer 188, polysorbate 80, potassium sorbate, povidone K-30, silica colloidal anhydrous, sucrose, titanium dioxide (CI 77891), triethyl citrate, xantham gum.

What CLARIHEXAL looks like and contents of the pack

CLARIHEXAL 125 P:

Granules: White to beige granules.

Ready-for-use suspension: White to beige suspension.

CLARIHEXAL 250 P:

Granules: White to beige granules.

Ready-for-use suspension: White to beige suspension.

CLARIHEXAL 125 P granules and CLARIHEXAL 250 P granules are supplied in 60 ml, 120 ml or 240 ml polyethylene (PE) bottles with natural screw closures press and turn with guarantee ring. For administration after reconstitution with water an oral Polyethylene/Polypropylene (PE/PP) measuring syringe or a polypropylene measuring spoon is used.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

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Registration numbers

CLARIHEXAL 125 P: A39/20.1.1/0292

CLARIHEXAL 250 P: A39/20.1.1/0293

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07