PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

CLARIHEXAL 500 XL (Modified Release Film-coated Tablets)

Clarithromycin

Sugar free

Read all of this leaflet carefully before you start taking CLARIHEXAL 500 XL

- 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 500 XL 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 500 XL is and what it is used for
2. What you need to know before you take CLARIHEXAL 500 XL
3. How to take CLARIHEXAL 500 XL
4. Possible side effects
5. How to store CLARIHEXAL 500 XL
6. Contents of the pack and other information

1. WHAT CLARIHEXAL 500 XL IS AND WHAT IT IS USED FOR

Each CLARIHEXAL 500 XL tablet contains 500 mg of the active ingredient, clarithromycin. CLARIHEXAL 500 XL belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) which cause infections.

CLARIHEXAL 500 XL is indicated in the treatment of:

- Lower respiratory tract infections such as bronchitis and pneumonia.
- Upper respiratory tract infections such as pharyngitis and sinusitis.
- Skin and soft tissue infections such as folliculitis, cellulites or erysipelas

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLARIHEXAL 500 XL

Do not take CLARIHEXAL 500 XL:

- If you are hypersensitive (allergic) to clarithromycin, any macrolide antibiotics (erythromycin or azithromycin) or any of the other ingredients of CLARIHEXAL 500 XL (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.
- If you have a history of QT prolongation (an abnormality of the electrocardiogram (ECG)) or an irregular heartbeat (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

CLARIHEXAL 500 XL should be used with caution in:

- If you have kidney and severe liver disease. You may have an increased chance of side effects.
- If you experience rhabdomyolysis (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 500 XL, 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 (SJS), and toxic epidermal necrolysis, CLARIHEXAL 500 XL 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 500 XL

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 which 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 for 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 heart burn 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.
- Contraceptive used to prevent pregnancy.

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 500 XL.

Driving and using machines

It is not always possible to predict to what extent CLARIHEXAL 500 XL 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 500 XL affects them. CLARIHEXAL 500 XL may make you dizzy, drowsy, confused or disorientated.

3. HOW TO TAKE CLARIHEXAL 500 XL

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.

Adults:

500 mg once daily with food.

In more severe infections, the dosage may be increased to 1 000 mg (2 x 500 mg) daily.

Tablets should be swallowed whole.

The usual duration of treatment is 7 to 14 days.

If you take more CLARIHEXAL 500 XL 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 500 XL

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

4. POSSIBLE SIDE EFFECTS

CLARIHEXAL 500 XL can have side effects.

Not all side effects reported for CLARIHEXAL 500 XL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLARIHEXAL 500 XL, please consult your health care provider for advice.

If any of the following happens, stop taking CLARIHEXAL 500 XL 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 500 XL. 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 which 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 that are not there (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 500 XL. Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via Patientsafety.sacg@novartis.com.

4. HOW TO STORE CLARIHEXAL 500 XL

Store at or below 25 °C.

STORE OUT OF REACH OF CHILDREN.

5. CONTENTS OF THE PACK AND OTHER INFORMATION

What CLARIHEXAL 500 XL contains

The active substance is 500 mg Clarithromycin.

Core excipients:

Calcium stearate, cellulose microcrystalline, glycerol dibehenate, hypromellose (Methocel E-50), polysorbate 80, povidone K-25, silica colloidal anhydrous, stearic acid, talc.

Coating Excipients:

Ferric oxide (E 172) yellow, hypromellose (Pharmacoat 606), hypromellose (Methocel E-15), hydroxypropylcellulose, macrogol 400, talc, titanium dioxide, vanilla cream flavour.

What CLARIHEXAL 500 XL looks like and contents of the pack

CLARIHEXAL 500 XL are light ochre – yellow, oval, biconvex film-coated tablets with debossing “500” on one side and “CXL” on the other side.

CLARIHEXAL 500 XL is packed in aluminium/aluminium blister packs of 5 or 10 tablets packed into carton boxes.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Not applicable.

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