

### **WHAT IS IN THIS LEAFLET**

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### **WHAT CLARIWIN IS AND WHAT IT IS USED FOR**

Clarithromycin belongs to a group of medicine called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) which cause infections.

Clarithromycin tablets are used to treat following infections:

- Chest infections such as bronchitis and pneumonia,
- Throat and sinus infections,
- Skin and soft tissue infections,
- Helicobacter pylori infections associated with duodenal ulcers.

Clarithromycin tablets are indicated in adults and children 12 years and older.

### **WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLARIWIN**

#### **Do not take Clarithromycin Tablets if you:**

- Are allergic to clarithromycin or other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of Clarithromycin Tablets.
- Are taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers for migraine.
- Are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach disorders) or pimozide (for mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- Are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).
- Are taking oral midazolam (a sedative)
- Have abnormally low levels of potassium in the blood (a condition known as hypokalaemia)
- Are taking other medicines which are known to cause serious disturbances in heart rhythm

You or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsade de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.

- Have **severe** liver disease with kidney disease.
- You are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina)
- Are taking colchicine (usually taken for gout)

#### **Take special care with Clarithromycin tablets**

- If you have abnormally low levels of magnesium in your blood (hypomagnesaemia) consult your doctor before taking these tablets.

**Clarithromycin tablets are not suitable for use in children under 12 years of age.**

#### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Clarithromycin tablets;

- If you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or low levels of magnesium in the blood)
- you are pregnant or breast-feeding
- if you have, or are prone to, fungal infections (e.g. thrush)
- if you have any liver or kidney problems

**Other medicines and Clarithromycin tablets:**

You should not take Clarithromycin tablets if you are taking any of the medicines listed in the section above “Do not take Clarithromycin tablets if you;”

Tell your doctor if you are taking any of the following medicines as your dose may need to be changed or you may need to have regular tests performed.

- Digoxin, disopyramide or quinidine (for heart problems)
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy)
- Atorvastatin, rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood). Statins can cause rhabdomyolysis (a condition which cause the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- Theophylline (used in patients with breathing difficulties such as asthma)
- Triazolam, alprazolam or intravenous or oromucosal midazolam (sedatives)
- Cilostazol (for poor circulation)
- Methylprednisolone (a corticosteroid)
- Warfarin (for thinning the blood)
- Nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (used to lower blood glucose levels)
- Gliclazide or glimepiride (sulphonylureas used in the treatment of type II diabetes)
- Vinblastine (for treatment of cancer)
- Ciclosporin, sirolimus or tacrolimus (immune suppressants)
- Etravirine, efavirenz, Nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral drugs used in the treatment of HIV)
- Rifampicin, Rifapentine, fluconazole, itraconazole or rifabutin (used for treatment of certain bacterial infections)
- Tolterodine (for overactive bladder)
- Verapamil, amlodipine, diltiazem (for high blood pressure)
- St John’s Wort (a herbal product used to treat depression)
- Quetiapine or other antipsychotic medicines

*Other macrolide medicines*

- Lincomycin and clindamycin (lincosamides – a type of antibiotic)

Please tell you’re if you are taking oral contraceptive pills and diarrhea or vomiting occurs, as you may need to take extra contraceptive precautions such as using a condom.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

*Taking Clarithromycin Tablets with food and drink*

Clarithromycin Tablets may be taken with or without food.

*Pregnancy, breast-feeding and fertility*

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as the safety of Clarithromycin tablets in pregnancy and breast-feeding is not known. Ask your doctor or pharmacist for advice before taking any medicine.

### *Driving and using machines*

Clarithromycin tablets may make you feel dizzy or drowsy. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

### **3. HOW TO TAKE CLARIWIN**

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

Do not give these tablets to children under 12 years. Your doctor will prescribe another suitable medicine for your child.

The dose of Clarithromycin varies with the condition being treated. The dose you should take will be on the pharmacist's label. Always take the tablets exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Clarithromycin Tablets should be swallowed with at least half a glass of water.

- For treating chest infections, throat or sinus infections and skin and soft tissue infections:

Usual dose of clarithromycin tablets for adults and children over 12 years is 250mg twice daily for 6 to 14 days, e.g. one 250mg tablet in the morning and one in the early evening.

Your doctor may increase the dose to 500mg twice daily in severe infections.

- **For treating *Helicobacter pylori* infections associated with duodenal ulcers:**

There are a number of effective treatment combinations available to treat *Helicobacter pylori* in which clarithromycin tablets are taken together with one or two other drugs.

These combinations include the following and are usually taken for 6 to 14 days:

- a) One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- b) One Clarithromycin 500 mg tablet taken twice a day together with metronidazole, 400 mg taken twice a day plus lansoprazole, 30 mg twice a day.
- c) One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day or metronidazole, 400 mg taken twice a day plus omeprazole, 40 mg a day.

One Clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus omeprazole, 20 mg taken once a day.

The treatment combination that you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking or how long you should be taking them for, please consult your doctor for advice.

#### ***If you take more Clarithromycin Tablets than you should***

If you or accidentally take more Clarithromycin tablets in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor or nearest hospital emergency department immediately. An overdose of Clarithromycin tablets is likely to cause vomiting and stomach pains.

#### ***If you forget to take Clarithromycin tablets***

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

#### ***If you stop taking Clarithromycin Tablets:***

Do not stop taking Clarithromycin Tablets, even if you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### **4. POSSIBLE SIDE CLARIWIN**

Like all medicines, **this medicine** can cause side effects, although not everybody gets them. Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters

(exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

If you suffer from any of the following at any time during your treatment STOP TAKING your tablets and contact your doctor immediately:

- Severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor.
- A rash, difficulty breathing, fainting or swelling of the face and throat. This is a sign that you may have developed an allergic reaction.
- Severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- Yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your liver may not be working properly.
- Henoch-Schönlein purpura (a rash which appears as purple spots on the skin).
- Muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).
- Drug reaction with eosinophilia and systemic symptoms (DRESS). This can include symptoms such as rash, fever abnormal blood count and inflammation of internal organs.

Common side effects (may affect up to 1 in 10 people) include;

- Headache
- Difficulty sleeping
- Changes in sense of taste
- Widening of blood vessels
- Stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- A change in the way the liver works
- Skin rash
- Increased sweating

Uncommon side effects (may affect up to 1 in 100 people) include;

- High temperature
- Swelling, redness or itchiness of the skin. Sometimes brown scales may appear
- Oral or vaginal 'thrush' (a fungal infection)
- Inflammation of the stomach and intestines
- Decrease of the levels of blood platelets (blood platelets help stop bleeding)
- Decrease in white blood cells (leukopenia)
- Decrease in neutrophils (neutropenia)
- Stiffness
- Increase of eosinophils (white blood cells involved in immunity)
- Exaggerated immune response to a foreign agent
- Lack or loss of appetite
- Anxiety, nervousness
- Drowsiness, tiredness, dizziness or shaking
- Involuntary muscle movements
- Ringing in the ears or hearing loss
- Vertigo
- Chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat
- Asthma: lung disease associated with tightening of air passages, making breathing difficult
- Nose bleed

- Blood clot that causes sudden blockage in a lung artery (pulmonary embolism)
- Inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- Anal pain
- Inflammation of the tongue, mouth and lips
- 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)
- Inflammation of the liver
- inflammation of the skin characterized by the presence of the bullae which are filled with fluid, itchy and painful rash
- Muscle spasms, muscle pain or loss of muscle tissue. If your child suffers from myasthenia gravis (a condition in which the muscles become weak and tire easily), clarithromycin may worsen these symptoms.
- Raised abnormal kidney and liver function blood test and raised blood tests
- Feeling weak, tired and having no energy

Not known side effects (frequency cannot be estimated from the available data)

- Inflammation of the colon
- Bacterial infection of the outer layers of skin

Reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)

- Swelling of the lips and eyes
- Confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares and mania (feeling of elation or over-excitement)
- Convulsion (fits)
- paraesthesia, more commonly known as ‘pins and needles’
- Loss of taste or smell or inability to smell properly
- Type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- Loss of blood (haemorrhage)
- Inflammation of the pancreas
- Discolouration of the tongue and/or teeth
- Change in the levels of products made by the liver, inflammation of the liver or an inability of the liver to function properly (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin)
- Stevens-Johnson syndrome: skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth
- 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
- Acne
- Change in the levels of products produced by the kidney, inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)

## **5. HOW TO STORE CLARIWIN**

Keep out of the sight and reach of children.

Do not store above 30°C. Keep in a dry place in the original package.

Do not use Clarithromycin Tablets after the expiry date stated on the carton or label.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### ***What Clariwin 500 contains,***

The active substance is clarithromycin.

Each Film-coated Tablet contains: Clarithromycin USP .....500 mg

### ***What Clariwin looks like and contents of the pack***

Yellow coloured, oblong shaped, film coated tablets with break line on one surface

10 Tablets are packed in a Alu/Alu Blisters pack. Such 1 blister Is packed in a carton along with pack insert

### **Manufacturer**

**MICRO LABS LIMITED**

92, SIPCOT,

HOSUR-635 126, INDIA

### **Marketing Authorization Holder**

Micro labs Limited

# 27 Race course road

Bangalore-560001

### **Date of Revision**

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