

PATIENT INFORMATION LEAFLET

CLARIE OD (CLARITHROMYCIN EXTENDED-RELEASE TABLETS USP)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor, health care provider or pharmacist.

In this leaflet

- a) What Clarithromycin is and what it is used for
- b) Before you take Clarithromycin
- c) How to take Clarithromycin
- d) Possible side effects
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a) WHAT CLARITHROMYCIN IS AND WHAT IT IS USED FOR

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

Clarithromycin tablets are used to treat infections such as:

- Chest infections such as bronchitis and pneumonia.
 - Throat and sinus infections.
 - Mild to moderate skin and tissue infections, e.g. cellulitis, folliculitis or erysipelas.
- Clarithromycin Tablets are used in adults and children 12 years and older.

b) BEFORE YOU TAKE CLARITHROMYCIN

Do not take Clarithromycin

- If you know that you are allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the tablets medicine (listed in section “F”)
- If you are taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers for migraine.
- If you are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride or domperidone (for stomach problems) or pimozone (for

mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.

- If you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- If you 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).
- If you are taking oral midazolam (a sedative).
- If you are taking a medicine containing lomitapide.
- If you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- If you have severe liver disease with kidney disease.
- If you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.
- If you are taking medicines called ticagrelor, ivabradine or ranolazine (for heart attack, chest pain or angina)
- If you are taking colchicine (usually taken for gout)

Take special care with Clarithromycin

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,)
- If you have any liver or kidney problems
- If you have, or are prone to, fungal infections (e.g. thrush)
- If you are pregnant or breast feeding

Children

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

Taking other medicines

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as your dose may need to be changed or you may need to have regular tests performed:

- Digoxin, quinidine or disopyramide (for heart problems)
- Ibrutinib (for cancer treatment)
- Warfarin, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (for blood thinning)
- 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 causes the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.

- Nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (used to lower blood glucose levels)
- Gliclazide or glimepiride (sulphonylureas used in the treatment of type ii diabetes)
- Theophylline (used in patients with breathing difficulties such as asthma)
- Triazolam, alprazolam or intravenous or oromucosal midazolam (sedatives)
- Cilostazol (for poor circulation)
- Methadone (used in the treatment of opioid addiction)
- Corticosteroids (e.g. methylprednisolone), given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions)
- Vinblastine (for treatment of cancer)
- Cyclosporin, Sirolimus And Tacrolimus (Immune Suppressants)
- Etravirine, Efavirenz, Nevirapine, Ritonavir, Zidovudine, Atazanavir, Saquinavir (Anti-Viral Drugs Used In The Treatment Of Hiv)
- Rifabutin, Rifampicin, Rifapentine, Fluconazole, Itraconazole (used in the treatment of certain bacterial infections)
- Tolterodine (for overactive bladder)
- Verapamil, Amlodipine, Diltiazem (for high blood pressure)
- Sildenafil, Vardenafil And Tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- 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)
- Hydroxychloroquine or Chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). taking these medicines at the same time as clarithromycin may increase the chance of getting abnormal heart rhythms and other serious side effects that affect your heart.

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

Taking Clarithromycin with food and drink

Clarithromycin tablets should be taken with food and must be swallowed whole and not chewed.

Pregnancy and breast-feeding

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

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

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.

Important information about some of the ingredients of Clarithromycin

Clarithromycin Contains Lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you are allergic (hypersensitive) to other ingredients of this medicine listed in section “f”).

c) HOW TO TAKE CLARITHROMYCIN

Always take Clarithromycin exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider 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 recommended dose of Clarithromycin tablets for adults and children over 12 years is one 500 mg tablet once a day for 6 to 14 days.

Your doctor may increase the dose to two 500 mg tablets daily in severe infections. Clarithromycin tablets should be taken with food and must be swallowed whole and not chewed.

If you take more Clarithromycin than you should

If you 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

If you forget to take a dose of Clarithromycin tablets, take it as soon as you remember. Do not take more tablets in one day than your doctor has told you to.

If you stop taking Clarithromycin

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 or pharmacist.

d) POSSIBLE SIDE EFFECTS

Like all medicines, Clarithromycin can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

- 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, tongue, lips, eyes and throat.
- This is a sign that you may have developed an allergic reaction.
- Yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These are signs that your liver may have inflammation and not be working properly.
- 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). The frequency of this side effect is not known (cannot be estimated from the available data).
- 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.
- Muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

Other side effects

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

- Difficulty sleeping
- Changes in sense of taste
- Headache
- Widening of blood vessels
- Stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhea.
- Increased sweating

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

- High temperature
- Swelling, redness or itchiness of the skin.
- 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
- Chills
- 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
- Vertigo
- Ringing in the ears or hearing loss
- 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.
- Nosebleed
- 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
- 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 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 you suffer 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 the skin
- Reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- 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 or teeth
- 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).

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

e) **HOW TO STORE CLARITHROMYCIN**

Keep out of the reach and sight of children.

Store below 30°C. Protect from light & moisture.

Do not use Clarithromycin after the expiry date which is stated on the carton after Expiry date. The expiry date refers to the last day of that month.

Do not use Clarithromycin if you notice visible signs of deterioration.

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

f) **FURTHER INFORMATION**

What Clarithromycin contains

Tablet Core

- Lactose Monohydrate
- Hypromellose
- Hypromellose Phthalate
- Talc
- Magnesium Stearate

Film Coat

- Hypromellose
- Lactose Monohydrate
- Macrogol
- Quinoline Yellow Aluminium Lake (E104)
- Talc
- Titanium Dioxide (E171)

What Clarithromycin looks like and contents of the pack

Film-coated extended-release Tablets.

Clarithromycin Extended-Release Tablets USP 500mg: Yellow coloured, film coated, oblong shaped, biconvex tablet, with both sides plain.

Primary Packaging

Blister pack of 7 tablets packed using Rigid PVC film coated with PVdC Pharma Grade (Clear, 90gsm coated) and Printed Aluminium foil.

Secondary Packaging

Such one blister of 7 tablets is packed in a carton along with insert.

Name and Full Physical Address of Marketing Authorization Holder and Manufacturing Site:

MARKETING AUTHORISATION HOLDER

Ind-Swift Limited

MANUFACTURED BY:



Ind-Swift Ind-Swift Limited

Off. NH-21, Village Jawaharpur,
Tehsil Derabassi, District SAS Nagar (Mohali)
Punjab-140507, India

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