

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

CLARIDE XL 500 mg modified release tablets

Clarithromycin as clarithromycin citrate

Contains sugar: lactose monohydrate 298 mg

Read all of this leaflet carefully before you start taking CLARIDE XL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CLARIDE 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 CLARIDE XL is and what it is used for
2. What you need to know before you take CLARIDE XL
3. How to take CLARIDE XL
4. Possible side effects
5. How to store CLARIDE XL
6. Contents of the pack and other information

1. What CLARIDE XL is and what it is used for

CLARIDE XL is an antibiotic which belongs to a group of medicines called macrolides.

Antibiotics stop the growth of bacteria which causes infections.

CLARIDE XL tablets are used to treat infections such as:

- Chest infections such as bronchitis and pneumonia (infection of the lungs).
- Sinusitis (infection of the sinuses).
- Pharyngitis and tonsillitis (infection of the throat and tonsils).
- Skin and soft tissue infections that are not severe.

2. What you need to know before you take CLARIDE XL

Do not take CLARIDE XL

- if you are hypersensitive (allergic) to clarithromycin, other macrolide antibiotics or any of the other ingredients of CLARIDE XL (listed in section 6).
- if you taking the following medications. Consult your doctor for advice on alternative medicines or ask if you are not sure:
 - Ergotamine or dihydroergotamine tablets or use ergotamine inhalers (medicines used to treat migraines). Combining these with CLARIDE XL tablets may cause your blood vessels to narrow. This will lead to a decrease of blood supply to tissues.
 - Cisapride (to treat stomach disorders), pimozide (to treat some mental illnesses), terfenadine or astemizole (to treat hay fever or allergy). Combining these medicines with CLARIDE XL tablets can cause serious changes in your heart rhythm.
 - Lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood as this may increase your chances of developing rhabdomyolysis (a condition where muscle tissue is broken down, causing a release of a damaging protein into the blood)).
 - Colchicine which is used to treat gout.
 - Oral midazolam (used as a sedative).

- Ticagrelor or ranolazine (for heart attack, chest pain or angina).
- If your potassium levels are low (hypokalaemia).
- If you have severe liver disease with kidney disease.
- If you have an irregular heart rhythm.

Warnings and precautions

Take special care with CLARIDE XL and tell your doctor or healthcare provider:

- If you have a heart condition.
- If you have any kidney problems.
- If you have liver problems.
- If you have or are prone to fungal infections (such as thrush).
- If you suffer from myasthenia gravis which is a condition that causes weakness of the muscles.
- If you take a group of medicines called benzodiazepines to calm you down.
- If you take an antibiotic from a group of antibiotics called aminoglycosides.
- If you take medicine to lower your cholesterol (fat in the blood).
- If you take medicine to lower your blood sugar or thin your blood.

Children

CLARIDE XL is not suitable for children younger than 12 years.

Other medicines and CLARIDE XL

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

You should not take CLARIDE XL tablets if you are taking any of the following medicines (see Do not take CLARIDE XL) as it can cause disturbances in heart rhythm:

- Cisapride (to treat stomach disorders).
- Pimozide (to treat mental illness).
- Terfenadine or astemizole (to treat hay fever or allergies).
- Ergotamine or dihydroergotamine (to treat migraines).
- Lovastatin or simvastatin (to treat high cholesterol).

Tell your doctor if you are taking any of the following medicines. Because of the possibility of reactions your doctor will decide if you can still take CLARIDE XL tablets:

- Digoxin (to treat heart failure). It may cause irregular heart beat and may also increase your risk of side effects.
- Quinidine or disopyramide (to treat abnormal heart rhythm). This may cause you to experience seriously irregular heartbeat.
- Warfarin or acenocoumarol (to thin the blood). These medicines may change the rate at which your blood clots. This might result in toxic effects.
- Ibrutinib (to treat cancer).
- Triazolam, alprazolam or midazolam (sedatives). These medicines may cause sleepiness and confusion.
- Statins (to treat high cholesterol). These medicines may lead to pain or weakness in muscles, or abnormal muscle breakdown. This can lead to kidney problems.
- Zidovudine (anti-viral agent used to treat HIV). This may change the effectiveness of zidovudine.
- Rifabutin, rifampicin, rifapentin (used to treat tuberculosis (TB)). These medicines may change the effectiveness of CLARIDE XL tablets.
- Efavirenz, nevirapine (HIV treatments). These medicines may change the effectiveness CLARIDE XL tablets.

Taking the following medicines with CLARIDE XL tablets may increase your risk of side effects. Tell your doctor if you are taking any of the following:

- Carbamazepine, valproate, phenobarbital or phenytoin (to treat epilepsy).
- Cilostazol (to treat poor circulation).
- Methylprednisolone (to treat inflammation).
- Sildenafil, tadalafil, vardenafil (to treat erection problems).
- Vinblastine (to treat cancer).
- Omeprazole (to treat indigestion/ulcers in your digestive tract).
- Tolterodine (to treat urinary frequency).
- Ciclosporin, tacrolimus, sirolimus (to help prevent rejection after a transplant).
- Theophylline (to treat asthma).
- Itraconazole or fluconazole (to treat fungal infections).
- Etravirine, ritonavir, atazanavir, saquinavir (anti-viral and anti-HIV medicines).
- Nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (to treat diabetes).
- Verapamil (to treat high blood pressure).
- St John's Wort (a herbal product).
- Oral contraceptive. If you develop vomiting, diarrhoea and/or breakthrough bleeding, your oral contraceptive might fail i.e., you may fall pregnant.

CLARIDE XL with food and drink

CLARIDE XL should be taken with food.

Pregnancy, breastfeeding and fertility

Do not take CLARIDE XL tablets if you are pregnant without consulting your doctor first. Do not take CLARIDE XL tablets if you are breastfeeding without consulting your doctor first.

This is because small amounts of this medicine can pass into breast milk.

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 healthcare provider for advice before taking CLARIDE XL.

Driving and using machines

CLARIDE XL tablets may cause dizziness or a spinning feeling (vertigo) as a possible side effect. If you experience these effects, you should not drive or operate machines.

It is not always possible to predict to what extent CLARIDE XL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CLARIDE XL affects you (see section 4).

CLARIDE XL contains lactose monohydrate

CLARIDE XL contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CLARIDE XL.

3. How to take CLARIDE XL

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

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

The usual dose of CLARIDE XL for adults is one tablet (500 mg) once daily swallowed whole with food.

Your doctor may increase the dose to two tablets (1000 mg) once daily to treat severe infections.

Your doctor will tell you how long your treatment with CLARIDE XL will last. Do not stop treatment early. If you have the impression that the effect of CLARIDE XL is too strong or too weak, tell your doctor or pharmacist.

If you take more CLARIDE XL than you should

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

An overdose of CLARIDE XL tablets is likely to cause vomiting, stomach pains, changes in awareness, movement and behaviour (altered mental status and/or paranoid behaviour).

If you forget to take CLARIDE XL

Take the dose as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CLARIDE XL

Do not stop taking CLARIDE XL because you feel better. It is important to take the tablets for as long as your doctor has told you to, otherwise the infection might come back.

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

4. Possible side effects

CLARIDE can have side effects.

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

If any of the following happens, stop taking CLARIDE 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,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

These are all very serious side effects. If you have them, you may have had a serious reaction to CLARIDE 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:

- Severe or prolonged diarrhoea, which may have blood or mucus in it (pseudomembranous colitis).
- Deafness.
- Upper abdominal pain that may radiate to the back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting as these may be symptoms of acute pancreatitis (inflammation of the pancreas).
- Abnormal heart rhythm, sudden collapse, no pulse, chest pain, no breathing, loss of consciousness as these may be symptoms of a serious heart condition.
- Dark, reddish urine, a decreased amount of urine, weakness and muscle aches as these may be symptoms of rhabdomyolysis (a life-threatening condition caused by muscle breakdown and muscle death).
- Decreased urine output, fluid retentions, shortness of breath, fatigue, confusion, irregular heartbeat as these may be symptoms of kidney failure.

- Convulsion.
- Bleeding.
- Shortness of breath or other problems with breathing including asthma.
- Agranulocytosis (a blood cell disorder that makes it easier for you to get infections), thrombocytopenia (a decrease in a type of blood cell that causes you to bleed easily).
- Leukopenia (reduction in the number of white blood cells, which makes infections more likely), eosinophilia and neutropenia (white blood cell disorder), thrombocythaemia (increase in blood platelets, which increases the risk of bleeding or blood clots).

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

- Abnormal liver function tests (doctor will let you know),
- change in sense of taste (dysgeusia, taste perversion), headache,
- abdominal pain, diarrhoea, indigestion, feeling sick, vomiting, bloating,
- difficulty sleeping (insomnia),
- increased sweating,
- thrush, ulcers in your mouth (oral candidiasis),
- vasodilation can cause dizziness when standing up for example or flushing,
- increased sweating (hyperhidrosis).

Less frequent side effects:

- Gastroenteritis (inflammation of the stomach and intestines), vaginal bacterial or fungal infection, bacterial skin infection (erysipelas),

- anorexia (loss of appetite), or decreased appetite
- anxiety (feeling anxious) and nervousness,
- dizziness, tremor (shaking), somnolence (sleepiness),
- tinnitus (ringing in the ears) or hearing loss, vertigo (spinning sensation),
- epistaxis (nose bleeds),
- constipation, dry mouth, belching, flatulence (wind), bleeding from stomach and intestines,
- increased liver enzymes found on doing a laboratory blood tests,
- dry skin,
- muscle pain (myalgia),
- asthenia (weakness or lack of energy)

Side effects with an unknown frequency:

- Hypoglycaemia (low blood sugar which can cause fatigue, fast heartbeat, pale skin, excessive hunger, shakiness, anxiety, sweating and irritability).
- Psychotic disorder (disorder of the mind), depersonalisation (the feeling of your surroundings being unreal), depression (low mood), hallucination (seeing or hearing things that are not real), abnormal dreams, mania (high mood), confusional state.
- Ageusia (loss of taste), parosmia (smell disorder), anosmia (loss of smell), paraesthesia (feeling of 'pins and needles').
- Tongue discolouration, tooth discolouration.
- Acne.
- Changes in liver or kidney function tests or blood tests, prothrombin time prolongation (increased blood clotting time).

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**: Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of CLARIDE XL.

5. How to store CLARIDE XL

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from light and moisture.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What CLARIDE XL contains

The active substance is 500 mg of clarithromycin citrate.

The other ingredients are Lactose Monohydrate, Hypromellose, Hypromellose Phthalate, Purified Talc, Magnesium Stearate, Purified Water.

Coating Material: Opadry II Yellow 31G52300 (Hypromellose, Lactose Monohydrate, Titanium Dioxide E171, Macrogol / PEG 4000, Talc, Quinoline Yellow Aluminium Lake E104, Macrogol / PEG 400)

Contains sugar: Lactose monohydrate 298 mg per tablet.

What CLARIDE XL looks like and contents of the pack

Modified release tablets

CLARIDE XL is a yellow coloured film coated, oblong shaped, and biconvex tablet with both sides plain.

An outer cardboard carton containing a PVC film coated with PVDC–Aluminium blister strip containing 7 tablets.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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