Abbott
A Promise for Life

Patient Information Leaflet

Read all of this leaflet carefully before you take these tablets. It gives a summary of the information available on this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions or are not sure about anything, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as yours.

Scheduling status: S4

Proprietary name and dosage form:

Klacid XL Tablets

Clarithromycin

What Klacid XL contains:

Klacid XL tablets are modified release tablets, which means that the active ingredient is released slowly from the tablet, so that you have to take them only once a day.

Each **Klacid XL** tablet contains 500 mg clarithromycin (6-o-methyl erythromycin A) as the active ingredient.

Other ingredients include: Citric acid, sodium alginate, sodium calcium alginate, lactose, povidone, talc, stearic acid, magnesium stearate, methyl hydroxypropyl cellulose, polyethylene glycol, titanium dioxide (E171), sorbic acid and quinoline yellow dye (E104).

What Klacid XL is used for:

Klacid XL is an antibiotic belonging to a group called macrolides. Antibiotics stop the growth of bacteria (bugs) which cause infections. Its use is described below.

Klacid XL is used to treat infections such as:

1. Chest infections, such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and tissue infections such as cellulitis, folliculitis or erysipelas

Before taking Klacid XL tablets:

Do not take Klacid XL tablets:

- 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.
- Do not take ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine while taking **Klacid XL**. Consult your doctor, pharmacist or other health care professional for advice for advice on alternative medicines.
- Do not take terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride or pimozide tablets while taking **Klacid XL**, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your

doctor, pharmacist or other health care professional for advice for advice on alternative medicines.

- If you have any liver or kidney problems, consult your doctor before taking these tablets.
- Do not take colchicines (usually taken for gout), while receiving **Klacid XL**, as this can also cause serious side effects.

Take special care with Klacid XL:

- If you have any liver or kidney problems, speak to your doctor before taking these tablets.
- If you develop severe or prolonged diarrhoea during or after taking **Klacid XL**, tell your doctor immediately.

Taking Klacid XL with food and drink:

Klacid XL must be taken with food and must be swallowed whole and not chewed.

Pregnancy and Breast-feeding:

If you are pregnant or breast feeding a baby, do not take **Klacid XL** tablets without consulting your doctor, pharmacist or other health care professional for advice first, as the safety of **Klacid XL** tablets in pregnancy and breastfeeding is not known.

Driving and using machinery: N/A

Important information about some of the ingredients of Klacid XL: N/A

Taking other medicines with Klacid XL:

If you are taking medicines on a regular basis, using **Klacid XL** at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice if you are taking any of the following drugs: digoxin (heart drug), warfarin (blood thinner), ergotamine or dihydroergotamine (for migraine), colchicine (for gout), carbamazepine, phenytoin or valproate (drugs for epilepsy), theophylline (helps breathing), terfenadine or astemizole (for hay fever or allergy), alprazolam, triazolam or midazolam (sedatives), disopyramide or quinidine (heart drugs), simvastatin or lovastatin (for high cholesterol), cisapride or omeprazole (for stomach disorders), cyclosporin (drug taken following an organ transplant), pimozide, rifabutin, efavirenz, nevirapine, rifampicin, rifapentine, fluconazole or itraconazole (for treatment of some infections), ritonavir, zidovudine, atazanavir or saquinavir (for treatment of HIV infection), tacrolimus (for organ transplants), vinblastine (for certain cancers), sildenafil, tadalafil or vardenafil (for erection problems), methylprednisolone (cortisone) or cilostazol (poor circulation), tolterodine (for bladder problems).

Klacid XL does not interact with oral contraceptives.

Instructions on how to use Klacid XL:

Klacid XL must be taken with food and must be swallowed whole and not chewed.

The usual dose of **Klacid XL** for adults and children over 12 years of age is 500 mg once daily for seven to fourteen days. Your doctor may increase the dose to two 500 mg tablets daily in

severe infections. These tablets are not suitable for children under 12 years of age as liquid medicines are generally preferable – your doctor will prescribe another suitable medicine for your child.

Do not stop taking **Klacid XL** tablets because 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 forget to take Klacid XL:

If you forget to take a **Klacid XL** tablet, take one as soon as you remember and then continue dosing as normal. Do not take more tablets in one day than your doctor has told you to. If you are concerned about having missed one or more doses of medicine, consult your doctor or pharmacist.

If you take more Klacid XL than you should:

If you accidentally take more than two **Klacid XL** tablets in one day, or if a child accidentally swallows some tablets, seek medical advice urgently - 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 **Klacid XL** tablets is likely to cause vomiting and stomach pains, and there is a possibility of allergic reactions.

REMEMBER, this medicine is for YOU. DO NOT share medicines prescribed for you with any other person. The medicine may harm them, even if their symptoms are the same.

Possible Side-Effects:

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Klacid XL can sometimes cause stomach problems such as feeling sick, vomiting, stomach pain or diarrhoea. You may also experience numbness or a feeling of 'pins and needles'. Headache, joint pain or muscle pain, or loss of muscle tissue have also been reported. If you develop severe or prolonged diarrhoea, which may have blood or mucous in it, during or after taking **Klacid XL** tablets, consult your doctor immediately.

If you have a blood test while taking **Klacid XL** it may show raised liver enzymes. These levels usually return to normal, and it is unlikely that you will show any symptoms. However, **Klacid XL** can rarely cause jaundice and other liver or gall bladder disorders, which can be severe or even fatal in extremely rare circumstances. If you feel generally unwell or develop yellow skin and/or eyes, or pale stools with dark urine, consult you doctor immediately. Kidney problems, including raised levels of protein normally excreted by the kidneys, and rarely kidney failure, have also been reported. Occasionally, a blood test may also show low levels of white blood cells.

Allergic reactions, including rashes, have been reported with **Klacid XL**. In very rare cases, difficulty in breathing, fainting and swelling of the face and throat can occur, which may need emergency treatment. Allergic rashes may range in severity from mild, itchy skin eruptions to a rarer, more serious condition called Stevens-Johnson syndrome (which causes severe

illness with ulceration of the mouth, lips and skin) or toxic epidermal necrolysis (which causes severe illness and sloughing of the skin).

Some people taking **Klacid XL** notice a funny taste in their mouth, or a change in their sense of taste and smell. However, these are only temporary effects and you should not stop taking the tablets because of them. Very rarely, the teeth become discoloured, but in most cases this can be removed by professional dental cleaning. There have also been reports of **Klacid XL** causing the tongue to swell or darken, sore mouth or tongue and 'thrush' in the mouth.

There have also been some reports of dizziness, loss of bearings, 'ringing' in the ears, difficulty in sleeping, depression, hallucinations (seeing things), bad dreams, confusion, change in sense of reality and panicking. These effects are usually short-lived and soon disappear. Very rarely, fainting due to low blood sugar, and mood and behavioural disorders have been reported, which in severe cases have required hospitalisation. Very rarely, some patients may experience unexpected bruising and their blood may take longer to clot after a cut to the skin. Changes in heart rhythm, inflammation of the pancreas and convulsions have also been reported rarely. There have been rare reports of loss of sense of smell and of hearing with **Klacid XL**, which is a temporary effect and is usually reversible on stopping treatment.

Consult your doctor immediately if you develop any of these problems or have any other unexpected or unusual symptoms.

Storage and disposal information (how should Klacid XL be stored):

Do not use these tablets after their 'use-by' (expiry) date, which is printed on the box and indented on the blister strip. If the tablets are out of date, return them to your pharmacist and, if necessary, get a new prescription from your doctor.

Store at room temperature (below 30°C) in a dry place, protected from light. Store in the original package.

Store all medicines out of reach of children – keep this medicine in a safe place where children cannot reach it.

If your doctor decides to stop your treatment with **Klacid XL**, return any remaining tablets to a pharmacist.

Presentation:

Klacid XL Tablets are supplied in blister packs of 5 or 10 tablets.

Identification of the medicine:

Klacid XL Tablets: Yellow, ovaloid, film-coated tablets, which are either plain or have the Abbott logo imprinted on one side.

Registration numbers of the medicines:

Klacid XL Tablets: 31/20.1.1/0379

Name, Business Address and Telephone Number of the Holder of the Certificate of Registration:

Abbott Laboratories SA (Pty) Ltd

Abbott Place

219 Golf Club Terrace

Constantia Kloof

South Africa

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Date of Publication of the Patient Information Leaflet: To be allocated

If you have any questions about your treatment, which are not answered by this leaflet, ask your doctor or pharmacist.