PATIENT INFORMATION LEAFLET FOR CLARIBAX

SCHEDULING STATUS

S4

CLARIBAX 500 mg film coated tablets

Clarithromycin

Sugar free

Read all of this leaflet carefully before you start taking CLARIBAX

- 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.
- CLARIBAX 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 CLARIBAX is and what it is used for
2. What you need to know before you take CLARIBAX
3. How to take CLARIBAX
4. Possible side effects
5. How to store CLARIBAX

6. Contents of the pack and other information

1. What CLARIBAX is and what it is used for

CLARIBAX contains the active ingredient clarithromycin which belongs to a group of medicines called macrolide antibiotics. Macrolide antibiotics stop the growth of certain bacteria that cause infections. CLARIBAX is used to treat infections such as:

- Lower respiratory tract infections, e.g. bronchitis, pneumonia.
- Upper respiratory tract infections, e.g. pharyngitis, sinusitis.
- Skin and soft tissue infections, e.g. folliculitis, cellulitis, erysipelas.
- *Helicobacter pylori* infections, associated with duodenal ulcers.
- Infections in human immunodeficiency virus-positive (HIV-positive) adults caused by a group of organisms called Mycobacteria.

Your doctor may prescribe CLARIBAX to you together with another medicine for the treatment of duodenal ulcers. Your doctor will prescribe CLARIBAX to you based on the type of bacteria causing the infection.

2. What you need to know before you take CLARIBAX

Do not take CLARIBAX:

- If you are hypersensitive (allergic) to clarithromycin, macrolide antibiotics or any of the other ingredients of CLARIBAX listed in section 6 of this leaflet.
- If you are taking any of the following medicines: terfenadine (used for allergies and hayfever), pimozide (used to treat Tourette syndrome), ergotamine or dihydroergotamine (used for migraines).

Warnings and precautions

Take special care with CLARIBAX:

Tell your doctor, pharmacist or health care provider immediately if you develop diarrhoea during or after your treatment with CLARIBAX.

Tell your doctor or health care provider:

- If you have any liver problems.
- If you have kidney problems.
- If you are taking colchicine (used for gout).
- If you are taking medicine for insomnia or anxiety.
- If you have heart problems.
- If you have abnormally low levels of potassium in your body (hypokalaemia).
- If you are taking domperidone (used for nausea and vomiting).
- If you have abnormally low levels of magnesium in your body (hypomagnesaemia).
- If you are taking any medicines that might affect your heart rhythm.
- If you have ever had any hypersensitivity (allergic) reaction to antibiotics.
- If you are taking medicine to lower your cholesterol.
- If you are taking medicine to lower your blood sugar levels.
- If you are taking any anticoagulants (used to prevent blood clots).

Tell your doctor immediately if you develop anorexia, dark urine, itching of your skin or a tender abdomen during your treatment with CLARIBAX. These are signs and symptoms of liver disease and your doctor may test your liver function.

Tell your doctor immediately if you develop diarrhoea during or after your treatment with CLARIBAX.

Other medicines and CLARIBAX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take CLARIBAX if you use:

- Pimozide (used to treat Tourette syndrome).
- Ergotamine or dihydroergotamine (used to treat migraines).

Tell your doctor or pharmacist before you take CLARIBAX if you use:

- Oral midazolam (used to treat insomnia and anxiety).
- Lovastatin or simvastatin (used to lower your cholesterol).
- St John's wort (herbal medicine).
- Efavirenz, nevirapine, etravirine, ritonavir, zidovudine, atazanavir or saquinavir (used to treat human immunodeficiency virus (HIV) infection).
- Rifampicin, rifabutin or rifapentine (used to treat tuberculosis (TB)).
- Cilostazol (used to improve blood flow in the legs).
- Ciclosporin (used to treat rheumatoid arthritis, psoriasis and used during organ transplants).
- Domperidone (used to treat nausea and constipation).
- Ibrutinib or vinblastine (used to treat certain types of cancer).
- Methylprednisolone (cortisone used to treat certain immune disorders, arthritis and allergies).
- Medicine to prevent blood clots (such as warfarin).
- Antipsychotic medicines (such as quetiapine, used to treat hallucinations and psychosis).
- Sirolimus (used during organ transplants).
- Tacrolimus (used to treat eczema).
- Disopyramide, digoxin (used to treat an irregular heartbeat) or quinidine (used to treat an

irregular heartbeat or malaria).

- Medicine to lower blood sugar levels (such as nateglinide, repaglinide or insulin).
- Omeprazole (used to treat excessive stomach acid and peptic ulcers).
- Sildenafil, tadalafil or vardenafil (used to treat erectile dysfunction (impotence)).
- Theophylline (used to treat asthma, bronchitis or emphysema).
- Phenytoin, valproate (used to treat seizures) or carbamazepine (used to treat seizures and nerve pain).
- Tolterodine (used to treat an overactive bladder).
- Alprazolam or triazolam (used to treat insomnia and anxiety).
- Colchicine (used to treat gout).
- Verapamil, amplodipine or diltiazem (used to lower blood pressure or treat irregular heartbeat).
- Itraconazole (used to treat fungal infections).
- Phenobarbital (used to treat insomnia, anxiety and seizures).

CLARIBAX with food

CLARIBAX can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CLARIBAX.

Driving and using machines

Your ability to drive and use machines may be affected by side effects, such as dizziness, vertigo, confusion and disorientation. Do not drive a vehicle or operate machinery until you know how

CLARIBAX affects you.

3. How to take CLARIBAX

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

Always take CLARIBAX exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 250 mg twice a day.

In more severe infections, the dosage can be increased to 500 mg twice a day.

Your doctor will decide your dose and tell you how long your treatment with CLARIBAX will last, depending on the type of infection and your kidney function.

Your doctor may prescribe you CLARIBAX with other medicines to treat your infection.

If you have the impression that the effect of CLARIBAX is too strong or too weak, tell your doctor or pharmacist.

If you take more CLARIBAX than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CLARIBAX

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your

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

4. Possible side effects

CLARIBAX can have side effects.

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

If any of the following happens, stop taking CLARIBAX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

Less frequent side-effects:

- Changes in the way your heart beats.
- Signs of recurrent infections, such as fever, chills or sore throat.
- Liver disease (causing unusual tiredness, nausea (feeling sick), vomiting (being sick), yellowing of skin or eyes).

The following side-effects have been reported with unknown frequency:

- Fast or irregular heartbeats.
- Pseudomembranous colitis (abdominal or stomach cramps and pain, severe abdominal tenderness, severe watery or bloody diarrhoea, fever).
- Kidney failure (drowsiness, shortness of breath, fatigue, confusion, nausea (feeling sick), fits, passing less urine than is normal for you).
- Liver diseases or liver failure (stomach pain, clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, nausea (feeling sick), vomiting (being sick) of blood, yellowing of skin or eyes).
- Interstitial nephritis (passing more or less urine than what is normal for you, blood in your urine, dark urine, nausea, vomiting).
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back).
- Bleeding or bruising more easily than normal.
- Red, blister forming rash with fever.
- Seizures (fits).
- Temporary paralysis or weakness of muscles.

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:

- Change in results when testing your liver function or liver enzymes.
- Infection (causing fever and feeling unwell).

- Abnormal physical weakness or lack of energy.
- Difficulty sleeping.
- Distortion of the sense of taste.
- Diarrhoea, pain in the stomach area and stomach cramps.
- Nausea (feeling sick) and vomiting (being sick).
- Headache or dizziness.
- Excessive sweating.

Less frequent side effects:

- Vertigo (causing dizzines and nausea), hearing impairment or ringing in the ears.
- Changes in results when testing your blood enzymes.
- Candidiasis or vaginal infection (causing vaginal itching, redness or irritation and a burning sensation when urinating).
- Gastritis (pain, nausea, vomiting, vomiting blood, blood in the stool), abdominal distension (causing belching, nausea and vomiting), constipation or flatulence.
- Mouth sores, a dry mouth or glossitis (causing swelling and pain of your tongue).
- Loss of taste or loss of smell.
- Chest pain.
- Anxiety.
- Loss of appetite and losing weight.
- Feeling excessively tired or tremors (involuntary trembling or shaking of hands and feet).
- Tingling or numbness of your hands and feet (pins and needles).
- General feeling of being unwell, fatigue and chills.

The following side-effects have been reported with unknown frequency:

- Psychotic disorder (causing anxiety, suspiciousness, depressed mood).

- Confusion, depersonalisation, depression, feeling disorientated or mania (causing racing thoughts, feeling energetic, talking fast and taking more risks).
- Hallucinations or having abnormal dreams.
- Haemorrhage (rupturing of a blood vessel).
- Erysipelas (causing a red, swollen and painful area of the skin, blisters and fever).
- Deafness.
- Easy or excessive bruising or bleeding and blood clotting slower than usual.
- Low blood sugar levels.
- Tongue or tooth discolouration.
- Abnormal urine colour.
- Muscle tenderness or weakness.
- Acne.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. 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 CLARIBAX.

5. How to store CLARIBAX

- Store at or below 30 °C.
- Keep the blister strip(s) in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLARIBAX contains

The active substance in CLARIBAX is clarithromycin.

Each film coated tablet contains 500 mg clarithromycin.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium (E468), magnesium stearate (E572), microcrystalline cellulose (E460), polyvinylpyrrolidone (E1201) and Opadry Y-1-7000 (containing Hypromellose (E464), polyethylene glycol (E1521) and titanium dioxide(E171)).

What CLARIBAX looks like and contents of the pack

White or almost white, capsular shaped film coated tablets inscribed with “S20” on one side and blank on the other side.

CLARIBAX is packed in white opaque PVC/PVdC and silver aluminium push through blister strip(s), packed in an outer cardboard carton.

CLARIBAX is available in pack sizes of 5 or 10 film coated tablets.

CLARIBAX 250 mg is not registered and marketed.

Holder of certificate of registration

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