

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****KLANBICID** (Powder for solution for infusion)**Clarithromycin****Read all of this leaflet carefully before you are given KLANBICID**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet.

1. What KLANBICID is and what it is used for
2. What you need to know before you are given KLANBICID
3. How to use KLANBICID
4. Possible side effects
5. How to store KLANBICID
6. Contents of the pack and other information

1. What KLANBICID is and what it is used for

KLANBICID contains the active ingredient clarithromycin. KLANBICID belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to stop the growth of bacteria that cause infections.

KLANBICID is used whenever an intravenous (injection into the vein) antibiotic is required to treat severe infections or, alternatively, if a patient cannot swallow tablets containing clarithromycin. KLANBICID is used to treat various infections.

KLANBICID should only be given to adults and children 12 years or older.

2. What you need to know before you are given KLANBICID

KLANBICID should not be administered to you:

- If you are hypersensitive (allergic) to clarithromycin, other macrolide antibiotics (e.g. erythromycin and azithromycin) or any of the other ingredients of KLANBICID;
- If you are taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers to treat migraines (throbbing headache);
- If you are taking medicines called cisapride or domperidone (for stomach disorders) or pimozide (for mental health problems) as combining these medicines can cause serious disturbances in heart rhythm;
- If you are taking other medicines which are known to cause serious disturbances in heart rhythm;
- If you have a history of heart rhythm disorders (ventricular cardiac dysrhythmia, 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 or ranolazine (for heart attack or chest pain caused by reduced blood flow to the heart)
- 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 suffer from abnormally low levels of potassium in your blood (hypokalaemia)
- If you suffer from severe liver disease with kidney disease
- If you are taking colchicine (a medicine to treat gout).
- If you are taking quetiapine, cariprazine, aripiprazole or other antipsychotic medicines.

Warnings and precautions

Tell your doctor or health care provider before being given KLANBICID or during treatment with KLANBICID:

- If you are pregnant or breastfeeding your baby

- If you suffer from liver problems
- If you suffer from kidney problems
- If you suffer from 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
- If you suffer from heart problems (e.g. heart disease, heart failure, an unusually slow heart rate, or abnormally low levels of magnesium in the blood (hypomagnesaemia)).

Children

KLANBICID should only be given to adults and children 12 years or older.

Other medicines and KLANBICID

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

Please inform your health care provider, before you take KLANBICID, if you are currently taking one of the following medicines:

- Digoxin, quinidine or disopyramide (for heart problems)
- Ibrutinib or vinblastine (for cancer treatment)
- Warfarin, or any other anticoagulant (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, gliclazide, glimepiride, rosiglitazone or insulin (used to lower blood glucose levels)
- 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 to treat inflammation)
- Ciclosporin and tacrolimus (immune suppressants)
- Etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral medicines used in the treatment of HIV)
- Rifabutin, rifampicin, rifapentine, fluconazole, itraconazole (used in the treatment of certain bacterial and fungal 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 (an herbal product used to treat depression)
- Quetiapine, cariprazine, aripiprazole or other antipsychotic medicines
- Other macrolide antibiotics such as azithromycin and erythromycin
- Lincomycin and clindamycin (lincosamides – a type of antibiotic)
- Oral contraceptives. 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.

Pregnancy and breastfeeding

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 health care provider for advice before taking KLANBICID.

You should not be given KLANBICID if you are pregnant or breastfeeding your baby.

KLANBICID is excreted in breast milk.

Driving and using machines

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

It is not always possible to predict to what extent KLANBICID 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 KLANBICID affects you.

3. How KLANBICID is given

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

You will not be expected to give yourself KLANBICID. It will be given to you by a person who is qualified to do so.

Adults

Clarithromycin is given to you, slowly through a needle, into your vein, over a period of at least an hour. The total time of treatment with KLANBICID should not exceed 14 days. Your doctor will work out the correct dose for you.

Children

Children under 12 years should not be given KLANBICID.

If more KLANBICID is given to you than you should

Since a healthcare provider will administer KLANBICID, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use KLANBICID

Since a healthcare provider will administer KLANBICID, it is unlikely that the dose will be missed.

If you stop using KLANBICID

Your treatment with KLANBICID will last for a period of 2 to 5 days. Since a health care provider will administer KLANBICID, your doctor will decide you how long your treatment with KLANBICID will last.

4. Possible side effects

KLANBICID can have side effects.

Not all side effects reported for KLANBICID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given KLANBICID, please inform your healthcare provider.

If any of the following happens while being given KLANBICID, inform your doctor or healthcare provider 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 immediately.
- 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 may be signs that your liver may have inflammation and not be working properly.
- 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).
- A red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis).

- An allergic skin reaction which cause severe illness with ulceration of the mouth, lips and skin which causes severe illness with rash, fever and inflammation of internal organs (DRESS).
- Muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

These are all very serious side effects. If you have them, you may have had a serious reaction to KLANBICID. You may need urgent medical attention.

Tell your doctor or health care provider if you notice any of the following:

Frequent side effects:

- Inflammation, tenderness or pain at the site of the injection
- Difficulty sleeping
- Changes in sense of taste
- Headache
- Widening of blood vessels
- Stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- Increased sweating.

Less frequent side effects:

- 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
- Deafness.

Frequency of side effects unknown:

- 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, ventricular fibrillation)
- 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 side effects

If you get side effects, talk to your doctor or pharmacist. 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 KLANBICID.

5. How to store KLANBICID

Store all medicines out of sight and reach of children.

Store the unopened vial below or below 25 °C (room temperature).

Store the unopened vial in the original container.

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

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

6. Contents of the pack and other information

What KLANBICID contains

- Each vial contains 500 mg clarithromycin and lactobionic acid as a solubilising agent.
- Sugar free

What KLANBICID looks like

Clarithromycin is white to off white cake lyophilized sterile powder supplied in 15 ml glass vial (small bottle), sealed with grey rubber stopper and dark grey aluminium cap with orange plastic flip-off seal. Each vial is packed in units of 1 vial per carton box.

Holder of Certificate of Registration

Juno Pharma SA (Pty) Ltd

106 16th Road

Midrand

South Africa

1686

This leaflet was last revised on

03 June 2024

Registration number

52/20.1.1/0243