

KLARIZON

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

KLARIZON 250 (clarithromycin 250 mg) Tablets
KLARIZON 500 (clarithromycin 500 mg) Tablets
Clarithromycin
Sugar free

Read all of this this leaflet carefully before you start taking KLARIZON tablets.

- 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.
- KLARIZON 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 KLARIZON is and what it is used for
2. What you need to know before you take KLARIZON
3. How to take KLARIZON
4. Possible side effects
5. How to store KLARIZON
6. Contents of the pack and other information

1. What KLARIZON is and what it is used for

KLARIZON belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) that cause infections. KLARIZON contains the active ingredient, clarithromycin. KLARIZON is used to treat bacterial infections in many different parts of the body.

Your doctor will prescribe KLARIZON to treat the following infections such as:

- chest infections (like pneumonia and bronchitis)
- infections of the middle ear
- tonsils
- skin and infections of the throat and sinuses
- KLARIZON in combination with another antibiotic, amoxicillin and a specific medicine indicated to reduce stomach acid can also be used for the treatment of a duodenal ulcer when this ulcer is caused by a bacteria, *Helicobacter pylori*.

Your doctor will tell you what you are being treated for.

2. What you need to know before you take KLARIZON

Do not take KLARIZON:

- If you are hypersensitive (allergic) to clarithromycin, any macrolide antibiotics or any of the ingredients of KLARIZON (listed in section 6).
- If you are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies), domperidone or cisapride (for stomach problems) or pimizole (for mental health problems), as combining these medicines can sometimes cause serious disturbances in heart rhythm.
- If you are taking certain antipsychotic medicines, such as quetiapine, cariprazine, and aripiprazole (for mental problems), it can make the levels of these antipsychotic medicines in your blood go up. This can lead to severe side effects (see section 'Other medicines and KLARIZON').
- Have a history of QT prolongation (an abnormality of the electrocardiogram (ECG)) or an irregular heartbeat (ventricular cardiac dysrhythmia).
- If you are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.
- If you are taking oral midazolam (a sedative).
- If you are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina).
- 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 colchicine (usually taken for gout).
- If you have hypokalaemia (a condition characterised by low levels of potassium in the blood).
- If you have severe liver disease with kidney disease.
- If you suffer from porphyria.

Warnings and precautions

Take special care with KLARIZON:

- If you have kidney and severe liver disease. You may have an increased chance of side effects.
- If you experience rhabdomyolysis, which is a condition in which skeletal muscle tissue dies, releasing substances into the blood that cause kidney failure.
- If you develop severe or prolonged diarrhoea (pseudomembranous colitis), which may have blood or mucus in it, during or after taking KLARIZON, contact your doctor immediately.
- If you have, or have had, heart problems (e.g., heart disease, heart failure, an unusually slow heart rate) or abnormally low levels of magnesium in the blood (hypomagnesaemia).
- If you have pneumonia (serious lung infection with fever, chills, shortness of breath, cough, phlegm or coughing blood).
- In the event of severe acute hypersensitivity reactions, such as anaphylaxis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, KLARIZON therapy should be discontinued immediately and appropriate treatment should be urgently initiated.
- If you suffer from blood clots or currently using blood thinning medicine.
- If you have a weak immune system (immunocompromised) you may experience nausea, vomiting, irregular taste, stomach pain, runny stomach, rash, flatulence (gas), headache, hearing disturbance, irregular liver test results and irregular low white blood cell and platelet counts or difficulty breathing, restlessness and dry mouth.

Other medicines and KLARIZON

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

The following medication may interact with clarithromycin and therefore you should notify your doctor or healthcare professional if you are taking medicines that contains any of the following before taking KLARIZON:

- Terfenadine or astemizole (used to treat hay fever or allergies) cisapride or domperidone (used to treat stomach disorders) or pimizole (used to treat certain mental disorders) as combining these medicines can sometimes cause serious disturbances in heart rhythm.
- Ergot alkaloids, e.g., ergotamine or dihydroergotamine used to treat migraines.
- Midazolam to treat disorders or insomnia (difficulty sleeping) is contraindicated.
- Atorvastatin, rosuvastatin, lovastatin or simvastatin 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.
- Carbamazepine, valproate, phenobarbital or phenytoin used to treat for epilepsy (fits).
- Rifabutin, rifampicin, rifapentine, fluconazole or itraconazole used to treat bacterial infections.
- Etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir or saquinavir used to treat HIV.
- Warfarin, rivaroxaban or apixaban also known as blood thinners used to treat blood clots.
- Quetiapine, cariprazine, or aripiprazole used to treat certain mental/mood disorders.
- Sildenafil, tadalafil or vardenafil used to treat erectile dysfunction.
- Tacrolimus used to treat eczema.
- Sirolimus used to prevent rejection of kidney transplant.
- Vinblastine used to treat certain types of cancer.
- Theophylline used to treat asthma.
- Nateglinide or repaglinide used to treat Type 2 diabetes.
- Omeprazole used to treat heart burn or stomach ulcers.
- Tolterodine used to treat overactive bladder.
- Colchicine used to treatment of gout.
- Digoxin, quinidine, disopyramide, calcium channel blockers (verapamil, amlodipine, diltiazem) used to treat irregular heartbeat.
- Itraconazole used to treat fungal infections.
- Contraceptives used to prevent pregnancy.

KLARIZON with food and drink

KLARIZON may be taken with or without meals.

Pregnancy, breastfeeding and fertility

Safety and effectiveness in pregnancy and breastfeeding have not been established.

KLARIZON is excreted in the 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 KLARIZON.

Driving and using machines

It is not always possible to predict to what extent KLARIZON may interfere with the daily activities of a patient. patients should ensure that they do not engage in the above activities until they are aware of the measure to which KLARIZON affects them. KLARIZON may make you dizzy, drowsy, confused or disorientated.

Important information about some of the ingredients of KLARIZON

KLARIZON contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take KLARIZON

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

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

KLARIZON may be taken with food or milk or on an empty stomach.

- The usual dose in adults is 250 mg twice a day, which could be increased to 500 mg twice a day for more severe infections.
- If you suffer from severe renal impairment, your doctor will reduce the dosage of KLARIZON by half e.g., 250 mg once daily or 250 mg twice daily for severe infections.
- For peptic ulcer caused by the bacteria *Helicobacter pylori* (in combination with amoxicillin and a medicine that specifically reduce stomach acid): 500 mg twice daily for 7 to 10 days.

- Prevention of infections in AIDS patients with very low CD4 cells, KLARIZON 500 mg twice daily.

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

If you take more KLARIZON than you should

Ingestion of large amounts of KLARIZON can be expected to produce gastrointestinal symptoms such as nausea, vomiting, diarrhoea, abdominal pain or cramps, tenderness, severe watery diarrhoea which may also be bloody.

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

If you forget to take KLARIZON

If you miss a dose do not worry, take it as soon as you remember. Do not take two doses together. If it is almost time for your next dose, wait until then.

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

If you stop taking KLARIZON

KLARIZON is an antibiotic and the course should be completed. Stopping your treatment early might lead to ineffectiveness of the treatment and resistance to bacteria making treatment in the future more difficult.

4. Possible side effects

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

If any of the following happens, stop taking KLARIZON 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.
- 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).
- A rare 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).

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

- irregular or fast heartbeat;
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage);
- fits (convulsions);
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;
- abdominal cramps or pain, tenderness, severe, watery diarrhoea which may also be bloody, fever.

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:

- difficulty sleeping
- headache, taste disturbances
- stomach discomfort or pain, diarrhoea, nausea and vomiting
- disturbed digestion and presence of excessive gas
- irregular liver function test
- rash
- excessive sweating

Less frequent side effects:

- irregular blood cells that may cause fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal
- oral or vaginal 'thrush' (a fungal infection)
- inflammation of the stomach and intestines
- lack or loss of appetite
- anxiety, nervousness
- drowsiness, dizziness or shaking
- ringing in the ears, vertigo or hearing loss
- nosebleed
- inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- bloating, constipation, wind, burping
- dry mouth
- anal pain
- inflammation of the tongue
- painful swelling and sores inside the mouth
- situation where the bile (fluid make by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis)
- increased liver enzymes
- inflammation of the skin characterised by the presence of the bullae which are filled with fluid, itchy and painful rash, hives
- muscle spasms or muscle pain
- raised abnormal kidney and liver function blood test and raised blood tests
- feeling weak, tired and having no energy, chills

Frequency unknown:

- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- a bacterial infection of the skin's outer layers
- depression
- seeing and hearing things that are not there
- abnormal dreams or nightmares
- mood of excitement, over activity and uninhibited behaviour
- tingling feeling in hands and feet also known as "pins and needles"
- loss of taste or smell or inability to smell properly
- deafness
- visual impairment or blurred vision
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- loss of blood (haemorrhage)
- low blood sugar levels
- tooth and tongue discolouration
- inflammation of the pancreas
- 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)
- abnormal urine colour
- blood is taking longer to clot, bleeding or clotting disorder.

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 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 KLARIZON.

5. How to store KLARIZON

Store at or below 25 °C and protect from light.

Keep the blisters in the carton until required for use.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not use after the expiry date stated on the blister or carton.

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

6. Contents of the pack and other information

What KLARIZON contains

The active substance is clarithromycin 250 mg or 500 mg respectively per tablet.

The other ingredients are:

Uncoated tablet:

Colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone K25, stearic acid, talc.

Film-coating:

Hydroxypropylmethyl cellulose, hydroxypropyl cellulose, propylene glycol, sorbic acid, sorbitan mono-oleate, titanium dioxide, quinoline yellow lake, vanilla dry flavour.

What KLARIZON looks like and contents of the pack

KLARIZON 250: Yellow, film coated, oval-shaped, biconvex tablets, scored on one side (14,5 mm).

KLARIZON 500: Yellow, film coated, oval-shaped, biconvex tablets, scored on one side (19,0 mm).

KLARIZON 250: PVC/PVDC blister packs containing 10 or 14 tablets, packed into an outer carton together with a patient information leaflet.

KLARIZON 500: PVC/PVDC blister packs containing 10 or 14 tablets, packed into an outer carton together with a patient information leaflet.

Holder of Certificate of Registration

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KLARIZON 500: A38/20.1.1/0725

KLARIZON

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

54

KLARIZON 250 (klaritromisien 250 mg) Tablette
KLARIZON 500 (klaritromisien 500 mg) Tablette
Klaritromisien
Suikervry

Lees hierdie hele pamflet noukeurig deur voordat jy begin om KLARIZON tablette te neem.

- Hou hierdie pamflet. Jy mag dit dalk weer moet deurlees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- KLARIZON is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

- Wat KLARIZON is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy KLARIZON neem
- Hoe om KLARIZON te neem
- Moontlike newe-effekte
- Hoe om KLARIZON te bewaar
- Inhoud van die pak en ander inligting

1. Wat KLARIZON is en waarvoor dit gebruik word

KLARIZON behoort aan ’n groep medisyne wat makroliede antibiotika genoem word. Antibiotika stop die groei van bakterieë (goggas) wat infeksies veroorsaak. KLARIZON bevat die aktiewe bestanddeel klaritromisien. KLARIZON word gebruik om bakteriële infeksies in baie verskillende dele van die liggaam te behandel.

Jou dokter sal KLARIZON voorskryf om die volgende infeksies te behandel soos:

- borsinfeksies (soos longontsteking en bronchitis)
- infeksies van die middel oor
- mangels
- vel en infeksies van die keel en sinusse
- KLARIZON in kombinasie met ’n ander antibiotika, amoksisillien en ’n spesifieke medisyne wat aangedui word om maagsuur te verminder, kan ook gebruik word vir die behandeling van ’n duodenale ulkus wanneer hierdie ulkus veroorsaak word deur ’n bakterie, *Helicobacter pylori*.

Jou dokter sal jou vertel waarvoor jy behandel word.

2. Wat jy moet weet voordat jy KLARIZON neem

Moenie KLARIZON neem nie:

- Indien jy hipersensitief (allergies) is vir klaritromisien, enige makroliede antibiotika of vir enige van die bestanddele van KLARIZON (gelys in afdeling 6).
- Indien jy medisyne genaamd terfenadien of astemisool gebruik (meestal geneem vir hooikoors of allergies), domperidoon of sisapried (vir maag-probleme) of pimosed (vir geestesgesondheidsprobleme), aangesien die kombinasie van hierdie medisyne soms ernstige verstourings in hartritme kan veroorsaak.
- Indien jy sekere antipsigotiese medisyne gebruik, soos quetiapien, kariprasien en aripiprasol (vir geestelike probleme), kan dit die vlakke van hierdie antipsigotiese medisyne in jou bloed laat styg. Dit kan lei tot ernstige newe-effekte (sien afdeling ‘Ander medisyne en KLARIZON’).
- ’n Geskiedenis het van QT-verlenging (’n abnormaliteit op die elektrokardiogram (EKG)) of ’n onreëlmatige hartklop (ventrikulêre hartdisritmie).
- Indien jy medisyne genaamd ergotamien- of dihidroergotamientablette gebruik of ergotamieninhaleerders vir migraine gebruik.
- Indien jy orale midasolaam neem (’n kalmeermiddel).
- Indien jy medisyne gebruik wat tikagrelor of ranolasin genoem word (vir hartaanval, borspyn of angina).
- Indien jy lovastatin of simvastatin (HMG-CoA reductase-inhibeerders, algemeen bekend as statiene, gebruik om cholesterolvlakke (’n tipe vet) in die bloed te verlaag).
- Indien jy kolgisien neem (gewoonlik geneem vir jig).
- Indien jy hipokalemie het (’n toestand wat gekenmerk word deur lae vlakke van kalium in die bloed).
- Indien jy ernstige lewersiekte met niersiekte het.
- Indien jy aan porferie ly.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met KLARIZON:

- Indien jy nier- en ernstige lewersiekte het. Jy kan ’n groter kans op newe-effekte hê.
- Indien jy rhabdomyolysis ervaar, wat ’n toestand is waarin skeletspierweefsel sterf, wat stowwe in die bloed vrystel wat nierversaking veroorsaak.
- Indien jy ernstige of langdurige diarree (pseudomembraankolitis) ontwikkel, wat bloed of slym daarin kan hê tydens of na die neem van KLARIZON, kontak jou dokter onmiddellik.
- Indien jy hartprobleme het of gehad het (byvoorbeeld hartsiektes, hartversaking, ’n buitengewoon stadige hartklop) of abnormaal lae magnesiumvlakke in die bloed (hipomagnesemie).
- Indien jy longontsteking het (ernstige longinfeksie met koors, kouekoors, kort van asem, hoes, slym of die ophoes van bloed).
- In die geval van ernstige akute hipersensitiwiteitsreaksies, soos anafлакse, Stevens Johnson se sindroom en toksiese epidermale nekrolise, moet KLARIZON-terapie onmiddellik gestaak word en toepaslike behandeling moet dringend begin word.
- Indien jy aan bloedklonte ly of tans bloedverduunningsmedisyne gebruik.
- Indien jy ’n swak immuunstelsel het (immunokompromitteer) jy kan naarheid, braking, onreëlmatige smaak, maagpyn, loopmaag, uitslag, wonderigheid (gas), hoofpyn, gehoorverstering, onreëlmatige lewertoetsresultate en onreëlmatige lae witbloedsel- en bloedplaatjietellings of probleme met asemhaling, rusteloosheid en droë mond ervaar.

Ander medisyne en KLARIZON

Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem.

(Dit sluit alle komplementêre of tradisionele medisyne in.)

Die volgende medisyne mag ’n interaksie met klaritromisien veroorsaak en daarom moet jy jou dokter of gesondheidsorgverskaffer inlig indien jy medisyne neem wat enige van die volgende bevat, voordat jy KLARIZON neem:

- Terfenadien of astemisool (wat gebruik word om hooikoors of allergiesê te behandel) sisapried of domperidoon (wat gebruik word om maagafwykings te behandel) of pimosed (wat gebruik word om sekere geestesversterings te behandel), aangesien die kombinasie van hierdie medisyne soms ernstige versterings in hartritme kan veroorsaak.
- Ergotalkaloïede, byvoorbeeld ergotamien of dihidroergotamien wat gebruik word om migraine te behandel.
- Midasolaam om versterings of slapeloosheid te behandel (probleme met slaap) is teenaangedui.
- Atorvastatien, rosuvastatien, lovastatien of simvastatien algemeen bekend as statiene, en word gebruik om cholesterolvlakke (’n soort vet) in die bloed te verlaag). Statiene kan rhabdomiolise veroorsaak (’n toestand wat spierweefsel afbreek wat nierskade tot gevolg kan hê) en tekens van miopatie (spierpyn of spierswakheid) moet gemonitor word.
- Karbamasepien, valproaat, fenobarbital of fenitoen wat gebruik word om epilepsie (aanvalle/ stuiptrekkings) te behandel.
- Rifabutien, rifampisien, rifapentien, flukonasool of itrakonasool gebruik om bakteriële infeksies te behandel.
- Etravirien, efavirenz, nevirapien, ritonavir, sidovudien, atazanavir of sakuinavir gebruik om MIV te behandel.
- Warfarien, rivaroksaban of apiksaban ook genoem bloedverduunners wat gebruik word om bloedklonte te behandel.
- Quetiapien, kariprasien, of aripiprasool wat gebruik word om sekere geestes/gemoedsversterings te behandel.
- Sildenafil, tadalafil of vardenafil gebruik om erektilie disfunksie te behandel.
- Takrolimus gebruik om ekseem te behandel.
- Sirolimus gebruik om verwerping van ’n nieroorplanting te voorkom.
- Vinblastien gebruik om sekere soorte kanker te behandel.
- Teofilien gebruik om asma te behandel.
- Nateglinïed of repaglinïde gebruik om Tipe 2 diabetes te behandel.
- Omeprasool gebruik om soolbrand of maagsere te behandel.
- Tolterodien gebruik om ’n ooraktiewe blaas te behandel.
- Kolgisien wat gebruik word vir die behandeling van jig.
- Digoksien, kinidien, disopiramied, kalsiumkanaalblokkers (verapamil, amlodipiën, diltiasem) gebruik om ’n onreëlmatige hartklop te behandel.
- Itrakonasool wat gebruik word om swaminfeksies te behandel.
- Voorbehoedmiddels wat gebruik word om swangerskap te voorkom.

KLARIZON met kos en drank

KLARIZON kan met of sonder etes geneem word.

Swangerskap, borsvoeding en vrugbaarheid

Veiligheid en doeltreffendheid gedurende swangerskap en borsvoeding is nog nie vasgestel nie.

KLARIZON word uitgeskei in die borsmelk.

Indien jy swanger is of borsvoed, dink dat jy swanger is of van plan is om ’n baba te hê, raadpleeg jou dokter, apteker of ander gesondheidsorg-verskaffer vir advies voordat jy KLARIZON neem.

Bestuur en die gebruik van masjiene

Dit is nie altyd moontlik om te voorspel tot watter mate KLARIZON kan inmeng met die daaglikse aktiwiteite van ’n pasiënt nie. Pasiënte moet versker dat hulle nie by die bogenoemde aktiwiteite betrokke raak totdat hulle bewus is van die mate waartot KLARIZON hulle affekteer nie. KLARIZON mag jou duiiselig, lomerig, verward of gedisoriënteer maak.

Belangrike inligting oor sommige van die bestanddele van KLARIZON

KLARIZON bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese ’natriumvry.

3. Hoe om KLARIZON te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd KLARIZON presies soos jou dokter jou vertel het. Maak seker by jou dokter of apteker indien jy nie seker is nie. KLARIZON mag saam met kos of melk geneem word of op ’n leë maag.

- Die gewone dosis in volwassenes is 250 mg twee keer per dag, wat verhoog kan word tot 500 mg twee keer per dag vir meer ernstige infeksies.

- Indien jy aan ernstige nierversaking ly, sal jou dokter die dosis KLARIZON met die helfte verminder, byvoorbeeld 250 mg een keer per dag of 250 mg twee keer per dag vir ernstige infeksies.
- Vir peptiese ulkus wat veroorsaak word deur die bakterieë *Helicobacter pylori* (in kombinasie met amoksisillien en ’n medisyne wat spesifiek maagsuur verminder): 500 mg twee keer per dag vir 7 tot 10 dae.

- Voorkoming van infeksies by vigs pasiënte met baie lae CD4-selle, KLARIZON 500 mg twee keer per dag.
- Indien jy die indruk het dat die effek van KLARIZON te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer KLARIZON neem as wat jy moet

Met die inname van groot hoeveelhede KLARIZON daar kan ver wag word dat dit gastro-intestinale simptome soos naarheid, braking, diarree, buikpyn of krampe, teerheid, ernstige waterige diarree sal veroorsaak wat ook bloedig kan wees.

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om KLARIZON te neem

Indien jy ’n dosis mis, moenie bekommerd wees nie, neem dit sodra jy onthou. Moenie twee dosisse saam neem nie. Indien dit amper tyd is vir jou volgende dosis, wag tot dan.

Moenie ’n dubbel dosis neem om op te maak vir vergete individuele dosisse nie.

Indien jy ophou om KLARIZON te neem

KLARIZON is ’n antibiotika en die kursus moet voltooi word. Vroegtydige staking van jou behandeling mag lei tot ondoeltreffendheid van die behandeling en weerstand teen bakterieë wat behandeling in die toekoms moeiliker maak.

4. Moontlike newe-effekte

KLARIZON kan newe-effekte hê. Nie alle newe-effekte wat vir KLARIZON aangemeld is word in hierdie pamflet bevat nie. Sou jou algemene gesondheid verswak of indien jy enige ongewenste eefekte ervaar terwyl jy KLARIZON neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om KLARIZON te neem en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat moeilike sluk of moeilike asemhaling mag veroorsaak.
- Erge velreaksies soos pylnlke blase van die vel, mond, lippe, oë en geslagsdele (simptome van ’n seldsame allergiese reaksie genaamd Stevens Johnson se sindroom/ toksiese epidermale nekrolise).
- ’n Rooi, skubberige uitslag met knoppe onder die vel en blasies (simptome van eksantematose pustulosis).
- ’n Seldsame allergiese velreaksies wat ernstige siektes veroorsaak met ulserasie van die mond, lippe en vel wat ernstige siektes veroorsaak met uitslag, koors en inflammasie van interne organe (DRESS).

Hierdie is almal baie ernstige newe-effekte. Indien jy hulle het mag jy dalk ’n ernstige reaksie op KLARIZON gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:

- Onreëlmatige of winnige hartklop;
- Spierpyn- of swakheid genaamd rbdomiolise (’n toestand wat die afbraak van spierweefsel veroorsaak wat kan lei tot nierskade);
- aanvalle (stuiptrekkings);
- vergelg van die vel en oë, donker uriene en moegheid wat simptome van lewerprobleme kan wees;
- buikkrampe of pyn, teerheid, erge, waterige diarree wat ook bloedig kan wees, koors.

Hierdie is almal ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde newe-effekte:

- moeilike slaap
- hoofpyn, smaakversterings
- maagongemak of pyn, diarree, naarheid en braking
- versterude vertering en teenwoordigheid van oormatige gas
- onreëlmatige lewerfunksietoets
- uitslag
- oormatige sweet

Minder gereelde newe-effekte:

- onreëlmatige bloedselle wat koors, erge kouekoors, seer keel of mondseer, bloeding en makliker kneusing as gewoonlik kan veroorsaak
- orale of vaginale ‘sproeï’ (’n swaminfeksie)
- inflammasie van die maag in ingewande
- gebrek aan of verlies aan eetlus
- angstigheid, senuweeagtigheid
- lomerigheid, duiiseligheid of bewing
- lui in die ore, vertigo of gehoorverlies
- neusbloeding
- inflammasie van die voering van die slukderm en die voering van die maag
- opgeblasenheid, hardlywigheid, wind, bult
- droë mond
- anale pyn
- inflammasie van die tong
- pynlike swelling en sere binne in die mond
- situasie waar die gal (vloeistof wat deur die lewer gemaak word en in die galblaas gestoor word) nie van die galblaas na die duodenum kan vloei nie (cholestase)
- verhoogde lewerensieme
- inflammasie van die vel gekenmer deur die teenwoordigheid van ‘bullae’ wat geul is met vloeistof, jeukerige en pynlke uitslag en korwe
- spierspasmas of spierpyn
- verhoogde abnormale nier- en lewerfunksie bloedtoets en verhoogde bloedtoets
- swak, moeg en sonder energie voel, kouekoors

Frekwensie onbekend:

- vermindering in die vlak van sekere bloedselle (wat infeksies meer waar-skyklik kan maak of die risiko van kneusing of bloeding kan verhoog)
- ’n bakteriële infeksie van die buitenste lae van die vel
- depressie
- dinge sien en hoor wat nie daar is nie
- abnormale drome of nagmerries
- bui van opwinding, ooraktiwiteit en onbelemmerde gedrag
- tintelende gevoel in hande en voete ook bekend as “naalde en spelde”
- verlies aan smaak of reuk of onvermoë om behoorlik te ruik
- doofheid
- sigversteruing of versterude visie
- tipe hartritmestoornis (Torsade de pointes, ventrikulêre tagikardie)
- verlies van bloed (bloeding)
- lae bloedsuikervlakke
- tand en tongverkleuring
- inflammasie van die pankreas
- aknee
- verandering in die vlakke van produkte wat deur die nier geproduseer word, inflammasie van die nier of ’n onvermoë van die nier om behoorlik te funksioneer (jy kan moegheid, swelling in die gesig, buik, dye of enkels of probleme met urinering opmerk)
- abnormale urienkleur
- bloed wat langer vat om te stol, bloeding of stollingsversteruing.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker daarvan in.

Aanmelding van newe-effekte

Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA aanmeld deur die vorm “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van KLARIZON te verskaf.

5. Hoe om KLARIZON te bewaar

Bewaar teen of benede 25 °C en beskerm teen lig. Hou die stulpstrok in die karton totdat dit benodig word vir gebruik. Bewaar alle medisyne buite bereik van kinders. Gee alle ongebruikte medisyne terug aan jou apteker. Moet nie gebruik word na die vervaldatum wat op die stulpstroom of karton aangedui word nie. Moenie ongebruikte medisyne in dreine of rioolstelsels (byvoorbeeld toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat KLARIZON bevat

Die aktiewe stof is klaritromisien 250 mg of 500 mg onderskeidelik per tablet.

Die ander bestanddele is:

Onbedekte tablet:

Kolloïdale anhidriese silika, kruiskarmellose natrium, magnesiumstearaat, mikrokristallyne sellulose, povidoon K25, steariensuur, talk.

Filmbedekking:

hidroksiopropiel sellulose, hidroksiopropiel sellulose, propieleenglikol, sorbiensuur, sorbitan mono-oleaat, titaandioksied, kinoliengeel meer, vanielje droë geur.

Hoe KLARIZON lyk en die inhoud van die pak

KLARIZON 250: Geel, filmbedekte, ovaalvormige, bikovekse tablette met ’n breeklyn aan die een kant (14,5 mm).

KLARIZON 500: Geel, filmbedekte, ovaalvormige, bikonvekse tablette met ’n breeklyn aan die een kant (19,0 mm).

KLARIZON 250: PVC/PVDC stulpakkie wat 10 of 14 tablette bevat, verpak in ’n buitenste karton met ’n pasiëntinligtingspamflet.
KLARIZON 500: PVC/PVDC stulpakkie wat 10 of 14 tablette bevat, verpak in ’n buitenste karton met ’n pasiëntinligtingspamflet.

Houer van die Sertifikaat van Registrasie

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Hierdie pamflet is laas hersien

21 November 2023

Registrasienuommer

KLARIZON 250: A38/20.1.1/0724

KLARIZON 500: A38/20.1.1/0725