

Clarithromycin HEC 500 mg

Prolonged-Release Tablet

clarithromycin (500mg)

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What *Clarithromycin HEC* is used for

Clarithromycin is indicated for treatment of infections due to susceptible organisms. Such infections include:

- 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)

How *Clarithromycin HEC* works

Clarithromycin HEC contains the active substance, Clarithromycin.

Clarithromycin is an antibiotic which belongs to a group of medicines called macrolides. Antibiotics stop the growth of bacteria (bugs) which cause infections.

Clarithromycin HEC is a prolonged-release tablet, which mean that the active substance clarithromycin is released slowly from the tablet so that you only have to take them once a day.

Before you use *Clarithromycin HEC***-When you must not use it**

- if you are allergic to clarithromycin or other macrolide antibiotics such as erythromycin or azithromycin or any of the other ingredients of this medicine.
- if you are children under 12 years of age
- if you are taking the following medicines:
 - terfenadine and astemizole (to treat hay fever or allergy)

- cisapride (to treat stomach disorders)
- pimozone (to treat some mental illnesses)
- ergotamine or dihydroergotamine tablets or use ergotamine inhalers (for migraine or certain circulatory disorders)
- lovastatin or simvastatin e.g. HMG-CoA-Reductase-inhibitors (used to treat high cholesterol)

- if you suffer from certain cardiac arrhythmias (QT prolongation)
- if you have low levels of potassium in the blood (Hypokalemia)
- if you have severe renal dysfunction
- if you have severe hepatic impairment.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety of *Clarithromycin HEC* in pregnancy and breast-feeding is not known.

-Before you start use it

Talk to your doctor or pharmacist before taking *Clarithromycin HEC* if you:

- are pregnant or breast feeding
- have any liver or kidney problems
- have coronary heart disease, severe cardiac insufficiency, abnormally low level of magnesium in the blood (hypomagnesaemia), slow heart beat (bradycardia)
- have, or are prone to, fungal infections (e.g. thrush)
- are taking other macrolide antibiotics, and the antibiotics lincomycin and clindamycin.
- suffer from myasthenia gravis (a disease that causes muscle weakness)
- concurrent use of clarithromycin with
 - oral hypoglycemic agents and/or insulin
 - oral anticoagulants such as warfarin (to prevent blood

clotting)

- lovastatin, simvastatin, atorvastatin or rosuvastatin (to treat high cholesterol)

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should NOT take *Clarithromycin HEC* if you are taking any one of the following medicines.

- terfenadine or astemizole (for hay fever or allergy)
- cisapride (for stomach disorders)
- pimozone (for mental illness)
- ergotamine type medicinal products (usually used for migraine, e.g. ergotamine or dihydroergotamine)

Your doctor may need to control blood levels or effects, to adjust the dosage, or to interrupt (for some time) the treatment if clarithromycin is used at the same time with medicines containing one of the substances listed below:

- digoxin (for heart failure)
- quinidine or disopyramide (for heart beat disorders)
- midazolam (sedatives/sleeping pills), triazolam (sleeping pills) or alprazolam (for anxiety)
- ritonavir, atazanavir, saquinavir, efavirenz, nevirapine and zidovudine (HIV treatments)
- rifabutin, rifampicin, rifapentine (antibiotics)
- warfarin (blood thinners)
- simvastatin, lovastatin, atorvastatin (cholesterol-lowering medicines)
- colchicines (a treatment for gout)
- itraconazole or fluconazole (used in fungal infections)

Clarithromycin may increase the effect of the following medicines:

- valproate, phenytoin or carbamazepine (for epilepsy)
- cilostazol (a treatment for leg cramps)
- methylprednisolone (used to treat inflammation)
- sildenafil, tadalafil, vardenafil (treatment for erection problems)

- vinblastine (a cancer treatment)
- tolterodine (used for urinary frequency)
- ciclosporin, tacrolimus, sirolimus (to help prevent rejections after a transplant)
- theophylline (for asthma)

It may still be all right for you to take the tablets and your doctor will be able to decide what is suitable for you.

How to use *Clarithromycin HEC*

-How much to use

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

The usual recommended dosage of *Clarithromycin HEC* in adults 12 years old of age or older is 500 mg once daily with food.

In more severe infections, the dosage may be increased to 1000 mg once daily (2 x 500 mg).

The usual duration of therapy is 5 - 14 days for all indications except for sinusitis and community-acquired pneumonia which need 6 to 14 days of treatment.

Clarithromycin HEC should not be used in patients with significant renal impairment. *Clarithromycin* 250 mg and 500 mg immediate release tablets may be utilized in this patient population.

Do not crush or chew clarithromycin modified release tablets.

Pediatric

The use of *Clarithromycin HEC* has not been studied in children less than 12 years of age.

When to use it

Clarithromycin HEC are for oral use. They should be taken with food and must be swallowed whole and not chewed. You should take each dose at the same time each day throughout your course of treatment.

How long to use it

Continue taking *Clarithromycin HEC* for as long as your doctor recommends.

If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Clarithromycin HEC*.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Clarithromycin HEC* to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you suffer from any of the following at any time during

your treatment stop taking *Clarithromycin HEC* and contact your doctor immediately.

Clarithromycin HEC may cause severe allergy and serious skin reactions.

Stop using ***Clarithromycin HEC*** and seek medical assistance immediately if you experience any of the following symptoms:

- Skin reddening, blisters, rash, fever, sore throat or eye irritation
- Swelling of the lips, face and neck leading to severe difficulty in swallowing or breathing, skin flushing and/or dizziness or fainting (severe allergic reaction)
- Severe or prolonged diarrhea which may contain blood or mucous
- Blistering of the skin, mouth, eyes or genitals (Stevens-Johnson syndrome)
- Muscles become weak and tire easily in patients who already suffer from this condition (worsen the symptoms of myasthenia gravis)

The following side effects have been reported:

Common

- insomnia
- headache
- changes in sense of taste
- stomach problems such as feeling sick, vomiting, dyspepsia, stomach pain, diarrhoea
- a change in the way the liver works
- skin rash
- increased sweating

Uncommon

- swelling, redness or itchiness of the skin. Sometimes brown scales may appear
- oral or vaginal 'thrush' (a fungal infection)
- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- loss of appetite, heartburn, bloating, constipation
- drowsiness, tiredness, dizziness, tremor or shaking
- ringing in the ears
- vertigo
- inflammation of the stomach, mouth and tongue

- chest pain or changes in heart rhythm such as palpitations
- a change in the levels of products made by the liver, inflammation of the liver or an inability of the liver to function properly (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin)
- a change in the levels of products produced by the kidney (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)
- a change in the levels of certain cells or products found in the blood.

Not known

- inflammation of the pancreas
- confusion, lose hearings, change in sense of reality or panicking, abnormal dreams or nightmares
- convulsion (fits)
- leaking of blood from blood vessels (haemorrhage)
- discoloration of the tongue or teeth
- muscle pain or loss of muscle tissue.
- If you suffer from myasthenia gravis (a condition in which the muscles become weak and tired easily), clarithromycin may worsen these symptoms
- hallucinations, depression, abnormal dreams or nightmares
- liver failure
- low blood sugar levels
- a change in levels of certain cells or products found in the blood.
- acne

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Clarithromycin HEC**-Storage**

Keep this medicine out of the sight and reach of children.

Store at temperature below 30°C

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description**-What it looks like**

White or almost white, capsular shaped film-coated tablets, debossed with “S57” on one side and blank on the other side.

-Ingredients

-Active ingredient
Clarithromycin 500 mg

- Inactive ingredients
lactose monohydrate,
hypromellose,
glycerol dibehenate
magnesium stearate
macrogol 6000
titanium dioxide(E171)
macrogol 400

- MAL number(s):
MAL****

Manufacturer

Sunshine Lake Pharma Co., Ltd.
Northern Industry Road, Northern
Industry Park of Song Shan Lake No.1
523808 Dongguan, Guangdong Province,
China

Product Registration Holder

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