CLERON TABLET

Clarithromycin (500mg)

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What Cleron tablets is used for

Cleron tablets is used to treat infections such as:

- Respiratory tract infections (pharyngitis, bronchitis, pneumonia)
- Acute otitis media (middle ears infection)
- Skin and skin structure infections (impetigo, folliculitis, cellulitis, abscess)
- Infections by mycobacterium (a type of germ)

How Cleron tablets works

Cleron belongs to a group of medicines called macrolide antibiotics. Antibiotics kill or stop the growth of bacteria (germs) which cause infections.

Before you use Cleron tablets

- When you must not use it
 - 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.
 - If you are taking medicines called

- ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine while taking Cleron tablets. Consult your doctor for advice on alternative medicines.
- If you are taking medicines called terfenadine or astemizole (taken for hay fever or allergies) or cisapride (for stomach disorders) or pimozide (for mental problems) while taking Cleron tablets, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant, or if you are breast-feeding, consult your doctor before taking Cleron tablets as the safety of Cleron tablets in pregnancy and breast-feeding is not known. Cleron tablets should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

- <u>Before you start use it</u> Take special care with Cleron tablets
 - if you have any liver or kidney problems
 - if you use clarithromycin long term or repeatedly.
- Taking other medicines
 Please tell your doctor or pharmacist if you are taking, or have recently

taken, any other medicines, including those obtained without a prescription. This is especially important if you are taking medicines for:

- heart problems (e.g digoxin, disopyramide).
- thinning your blood (e.g. warfarin).
- migraines (e.g. ergotamine or dihydroergotamine)
- epilepsy (carbamazepine or phenytoin)
- high cholesterol (e.g. lovastatin)

or if you are taking any medicines called;

- theophylline (used for asthma)
- terfenadine or astemizole (for hay fever or allergy)
- triazolam or midazolam (sedatives)
- cisapride (for stomach disorders)
- cyclosporin (immune suppressant)
- pimozide (for mental problems)

- How much to use

• zidovudine (to treat viral infection)

How to use Cleron tablets

- Always take Cleron tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
 Usual dose of Cleron for adults is 250 mg twice daily for 6 to 14 days,
 Your doctor may increase
- When to use it
 The recommended dosage is every 12 hours, e.g. one 250 mg tablet in the

the dose to 500 mg twice

daily in severe infections.

morning and one in the early evening. Cleron tablets should be swallowed with at least half a glass of water.

- How long to use it
 The usual duration of
 treatment for people with
 kidney problems is 5-10
 days, depending on the
 pathogen involved and the
 severity of the condition.
 Treatment for pharyngitis
 caused by streptococcus
 (germs) should be at least
 10 days.
- If you forget to use it
 If you forget to take Cleron tablets, take as soon as you remember. Do not take more than your doctor has told you to.
- If you use too much (overdose)

 If you accidentally take more Cleron tablets in one day than your doctor has told you to, or if a child accidentally swallows some tablets, contact your doctor or nearest hospital emergency department immediately. An overdose of Cleron tablets is likely to cause vomiting and stomach pains.

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 Cleron tablets.
 Tell your doctor
 immediately if you
 become pregnant while
 taking this medication.
- Things you must not do
 Do not stop taking Cleron
 tablets, even if 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.
Do not take any new medicines without consulting your doctor or pharmacist.
Do not give Cleron tablets 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 give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Cleron tablets can cause side effects although not everybody gets them.

- a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis (severe skin reactions such as blistering of the skin, mouth, lips and genitals)
- stomach problems such as nausea, vomiting, stomach pain, or diarrhoea
- headache
- inflammation of the mouth or tongue
- changes in sense of taste
- dizziness
- difficulty sleeping or nightmares
- anxiety, confusion, hallucinations (seeing things)
- liver problems

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Cleron tablets

- Storage
 Store below 25°C.
 Keep out of reach and sight of children.
 Do not use these tablets after their use-by (exp) date that is printed on the box and indented on the blister strip.
 Keep these tablets in a dry, safe place, protected from light.
- Disposal
 Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
 Cleron 500 mg tablets are yellow, oblong tablets, scored on one side.
- Ingredients
 - Active ingredient: Clarithromycin
 - Inactive ingredients:
 Povidone, sodium
 starch glycolate,
 microcrystalline
 cellulose, starch, stearic
 acid, magnesium
 stearate, talc, colloidal
 silicon dioxide,
 quinoline yellow lake
- <u>MAL number</u> MAL07031059AZ

Manufacturer

Delorbis Pharmaceuticals Ltd 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, 2081 Lefkosia Cyprus, European Union.

Product Registration Holder Apex Pharmacy Marketing Sdn Bhd No. 2, Jalan SS13/5, 47500 Subang Jaya, Selangor Darul Ehsan, Malaysia.

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