

Azithromycin-HEC[®] 250MG Film-Coated Tablet

Azithromycin-HEC[®] 500MG Film-Coated Tablet

Azithromycin dihydrate equivalent to azithromycin (250mg, 500mg)

What is in this leaflet

1. What *Azithromycin-HEC* is used for
2. How *Azithromycin-HEC* works
3. Before you use *Azithromycin-HEC*
4. How to use *Azithromycin-HEC*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Azithromycin-HEC*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Azithromycin-HEC* is used for
Azithromycin-HEC is used to treat a number of infections including:

- Infection of the lungs, sinus, and throat.
- Skin and soft tissue infection
- Infection of the ears
- Treatment of genital infection (eg, *Chlamydia trachomatis*, chancroid, *Neisseria gonorrhoeae*)

How *Azithromycin-HEC* works

Azithromycin is a macrolide antibiotic belonging to the azalide group. The mechanism of action is based upon the suppression of bacterial protein synthesis.

Before you use *Azithromycin-HEC*

When you must not use it

- if you are allergic to azithromycin, erythromycin, any macrolide or ketolide antibiotic, or any of the other ingredients of this medicine.
- if your children weigh less than 45kg

Pregnancy and lactation

Do not take *Azithromycin-HEC* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Azithromycin-HEC* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

- Talk to your doctor or pharmacist before taking *Azithromycin-HEC* tablets
- If you have any heart disease
- If you have kidney problems

- If you have liver problems
- If you have myasthenia gravis (weakness and rapid tiredness of any of the muscles)
- If you have or had any medical problems or any allergies/skin reactions.
- If you are taking medicines derived from ergot alkaloids
- If you have signs of other infections
- If you are currently having diarrhea

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- It is especially important to tell your doctor or pharmacist if you are taking:
- Medicines known as ergot derivatives
 - Antacids (for gastric). *Azithromycin-HEC* should be taken at least one hour before or two hours after you take your antacids.
 - Digoxin (for heart disease)
 - Zidovudine (for HIV)
 - Astemizole (to treat allergy symptoms), alfentanil (to relieve pain)
 - Atorvastatin (for high cholesterol)
 - Cisapride (for gastric)
 - Warfarin (blood thinner)
 - Ciclosporin (for organ transplant)
 - Rifabutin (antibiotic for tuberculosis)
 - Terfenadine (to treat allergy symptoms)
 - Fluconazole (antifungal)

How to use *Azithromycin-HEC*

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Azithromycin-HEC can be taken with or without food.

The usual dose is one tablet (250mg or 500mg) taken once a day.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking *Azithromycin-HEC* for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do 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.

Taking too many tablets may cause severe nausea, vomiting and diarrhoea and reversible loss of hearing.

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 *Azithromycin-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 *Azithromycin-HEC* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Serious hypersensitivity reactions with swelling of face, mouth and throat (sometimes fatal) have been rarely reported. If such symptoms occur stop taking *Azithromycin-HEC* and contact your doctor immediately.

Antibiotics can cause diarrhoea, which may be a sign of a serious bowel inflammation. If you have diarrhoea that is watery or bloody, call your doctor. Do not use any medicine to stop the diarrhoea unless your doctor has told you to.

Side effects

Like all medicines, *Azithromycin-HEC* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common effects include diarrhea, abdominal pain, nausea, and flatulence (wind).

Common side effect include dizziness, headache, tingling or prickling sensation, change in taste, change in visual, loss of hearing, vomiting, loss of appetite, rash, itchiness, joint pain, tiredness, and decrease or increase in certain blood cell count.

If you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to the Infantile Hypertrophic Pyloric Stenosis (IHPS).

Azithromycin-HEC may cause severe allergy and serious skin reactions. Stop using *Azithromycin-HEC* and seek medical assistance immediately if you experience any of the following symptoms:

- Skin reddening, blisters, rash, fever, sore throat or eye irritation

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 <http://npra.moh.gov.my> (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *Azithromycin-HEC*

- Storage

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

Store below 30°C

- 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

Azithromycin-HEC 250 mg film-coated tablets

White or almost white, capsular shaped film-coated tablets, inscribed "S19" on one side and blank on the other side.

Azithromycin-HEC 500 mg film-coated tablets

White or almost white, capsular shaped film-coated tablets, inscribed "S5" on one side and scored on the other side.

- Ingredients

- Active ingredient

Azithromycin dihydrate equivalent to azithromycin

- Inactive ingredients

microcrystalline cellulose
croscarmellose sodium
hypromellose
magnesium stearate
colloidal silica, anhydrous
sodium lauryl sulphate
pregelatinised starch
Opadry Y-1-7000 white
(hypromellose, macrogol 400
titanium dioxide)

- MAL numbers:

MAL****

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Manufacturer

Sunshine Lake Pharma Co., Ltd.
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Song Shan Lake, DongGuan,
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P.R. China

Product Registration Holder

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17.10.2018

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NPRA