

AZITH (POWDER FOR ORAL SUSPENSION 200 MG/5 ML)

Azithromycin 200 mg/5 mL

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What AZITH is used for

AZITH is used to treat infections caused by certain bacteria and other micro-organisms which include:

- Chest, throat, or nasal infections (such as bronchitis, pneumonia, tonsillitis, pharyngitis, and acute otitis media, and sinusitis)
- Skin and soft tissue infections
- Sexually transmitted diseases caused by organisms called Chlamydia or Gonorrhea

How AZITH works

AZITH is an antibiotic, which belong to the group of medicine called macrolide. It works by killing or stopping the growth of certain bacteria.

Before you use AZITH

When you must not use it

Do not use AZITH if you are allergic to azithromycin, erythromycin, other macrolide or ketolide antibiotic, or any ingredients listed at the end of this leaflet

Before you start to use it

Talk to your doctor before taking AZITH if you:

- have liver problems
- have heart problems
- have severe kidney problems
- have myasthenia gravis (a certain type of muscle weakness)
- are pregnant or plan to get pregnant
- are breast-feeding or plan to start breast-feeding

Taking other medicines

Tell your doctor if you are taking any medicine, including traditional products bought without a prescription, or if you are taking any of the following:

- antacid (to neutralize acid in stomach)
- digoxin (to treat heart failure)
- zidovudine and nelfinavir (to treat HIV infection)
- ergot derivatives (to treat migraine)
- coumarin-type oral anticoagulant (to prevent blood clots)
- cyclosporin (to prevent organ transplant rejection)
- fluconazole (to treat fungal infection)

How to use AZITH

How much to use

AZITH dose is based on body weight and must be determined by your doctor. In general, the total dose in children is 30 mg/kg.

For 3-day treatment:

10 mg/kg is given as single dose for 3 days.

For 5-day treatment:

10 mg/kg is given on day 1, then 5 mg/kg on day 2-5.

The maximum recommended total dose for any treatment is 1500 mg for children.

When to use it

Use AZITH as directed by your doctor.

How long to use it

Keep taking AZITH until the course is finished, even if you feel better.

If you stop taking AZITH too soon, the infection may come back. Also the bacteria may become resistant to the medicine and will then be more difficult to treat.

If you forget to use it

Take the missed dose as soon as you remember. If it is almost time

for the next dose, skip the missed dose and take your scheduled dose at the correct time. Do not double up the dose to make up for a missed dose.

If you use too much (overdose)

Seek for immediate medical attention if you have taken too much and are worried of your condition. Do it even if there are no signs of discomfort or poisoning, as you may need urgent medical attention.

While you are using it

Things you must do

- Take your medicine exactly as directed by your doctor
- Tell your doctors, dentists and pharmacists if you are taking AZITH
- Tell your doctor immediately if you become pregnant while taking AZITH

Things you must not do

- Do not stop taking the AZITH unless advised by your doctor
- Do not use any new medicines without consulting your doctor
- Do not give AZITH to anyone else, even the symptoms or conditions are similar

Things to be careful of

AZITH may cause side effects such as dizziness.

Do not drive or operate machinery until the symptoms disappear.

Side effects

All medicines can cause side effects although not everybody gets them.

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

- skin reddening, blisters, rash, fever, sore throat or eye irritation
- sudden difficulty in breathing, speaking and swallowing

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- swelling of the lips, tongue, face and neck
- extreme dizziness or collapse

Additionally, some conditions you may need to look out for include:

- diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever
- yeast infection especially of the mouth, infections of the vagina
- reduced in white blood cells or red blood cells, unusual bruising or bleeding
- loss of appetite
- dizziness, headache, tingling of the hands or feet, taste disturbance
- decreased skin sensitivity, drowsiness, sleeplessness
- muscle weakness (myasthenia gravis)
- vision impairment
- impair hearing, ringing in the ear, spinning sensation
- irregular or rapid heartbeat
- diarrhea, stomach upset, nausea, wind, vomiting, indigestion
- inflammation of the bowel, constipation
- if you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to Infantile Hypertrophic Pyloric Stenosis (IHPS)
- inflammation of the liver, changes in liver enzymes
- hypersensitivity, itchy rash, skin rash caused by sensitivity to sunlight
- joint pains
- increased or reduced urine output, or traces of blood in urine caused by kidney problem
- tiredness, chest pain, skin swelling, weakness

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of AZITH

Storage

Keep out of reach of children. Store in a dry place below 30°C in the original package. Once reconstituted, store the suspension below 30°C and used within 10 days.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist for proper way of disposal. This will help protect the environment.

Discard any unused suspension after 10 days.

Product Description

What it looks like

- AZITH is an off-white powder with a characteristic odour of vanilla and orange
- After reconstitution, a white to slightly yellow coloured, homogenous suspension exists
- AZITH is supplied in amber glass packed in a unit box

Ingredients

Active ingredient:
Azithromycin 200 mg/5 mL

Inactive ingredients:
Xanthan gum, hydroxypropyl cellulose, tribasic sodium phosphate, acetyl vanilla powder, orange powder, sucrose

MAL number

MAL

Manufacturer

Siam Bheasach Co., Ltd.,
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Product Registration Holder

SPG Pharma (Malaysia) Sdn. Bhd.,
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