

ZITHROMAX[®] POWDER FOR ORAL SUSPENSION

Azithromycin dihydrate (200 mg per 5 mL)

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What Zithromax is used for

Zithromax is used to treat infections caused by bacteria, which include:

- respiratory tract infections;
- ear infections;
- skin and soft tissue infections;
- sexually transmitted diseases (genital infections).

How Zithromax works

Zithromax contains azithromycin dihydrate which is a type of antibiotic called macrolides. It works by stopping the growth of the bacteria causing the infection.

Before you use Zithromax

- When your child must not use it

Do not give Zithromax if your child is allergic to:

- azithromycin, erythromycin, other similar antibiotic or any of the other ingredients of this medicine (listed in Product Description).

- Before your child start to use it

Tell your child doctor before giving Zithromax, if your child has or has had any of the following:

- history of diarrhea when using antibiotics
- signs of fungal infection
- a history of serious allergic reaction causing swelling of the face and throat, possibly with breathing problems, rash, fever, swollen glands
- liver, heart or kidney problems
- muscle weakness
- if your child has diabetes
- if your child is intolerant to certain type of sugar

Please tell your child doctor if your child has any of the following problems:

- are taking medicines that can affect heart rhythm such as medicines used for irregular heartbeat, psychosis, depression and fluoroquinolone antibiotic;
- have low levels of potassium or magnesium in your child blood.

- Taking other medicines

Tell your child doctor before giving Zithromax, if your child is taking any of the following medicines:

- antacids (for hyperacidity);
- digoxin (used to treat heart failure);
- colchicine (used to treat gout);
- zidovudine (used to treat HIV infections);
- warfarin (anticoagulants);
- cyclosporin (used to prevent rejection of a transplanted organ or bone marrow);
- ergot derivatives, such as ergotamine (used to treat migraine);
- atorvastatin (to lower cholesterol).

How to use Zithromax

- How much to use

Follow all directions given to you by your child 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 child doctor or pharmacist for help.

Tap the bottle to loosen the powder, add 9 mL of water.

Shake immediately prior to use.

If your child weighs less than 15 kg in bodyweight, you should measure the dose as clearly as possible. For children weighing 15 kg or more, use appropriate measuring device to deliver the medicine.

Your child doctor will advise the dosing schedule as per your child's infection type and your child's weight.

- When to use it

Take once a day or as directed by your child doctor or pharmacist.

Zithromax can be given with or without food.

- How long to use it

Give Zithromax for the duration that your child doctor recommends.

- If you forget to use it

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

- If you use too much (overdose)

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

While you are using it

- Things you must do

Give Zithromax only with a doctor's prescription.

Give the medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating your child that your child is taking Zithromax.

Stop using Zithromax and seek medical assistance immediately if your child experiences any of the following symptoms after taking this medicine:

- skin reddening, blisters, rash, fever, sore throat or eye irritation;
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Zithromax;
- yellowing of the skin or eyes (jaundice).

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- Things you must not do

Do not stop giving the medicine unless advised by your child's doctor.

Do not give any new medicines without consulting your child's doctor.

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

- Things to be careful of

Zithromax contains sucrose, a type of sugar (3.87 g in 5 mL). If you have been told by your child doctor that your child has an intolerance to some sugars contact your child doctor before giving Zithromax. If your child is diabetic, you may need to take this into account in your child diet.

Side Effects

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

Visit your child doctor or pharmacist immediately if your child experiences any side effects after taking this medicine.

Zithromax may cause severe allergy and serious skin reactions.

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

- skin reddening, blisters, rash, fever, sore throat or eye irritation.

The following side effects have been reported:

- low levels of white blood cells or platelet count
- hearing impairment, ringing in the ears, spinning sensation
- nausea, vomiting, diarrhea, indigestion, constipation, abdominal pain/cramps, flatulence, inflammation of large intestine, tongue discoloration
- rash, swelling of the skin and mucous membranes, itching, light sensitivity, hives
- yeast infection of the mouth and throat, inflammation of the vagina

- eating disorder (anorexia)
- aggressive reaction, nervousness, agitation, and anxiety
- dizziness, seizure, headache, hyperactivity, reduced or abnormal sense of touch, drowsiness, and loss of consciousness
- palpitation and abnormal heartbeat
- low blood pressure
- liver inflammation and yellowish discoloration of the skin and eyes (jaundice)
- joint pain
- kidney inflammation or failure
- weakness, fatigue, discomfort

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).

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

Storage and Disposal of Zithromax

- Storage

Keep out of the reach and sight of children.

Store below 30°C for the powder and the reconstituted suspension.

Any reconstituted medicine should be discarded after 5 days.

- 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

Zithromax Powder for Oral Suspension is packed in polyethylene bottles of 15 mL (600 mg). The off-white dry powder which upon dilution with water, forms a

suspension with color range between orange to brown.

- Ingredients

- Active ingredient
Azithromycin dihydrate.

- Inactive ingredients
Sucrose, sodium phosphate tribasic anhydrous, hydroxypropyl cellulose, xanthan gum, artificial cherry, artificial creme de vanilla and artificial banana flavours.

- MAL number

MAL19970271ACZ

Manufacturer

Haupt Pharma Latina S.r.l
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Product Registration Holder

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