

ZITHRACIN®

Zithracin® Film Coated Tablet 250 mg: Azithromycin 250 mg

Zithracin® Film Coated Tablet 500 mg: Azithromycin 500 mg

Zithracin® Powder for Oral Suspension 200 mg/5 mL: Azithromycin 200 mg/5 mL

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What Zithracin® is used for

Zithracin® 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 Zithracin® works

Zithracin® 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 Zithracin®

- When you must not use it

Do not take Zithracin® if you are allergic to:

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

- Before you start to use it

Tell your doctor before you take Zithracin®, if you have or have had any of the following:

- history of diarrhea when using antibiotics
- signs of fungal infection-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 you have diabetes.

Zithracin® Powder for Oral Suspension:

- This medicine contains Aspartame, not suitable if you have phenylketonurics.

Please tell your doctor if you have 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 blood.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breastfeeding before using any medicine.

Zithracin® must only be used during pregnancy if the benefits is more than the risks to the fetus.

Zithracin® is secreted into breast milk. Your doctor will discuss the risks and benefits of breastfeeding while you're taking Zithracin®.

- Taking other medicines

Tell your doctor before taking or giving Zithracin®, if you/your child are/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 Zithracin®

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.

Zithracin® Film Coated Tablet

In adults and children weighing more than 45 kg: For sexually transmitted diseases, the dose is 1 g daily taken as a single oral dose.

For all other infections, the usual dose in adults is 500 mg, taken as a single dose, daily for 3 days or for 5 days with 500 mg given on Day 1, then 250 mg daily on Days 2 to 5.

Zithracin® Powder for Oral Suspension

Tap the bottle to loosen the powder, add 10 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 doctor or pharmacist. Zithracin® can be taken with or without food.

Zithracin® Film Coated Tablet

The tablet should be swallowed whole.

- How long to use it

Use Zithracin® for the duration 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 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 Zithracin® only with a doctor's prescription.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you, that you are taking Zithracin®.

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

Stop using Zithracin® and seek medical assistance immediately if you or your child experience any of the following symptoms after taking this medicine:

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

- 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 Zithracin® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how Zithracin® affects you.

Zithracin® Powder for Oral Suspension

Zithracin® Powder for Oral Suspension contains sucrose, a type of sugar (3.24 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 Zithracin®. If your child is diabetic, you may need to take this into account in your child diet.

Side effects

Like all medicines, Zithracin® 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. Zithracin® may cause severe allergy and serious skin reactions.

Stop using Zithracin® 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 and tongue discoloration;
- rash, swelling of the skin and mucous membranes, itching, light sensitivity, hives;
- weakness, fatigue, discomfort;
- 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.

Zithracin® Powder for Oral Suspension

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 Pylorus 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 npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Zithracin®

- Storage

Zithracin® Film Coated Tablet: Store at temperature below 30°C. Protect from light and moisture.

Zithracin® Powder for Oral Suspension 200 mg/5 mL: Store below 30°C for the powder and the reconstituted suspension. Use within 5 days after reconstitution. Protect from light and moisture.


Keep out of reach of children.


- Disposal

Zithracin® should be disposed when your doctor or pharmacist tells you to stop taking this product or it has passed the expiry date. It should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose medicines that are no longer required. These measures will help to protect the environment.

Product description

- What it looks like

Zithracin® Film Coated Tablet 250 mg is a white colour film coated tablet in the shape of , one side impressed with 'YSP'.

Zithracin® Film Coated Tablet 500 mg is a white colour film coated tablet in the shape of , one side impressed with 'YSP 50', another side impressed with a score.

Zithracin® Powder for Oral Suspension 200 mg/5 mL:

Before reconstitution: A white to yellowish brown granular powder with fruity flavour.

After reconstitution: A white to yellowish brown suspension with fruity flavour.

- Ingredients

Active Ingredients

Azithromycin Dihydrate

Inactive ingredients

Zithracin® Film Coated Tablet

Tablet core

Calcium Phosphate, Dibasic Dihydrate

Croscarmellose Sodium

Lactose Monohydrate

Magnesium Stearate

Pregelatinized Starch

Sodium Lauryl Sulfate

Film coating

Hydroxypropyl Methylcellulose

Triacetin

Titanium Dioxide

Zithracin® Powder for Oral Suspension 200 mg/5 mL

Aspartame

Basic Butylated Copolymer

Cellulose

Icing Sugar

Methacrylate Sodium Lauryl Sulfate

Silicon Dioxide

Sodium Phosphate

Stearic Acid Fine Powder

Tutti Fruity Flavour and Purified Water

Xanthan Gum

- MAL number:

Zithracin® Film Coated Tablet 250 mg: MAL25116036AZ

Zithracin® Film Coated Tablet 500 mg: MAL25116029AZ

Zithracin® Powder for Oral Suspension 200 mg/5 mL: MAL24126028AZ

Manufacturer and Product Registration Holder

Y.S.P. INDUSTRIES (M) SDN. BHD.

Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

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