

AXCEL ERYTHROMYCIN ES-400 SUSPENSION

Erythromycin (400mg/5ml)

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What Axcel Erythromycin ES-400 Suspension is used for

Axcel Erythromycin ES-400 Suspension is indicated in the treatment of infections caused by susceptible organisms in the diseases listed below: upper and lower respiratory tract infections, pertussis (*whooping cough*), skin and soft tissue infections, otitis media, erythrasma (skin disease), listeriosis, diphtheria, primary syphilis (sexually transmitted infection) and prophylaxis of endocarditis (infection of the heart).

How Axcel Erythromycin ES-400 Suspension works

Erythromycin is an antibiotic that belongs to the group of medicines called macrolides. These medicines work by killing or stopping the growth of bacteria, which cause infections.

Before you use Axcel Erythromycin ES-400 Suspension

-When you must not use it

Do not take Axcel Erythromycin ES-400 Suspension if:

- You have ever had an allergic reaction to medicines containing erythromycin or to other antibiotics from the macrolide family.
- Some of the symptoms of an allergic reaction may include rash, itching or hives, swelling of face, lips, tongue or other parts of the body, shortness of breath,

wheezing or difficulty in breathing.

- You are allergic to any of the ingredients listed at the end of this leaflet.
- You have liver disease or liver impairment.

-Before you start to use it

Tell your doctor if:

- you are allergic to any medicines.
- you have impaired liver function.
- you have history of arrhythmias.
- you suffer from myasthenia gravis.
- you suffer from diarrhea or pseudomembrane colitis.
- you suffer from rhabdomyolysis (muscle injury) or kidney disease.
- Please consult your doctor before start to use Axcel Erythromycin ES-400 Suspension if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Axcel Erythromycin ES-400 Suspension against the benefits they expect it will have for you.

-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 as it may interact with your Axcel Erythromycin ES-400 Suspension such as:

- Medications causing liver or hearing injury
- Cimetidine, medicine for gastric
- Carbamazepine, phenytoin, Valproate, medicines for seizure
- Cyclosporine, medicine used for after organ transplant
- Alfentanil, pain killer
- Cisapride, medicine for stomach
- Lovastatin, medicine to lower the cholesterol
- Terfenadine, for allergic reaction
- Theophylline, for asthma
- Digoxin, medicine for heart
- Ergotamine, medicine for migraine
- Midazolam, medicine for anxiety

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking this medication.

How to use Axcel Erythromycin ES-400 Suspension

-How much to use

Adults: 400 mg (5 ml), 6 hourly or 800 mg (10 ml), 12 hourly.

Dosage may be increased up to 4 g per day according to the severity of the infection.

Children: 30-50 mg/kg daily in divided dose; double in severe infections.

Children 2 to 8 years: 1 g (12.5 ml) daily in divided doses.

Infant and children up to 2 years: 500 mg (6.25 ml) daily in divided doses.

Direction for mixing:

Shake bottle well to loosen granules. Remove cap and Dose Master™ adapter. Then, add some water to mix with the granules. After that, shake and top up to the mark. Place the Dose Master™ adapter and cap. Shake bottle well to mix medicine properly.

-When to use it

Your doctor will decide when it is appropriate for you to take Axcel Erythromycin ES-400 Suspension according to the type of infection you have.

-How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.
- Do not stop taking Axcel Erythromycin ES-400 Suspension, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

-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

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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)

- In case of overdosage, erythromycin should be discontinued.
- It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you did take Erythromycin ES-400 Suspension too much.

While you are using it

-Things you must do

- Tell your doctor if you need to take any other medicines.
- Take the Axcel Erythromycin ES-400 Suspension according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet
- If you are taking Axcel Erythromycin ES-400 Suspension for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.
- Tell your doctor if you become pregnant while taking Axcel Erythromycin ES-400 Suspension.
- If you get severe diarrhoea tell your doctor or pharmacist immediately.

-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 Axcel Erythromycin ES-400 Suspension to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

- Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi.
- Be careful driving or operating machinery until you know how

Axcel Erythromycin ES-400 Suspension affects you.

Side effects

Like all medicines, Axcel Erythromycin ES-400 Suspension can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

- Gastro-intestinal disturbances such as: stomach discomfort and cramp, nausea, vomiting, and diarrhea
- Pseudomembranous colitis (inflammation of large intestine), hepatotoxicity (liver poisoning), ototoxicity (ear poisoning).
- Allergic reactions ranging from urticaria (hives) to anaphylaxis (a severe, life threatening allergic reactions to a foreign substance that affects various parts of the body).
- Ventricular arrhythmias (abnormal rapid heart rhythm) including ventricular tachycardia (rapid heartbeat).
- Agranulocytosis (severe reduction in the number of white blood cells)
- Central neurotoxicity (damage to nervous tissue) including psychotic reactions (such as hallucination) and nightmares
- Myasthenia-like syndrome (weakness of muscle)
- Pancreatitis (inflammation of pancreas)

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).

Axcel Erythromycin ES-400 Suspension may cause severe allergy and serious skin reactions.

Stop using Axcel Erythromycin ES-400 Suspension and seek medical assistance immediately if you experience any of the following symptoms:

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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.moh.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Axcel Erythromycin ES-400 Suspension

-Storage

Keep Axcel Erythromycin ES-400 Suspension out of reach of children. Keep container well closed. Store at room temperature not exceeding 30°C until reconstitution. After reconstituted, store below 25°C and use within 35 days, refrigeration is not required.

-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

Axcel Erythromycin ES-400 Suspension is a white to off white homogenous suspension with banana flavour when reconstituted.

-Ingredients

Active Ingredient:

Erythromycin Ethylsuccinate

Inactive Ingredients:

Xanthan Gum, Dimethicone, Polysorbate, Icing Sugar, Sodium Saccharin, Sodium Citrate Dihydrate, Povidone, Disodium Hydrogen Phosphate Anhydrous, Aerosil 200 and Banana Flavor.

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-MAL number

MAL09082800AZ

**Manufacturer and product
registration holder**

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