

AXCEL ERYTHROMYCIN ES TABLET

Erythromycin Ethylsuccinate (400mg)

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What Axcel Erythromycin ES Tablet is used for

Axcel Erythromycin ES Tablet is used in the treatment of infections caused by susceptible strains of designated organisms in the diseases listed below:

- Upper and lower respiratory tract infections.
- Pertussis (whooping cough).
- Skin and soft tissue infections.
- Otitis media (Infection of the ear).
- Erythrasma (Skin disease).
- Listeriosis.
- Diphtheria.
- Primary syphilis (Sexually transmitted infection) in patients who has allergy to penicillin.
- Prophylaxis of endocarditis (infection of the heart).

How Axcel Erythromycin ES Tablet works

Axcel Erythromycin ES tablet consists of active substance Erythromycin.

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 Tablet

- When you must not use it

Do not take Axcel Erythromycin ES Tablet if:

- You have ever had an allergic reaction to medicines containing erythromycin or to other antibiotics from the macrolide family.
Some 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.
- You have liver impairment.

- Before you start to use it

Tell your doctor if:

- You have impaired liver function.
- You have myasthenia gravis.
- If you have a history of arrhythmias.
- 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 Tablet 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 Erythromycin ES Tablet 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.

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Erythromycin ES Tablet:

- Hepatotoxic or ototoxic drugs (medicines that can caused liver or ear poisoning).
- Cimetidine and Cisapride (medicine used to treat and

prevent heartburn from acid indigestion in the stomach).

- Carbamazepine, valproate and phenytoin (medicine used to treat seizures and nerve pain).
- Cyclosporine (medicines used to prevent organ rejection after organ transplant).
- Alfentanil (medicine used as anaesthesia in surgery).
- Lovastatin (medicine used to reduce the amount of cholesterol made by the liver).
- Bromocriptine (medicine used to treat Parkinson disease and to treat certain tumors that make too much prolactin).
- Terfenadine and astimazole (medicines used to treat allergic conditions).
- Theophylline (medicine used to prevent and treat wheezing, shortness of breath and chest tightness).
- Digoxin (medicine used to treat congestive heart failure).
- Ergotamine (medicine used to treat a migraine type headache).
- Midazolam (medicine used as a sedative before surgery or certain procedures).
- 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 Tablet

- How much to use

For oral administration only.

For adults: 400mg (1 tablet), 6 hourly or 800 mg (2 tablets), 12 hourly. Dosage may be increased up to 4 g per day according to the severity of the infection.

- When to use it

Used as directed by your doctor or pharmacist.

- How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.

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- Follow any recommendations and advices from your doctor or pharmacist.
- Do not stop taking Axcel Erythromycin ES Tablet, 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 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, Axcel Erythromycin ES Tablet should be discontinued.
- 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.

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 Tablet 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 Tablet 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 Tablet.
- 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.

- Things to be careful of

- Avoid prolonged or repeated use with high dosage as it may result in an overgrowth of non-susceptible bacteria or fungi.
- Be careful while driving or operating machinery until you know how Axcel Erythromycin ES Tablet affects you.

Side effects

Like all medicines, Axcel Erythromycin ES Tablet 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:

- Abdominal discomfort (pain that you feel in stomach region) and cramp.
- Nausea.
- Vomiting.
- Diarrhoea.
- Pseudomembranous colitis (inflammation of large intestine).
- Hepatotoxicity (liver poisoning).
- Ototoxicity (ear poisoning).
- Urticaria (hives/ skin rashes).
- Anaphylaxis (a severe allergic reaction that may cause death).
- Ventricular arrhythmias (abnormal rapid heart rhythm).
- 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 Tablet may cause severe allergy and serious skin reactions.

Stop using Axcel Erythromycin ES Tablet 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 calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of Axcel Erythromycin ES Tablet

- Storage

Keep Axcel Erythromycin ES Tablet out of reach of children.

Store below 30°C and protect from light.

- Disposal

Do not use Axcel Erythromycin ES Tablet after the expiry date which is stated on the carton.

Product description

- What it looks like

Axcel Erythromycin ES Tablet is an orange color, oval shaped, biconvex film coated tablets.

- Ingredients:

Active Ingredient (s):

Erythromycin EthylSuccinate

- Inactive Ingredients:

Microcrystalline Cellulose, Icing Sugar, Pregelatinized Corn Starch, Sorbic Acid, Sodium Citrate, Purified

AXCEL ERYTHROMYCIN ES TABLET

Erythromycin Ethylsuccinate (400mg)

Water, Polacrillin Potassium,
Magnesium Stearate and Opadry
Orange.

- *MAL Number*

MAL20020154AZ

**Manufacturer and Product
Registration Holder**

KOTRA PHARMA (M) SDN BHD
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