

AXCEL CLARITHROMYCIN-125 SUSPENSION

Clarithromycin (125mg/5ml)

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What Axcel Clarithromycin-125 Suspension is used for

Axcel Clarithromycin-125 Suspension is used to treat infections caused by bacteria in the:

- Chest.
- Throat.
- Sinuses.
- Ears [particular inflammation of middle ear (otitis media)].
- Skin and the layers of flesh just under the skin.

How Axcel Clarithromycin-125 Suspension works

Clarithromycin is an antibiotic from macrolide class. Clarithromycin works by destroying some types of bacteria that cause certain infections.

Before you use Axcel Clarithromycin-125 Suspension

-When you must not use it

Do not take Axcel Clarithromycin-125 Suspension if:

- You are hypersensitive to macrolides.
- You are receiving terfenadine therapy have pre-existing cardiac abnormalities such as abnormal heartbeat, heart disease (reduce blood supply to the heart), heart failure, etc. or electrolyte disturbances.
- You are having impaired kidney or liver function.
- It is not prescribed by a qualified doctor or pharmacist for you.

- You are pregnant, trying to get pregnant or think you may be pregnant.
- You are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Tell your doctor if:

- You are allergic to any medicines, food and dyes.
- You are taking any other medicines (including those not prescribed by your doctor).

-Taking other medicines

You should tell your doctor or pharmacist if you are taking the following medicine as it may interact with your Axcel Clarithromycin-125 Suspension:

- Carbamazepine and theophylline.
- Drug metabolized by the cytochrome P-450 system (eg., digoxin, warfarin).
- Terfenadine.

It may still be all right for you to take Axcel Clarithromycin-125 Suspension and your doctor will be able to decide what is suitable for you.

How to use Axcel Clarithromycin-125 Suspension

-How much to use

Axcel Clarithromycin-125 Suspension:

Children:

The recommended dosage is based on 7.5mg/kg twice daily regimen. Doses up to 500mg twice daily have been used in the treatment of serious infections.

*Children less than 8kg should be dosed on a per kg basis (approximately 7.5mg/kg twice daily).

Dosage in individuals with kidney impairment:

- Your doctor might prescribe a lower dose for you if you have kidney disease.
- Dosage would be continued beyond 14 days in such condition.

Dosage in individuals with mycobacterial infections:

- Usual duration of treatment for 5-10 days depending on the pathogen involved and the severity of the condition.
- Treatment of *Streptococcal pharyngitis* should be at least 10 days.

Direction for mixing:

Slowly add water up to arrow on the side of the label. Put cap on shake vigorously. This makes 60ml suspension.

-When to use it

Your doctor will decide when it is appropriate for you to use Axcel Clarithromycin according to the type of condition you have.

-How long to use it

Continue taking Axcel Clarithromycin-125 Suspension for as long as doctor recommends.

-If you forget to use it

Consult your doctor or pharmacist on what you should do 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)

- Allergic reactions accompanying overdosage should be treated by the prompt elimination of unabsorbed drug supportive measures.

It is advisable for you to contact and inform your doctor if you did take Axcel Clarithromycin-125 Suspension too much.

While you are using it

-Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you

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are taking Axcel Clarithromycin-125 Suspension.

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

-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 Clarithromycin-125 Suspension to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

- Avoid prolonged use with high dosage.
- Caution should be taken while taking Axcel Clarithromycin-125 Suspension during pregnancy and nursing baby.

Side effects

Like all medicines, Axcel Clarithromycin-125 Suspension can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following common side effects have been reported:

- Gastro-intestinal disturbances.
- Taste disturbances.
- Inflammation of the mucous membrane of the mouth.
- Inflammation of tongue.
- Abnormal liver test results.
- Jaundice (yellowing of skin and eye).
- Liver inflammation.
- Headache and rashes from mild skin eruptions to rarely, Steven-Johnson syndrome.
- Transient Central Nervous System (CNS) effects such as anxiety, dizziness, insomnia, hallucinations and confusion.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of Axcel Clarithromycin-125 Suspension

-Storage

Keep Axcel Clarithromycin-125 Suspension out of reach of children. Keep container well closed and protect from light. Store below 30°C until mix. After mixing, refrigerate between 2°C to 8°C.

-Disposal

Do not use Axcel Clarithromycin-125 Suspension after the expiry date which is stated on the carton. 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 Clarythromycin-125 Suspension is a white colour granule which gives a white coloured suspension with fruity flavour when reconstituted.

-Ingredients

- Active Ingredient:
Clarithromycin
- Inactive Ingredients:
Icing Sugar, Refined Sugar PXX, Sodium Saccharin, Kollodon K30, Citric Acid, Xanthan Gum, Aerosil, Potassium Sorbate, Titanium Dioxide and Exotic Blend Powder.

-MAL Number

MAL20040904AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd
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Date of revision

23/04/2018

Serial number

NPRA(R4/1)230418/00115