AXCEL CEFUROXIME-125 FOR ORAL SUSPENSION

Cefuroxime (125mg/5ml)

What is in this leaflet.

- 1. What Axcel Cefuroxime-125 For Oral Suspension is used for.
- 2. How Axcel Cefuroxime-125 For Oral Suspension works.
- 3. Before you use Axcel Cefuroxime-125 For Oral Suspension.
- 4. How to take Axcel Cefuroxime-125 For Oral Suspension.
- 5. While you are using it.
- 6. Side effects.
- Storage and disposal of Axcel Cefuroxime-125 For Oral Suspension.
- 8. Product description.
- 9. Manufacturer and product registration holder.
- 10. Date of revision.

What Axcel Cefuroxime-125 For Oral suspension is used for

Axcel Cefuroxime-125 For Oral Suspension is used to treat:

- Upper respiratory tract infections (for example: ear, nose and throat infections, such as inflammation of middle ear, sinusitis, inflammation of tonsils and sore throat).
- Lower respiratory tract infections (for example: lung infection, inflammation of the bronchial tubes and sudden worsening of obstructive lung disease).
- Genito-urinary tract infections (for example: kidney infection, inflammation of the bladder and inflammation of the urethra).
- Gonorrhoea, acute uncomplicated gonococcal urethritis and inflammation of uterine cervix.
- Skin and soft tissue infections (for example: the simultaneous occurrence of boils on the skin, skin infection with formation of pus and impetigo a contagious bacterial skin infection forming pustules and yellow, crusty sores).

How Axcel Cefuroxime-125 For Oral Suspension works

Cefuroxime is an effective antibacterial agent which has bactericidal activity to kill the bacteria that can cause infections. Cefuroxime interferes with the process of building and repairing the bacterial cell wall by affecting the bonds that hold the bacterial cell wall together. This causing holes to appear in the cell wall

and killing the bacteria, as the cell wall is essential for survival of bacteria.

Before you use Axcel Cefuroxime-125 For Oral Suspension

- When you must not use it

Do not take Axcel Cefuroxime-125 For Oral Suspension if:

 You are allergic or hypersensitive to cephalosporin antibiotics.

- Before you start to use it

Tell your doctor if:

- You have experience of an allergic reaction to penicillins or other betalactams.
- You are pregnant or nursing baby.

- Taking other medicines

You should tell your doctor if you are taking any medicines as it may interact with your Axcel Cefuroxime-125 For Oral Suspension

How to use Axcel Cefuroxime-125 For Oral Suspension

- How much to use

 Follow recommendations and advices from your doctor or pharmacist.

- When to use it

Your doctor will decide when it is appropriate for you to take Axcel Cefuroxime-125 For Oral Suspension according to the type of infection you have.

- How long to use it

 Follow recommendations and advices from your doctor or pharmacist.

- If you forget to use it

 Do not double up the dosage as Axcel Cefuroxime-125 For Oral Suspension may give you unacceptable side effects.

- If you use too much (overdose)

You must inform your doctor immediately if you have taken too much Axcel Cefuroxime-125 For Oral Suspension.

While you are using it

- Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Axcel Cefuroxime-125 For Oral Suspension according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

- Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

- Things to be careful of

- Avoid prolonged use with high dosage.
- As this medicine may cause dizziness, hence no driving or operating machinery when feeling drowsy.

Side effects

Like all medicines, Axcel Cefuroxime-125 For Oral 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:

- Erythema multiforme (abnormal redness and inflammation of the skin)
- Steven-Johnson syndrome (a severe and sometimes fatal form of erythema multiforme)
- Toxic epidermal necrolysis (a rare, life-threatening skin condition caused by a reaction to drugs, where the top layer of skin to detach from the lower layers of the skin, all over the body)
- Hypersensitivity reactions including skin rashes (inflammation), urticaria (one kind of skin rash with pale red, raised, itchy bumps), pruritus (itching), drug fever, serum sickness (delayed allergic response after exposure to antibiotics or antiserum) and anaphylaxis (severe, potentially life-threatening allergic reactions).

AXCEL CEFUROXIME-125 FOR ORAL SUSPENSION

Cefuroxime (125mg/5ml)

- Gastrointestinal disturbances including diarrhoea, nausea and vomiting
- Pseudomembranous colitis
 (Inflammation of the colon)
- Headache
- An abnormal high number of eosinophils (one type of white blood cell) in the blood
- Transient increases of kidney enzyme levels
- Thrombocytopenia (relative decrease of platelet in blood)
- Leucopenia (decrease in number of white blood cells)
- Haemolytic anaemia (decrease in number of red blood cells due to abnormal breakdown of red blood cells)

Axcel Cefuroxime-125 For Oral Suspension may cause severe allergy and serious skin reactions.

Stop using Axcel Cefuroxime-125 For Oral Suspension and seek medical assistance immediately if you experience any of the following symptoms:

• Skin reddening, blisters, rash, fever, sore throat or eye irritation

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 Cefuroxime-125 For Oral Suspension

- Storage

Keep Axcel Cefuroxime-125 For Oral Suspension out of reach of children. Store below 30°C. Keep container well closed and protect from light. After reconstitution, refrigerate between 2°C to 8°C and use within 10 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

Axcel Cefuroxime-125 For Oral Suspension is off white to pale yellow granules which gives off white to pale yellow suspension with fruity flavor after reconstituted.

- Ingredients

Active Ingredient (s):
Cefuroxime Axetil

Inactive Ingredients:

Refined Sugar, Aerosil 200, Crospovidone, Lemon Flavour and Aromatic Flavour.

- MAL Number

MAL14095051AZ

Manufacturer and product registration holder

Kotra Pharma (M) SDN BHD No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

Date of revision

30/09/2019

Serial number

NPRA(R2/1)190516/148