AXCEL CEFACLOR CAPSULE

Cefaclor Monohydrate (250mg, 500mg)

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What Axcel Cefaclor Capsule is used for

Axcel Cefaclor Capsule is used to treat the infections caused by susceptible organisms:

- Infection of inner ear.
- Lower respiratory tract infections.
- Upper respiratory tract infections.
- Urinary tract infections.
- Inflammation of the urinary tract caused by gonorrheal infection).
- Sinusitis (infection of the sinuses).
- Skin and soft tissue infections.

How Axcel Cefaclor Capsule works

Cefaclor is a type of antibiotic called cephalosporin. Cefaclor is used to treat infections caused by bacteria.

Before you use Axcel Cefaclor Capsule

-When you must not use it

Do not take Axcel Cefaclor Capsule if:

- You are allergic or hypersensitive to Cefaclor or other cephalosporins.
- 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.

-<u>Before you start to use it</u>

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).
- You are allergy to penicillin.
- You have kidney impairment.
- You have history of stomach and intestinal disease.

-Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Cefaclor Capsule:

- Oral anticoagulants (medicines used to prevent blood clots such as warfarin).
- Beta-lactam antibiotics and Probenecid (a medicine used to treat gout or to prolong the action of certain antibiotics).

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

It may still be all right for you to take Axcel Cefaclor Capsule and your doctor will be able to decide what is suitable for you.

How to use Axcel Cefaclor Capsule -How much to use

For oral administration only.

- Adult: 250mg-500mg every 8 hours and can be a total of 4g in a day.
- Bronchitis (inflammation of the air passages) and pneumonia (infection of lung tissue): 250mg 3 times daily.
- Sinusitis (infection of the sinuses): 250mg 3 times daily for 10 days.
- For more severe infections, such as pneumonia or those caused by less susceptible organisms, doses may be double.
- Acute gonococcal urethritis (inflammation of the urinary tract caused by gonorrheal infection): a single dose of 3g combined with 1g of probenecid.

-When to use it

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

-How long to use it

Continue taking Axcel Cefaclor Capsule for as long as your 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)

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

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Cefaclor Capsule.
- Tell your doctor immediately if you become pregnant while talking 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 Cefaclor Capsule to anyone else, even if they have the same symptoms or condition as you.

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-Things to be careful of

- Avoid prolonged use.
- While you are pregnant or nursing baby.

Side effects

Like all medicines, Axcel Cefaclor Capsule 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:

- Hypersensitivity reactions including skin rashes, hives, fever, serum-sickness-like reaction and anaphylaxis (serious allergic reaction).
- Transient increases in liver enzymes.
- Hepatitis (inflammation of liver) and cholestatic jaundice (yellowish pigmentation of skin).
- Seizure and other signs of Central Nervous System (CNS) toxicity.
- Gastrointestinal disturbance such as nausea, vomiting, diarrhea.
- Blood disorder.
- Reversible interstitial nephritis (spaces between the kidney tubules become swollen).
- Hyperactivity.
- Nervousness.
- Sleep disturbances.
- Confusion.
- Hypertonia (damage to the central nervous system).
- Dizziness.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Ask your doctor or pharmacist if you do not understand anything in this list.

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 Cefaclor Capsule

-Storage

Keep Axcel Cefaclor Capsule out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

-Disposal

Do not use Axcel Cefaclor Capsule 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 Cefaclor-250 Capsule is purple/white hard gelatin capsule in size 2.

Axcel Cefaclor-500 Capsule is purple/white hard gelatin capsule in size 0.

-Ingredients

- Active Ingredient: Cefaclor Monohydrate.
- Inactive Ingredients: Sodium Starch Glycollate and Magnesium Sterate.

-MAL Numbers

Axcel Cefaclor-250 Capsule MAL20014010AZ

Axcel Cefaclor-500 Capsule MAL20014011AZ

Manufacturer and product registration holder

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

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