

PHARMANIAGA CEPHALEXIN SUSPENSION

Cephalexin (125mg per 5ml, 250mg per 5ml)

What is in this leaflet

1. What Pharmaniaga Cephalexin Suspension is used for
2. How Pharmaniaga Cephalexin Suspension works
3. Before you use Pharmaniaga Cephalexin Suspension
4. How to use Pharmaniaga Cephalexin Suspension
5. While you are using it
6. Side effects
7. Storage and Disposal of Pharmaniaga Cephalexin Suspension
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Pharmaniaga Cephalexin Suspension is used for

Pharmaniaga Cephalexin Suspension is one of a group of antibiotics called cephalosporins. It is used to treat infection in blood, bone and joint infections, including burn wound infections and urinary tract infections caused by bacteria.

Pharmaniaga Cephalexin Suspension also as possible alternative for penicillin treatment to treat lung and heart infection caused by staphylococcal bacteria.

How Pharmaniaga Cephalexin Suspension works

Cephalexin is a first-generation cephalosporin antibiotic. It possesses bactericidal effect similar to the penicillins, which acts by inhibiting synthesis of the bacterial cell wall.

Before you use Pharmaniaga Cephalexin Suspension

-When you must not use it

Do not take Pharmaniaga Cephalexin Suspension if you are allergic to cephalexin or any other cephalosporin antibiotics or any of its ingredients listed at the end of this leaflet.

Pregnancy and lactation

- Do not use it if you are pregnant or suspected for pregnant.
- Do not take Pharmaniaga Cephalexin Suspension if you are breast feeding.

Consult with your doctor or pharmacist before taking any medicine if you are breast feeding.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

-Before you start use it

Tell your doctor or pharmacist:

- if you had experiencing allergy reaction or have known histories of allergy with cephalosporins, penicillins or any other antibiotics previously
- if you have kidney problems
- if you are planning to get pregnant or planning to breastfeed.

-Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicine might have interaction with Pharmaniaga Cephalexin Suspension when it taken concurrently. This includes:

- Contraceptive medication: There has been reported cephalexin will reduce efficacy of oestrogen containing in oral contraceptives.
- Nephrotoxic medication (medication to treat kidney toxicity); such as aminoglycosides or potent diuretic, for example frusemide, ethacrynic acid and piretamide: Taken concurrently with Pharmaniaga Cephalexin Suspension might have adversely effect on kidney function.

How to use Pharmaniaga Cephalexin Suspension

Always take the medicine exactly as your doctor or pharmacist has told you. Read the direction labels carefully. If you have any concerns about how to take this medicine, talk to your doctor or pharmacist.

Direction for reconstitution: Shake the bottle to loosen the powder. Add freshly boiled and cooled water and shake well.

Make up to volume. Use reconstituted suspension within 7 days. Shake the container well each time before use.

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults: 1 to 2 g daily given in divided doses at 6, 8 or 12 hourly intervals

Infants and children:

25 to 100 mg per kg body-weight daily in divided doses to a maximum 4g daily.

Common dosage regimen for children as below:

Under 1 year – 62.5mg to 125 mg twice daily.

1 to 5 years – 125mg three times daily.

5 to 12 years – 250mg three times daily.

-When to use it

Take this medication at regular intervals preferably before meals and complete the prescribed course as directed by your doctor or pharmacist.

-How long to use it

Continue taking Pharmaniaga Cephalexin Suspension 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.

Signs and symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhea and presence of blood in the urine.

While you are using it

-Things you must do

Take the medication exactly as your doctor prescribed.

Tell your doctor if you experiencing allergy reaction during taking Pharmaniaga Cephalexin Suspension. You might consult with doctor before taking this medication if you are known or have experiencing allergy reaction previously while using any antibiotic especially penicillin.

Tell your doctor or pharmacist what other prescription and nonprescription medicines that you are taking.

Tell your doctor if you have or have had kidney or liver problems, ulcer or stomach problems.

If you are having a surgery including dental surgery, inform your doctor or dentist that you are taking Pharmaniaga Cephalexin Suspension.

If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after Pharmaniaga Cephalexin Suspension has been stopped. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicine for diarrhoea without first checking with your doctor or pharmacist.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine. Pharmaniaga Cephalexin Suspension may affect the results of some of these tests by giving false positive result.

If your infection gets worse or you do not start to feel better within a few days or a new infection develops, seek advice from your doctor or pharmacist immediately.

-Things you must not do

Do not stop taking this medication even after you feel much better with consultation with your doctor. Stop taking this medication only when your doctors tell you so. Do not take any new medicines without consulting your doctor.

Do not give Pharmaniaga Cephalexin Suspension to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If these suspensions make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Pharmaniaga Cephalexin Suspension can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experienced any side effects after taking this medicine. You may not experience any of them.

Tell your doctor or pharmacist if you notice or experiencing any of the following side effects:

- Nausea and vomiting
- Diarrhoea
- Abdominal discomfort
- Allergic reactions such as skin rashes and urticarial. Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, throat or other parts of the body, muscle pain or tenderness or joint pain or rash, itching or hives on the skin.
- Neutropenia symptoms which may increase susceptibility to infection. The symptoms include fever, sore mouth, pneumonia, cough and many more.

Secondary infection with resistant microorganism might developed during the administration, however it is very rare occurring.

For serious side effects, you may need medical attention. Most of these side effects are rare. If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Emergency department at your nearest hospital.

You may need urgent medical attention or hospitalization. Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549 or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF)/Vaccine (AEFI)).

Storage and Disposal of Pharmaniaga Cephalexin Suspension

Keep this medicine away and out of reach for children.

Do not use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month.

-Storage

Pharmaniaga Cephalexin Suspension 125mg/5ml

Keep the medicines in a cool dry place where the temperature stays below 30°C. Protect from light. Keep this medicine in tightly closed container.

Pharmaniaga Cephalexin Suspension 250mg/5ml

Keep the medicines in a cool dry place where the temperature stays below 25°C. Protect from light. Keep this medicine in tightly closed container.

-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

Pharmaniaga Cephalexin Suspension
125mg/5ml

Before reconstitution: White to off-white, granular powder, practically free from visible impurities.

After reconstitution: Orange coloured, viscous, free flowing, homogenous suspension, practically free from visible impurities.

Pharmaniaga Cephalexin Suspension
250mg/5ml

Before reconstitution: Light yellow, free flowing granules with a characteristic fruity fragrance.

After reconstitution: Light yellow, sweet, viscous suspension with a characteristic fruity flavor.

-Ingredients:

Pharmaniaga Cephalexin Suspension
125mg/5ml

-Active Ingredient:

Each 5ml of reconstituted suspension contains 125mg of Cephalexin.

-Inactive ingredients: Tutti Frutti Flavour, Castor Sugar, Sunset Yellow, Sodium Benzoate, Sodium Saccharin, Talcum, Carboxymethylcellulose, Sodium Dihydrogen Phosphate, Sodium Bicarbonate

Pharmaniaga Cephalexin Suspension
250mg/5ml

-Active Ingredient:

Each 5ml of reconstituted suspension contains 250mg of Cephalexin.

-Inactive ingredients: Talcum, Colloidal Silsion Dioxide, Carboxymethylcellulose Sodium, Quinoline Yellow, Refined Sugar, Tutti Frutti Flavour, Sodium Phosphate Monobasic, Sodium Saccharin, Sodium Bicarbonate

-MAL Number(s):

Pharmaniaga Cephalexin Suspension
125mg/5ml

MAL19940383AZ

Pharmaniaga Cephalexin Suspension
250mg/5ml

MAL19973678AZ

Manufacturer & Product Registration

Holder:

Pharmaniaga Manufacturing Berhad
(60016-D),
11A, Jalan P/1, Kawasan Perusahaan
Bangi,
43650 Bandar Baru Bangi, Selangor
Darul Ehsan, Malaysia.

Date of revision:

16/7/2018

Serial Number

NPRA(R4/1)160718/00196