

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

It is used to treat septicaemia (blood poisoning due to bacterial infection), bone and joint infections, including burn wound infections and urinary tract infections caused by bacterial infection. They are not effective in treating infection on nervous system.

Pharmaniaga Cephalexin Suspension also as possible alternative for penicillin treatment to treat pneumonia (lung infection) and bacterial endocarditis (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 Pharmaniaga Cephalexin Suspension or any other cephalosporin antibiotics or any of its ingredients listed at the end of this leaflet.

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 if you have allergies to cephalosporins, penicillins or any other antibiotics. You may have an increased chance of being allergic to Pharmaniaga Cephalexin Suspension if you are allergic to any of these medicines.

- About 10% of penicillin sensitive individual will also be allergic to cephalosporins and, therefore great care should be taken if Pharmaniaga Cephalexin Suspension is given to individuals known to be hypersensitive to penicillin. Care is also necessary in patients with known histories of allergy.
- Reduced dosage is recommended in individuals with severe renal impairment.
- Prolonged use of Pharmaniaga Cephalexin Suspension may result in the overgrowth of resistant organism to antibiotic.
- Avoid to take Pharmaniaga Cephalexin Suspension if you have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency.
- Precaution should be taken if you have diabetes.

Pregnancy and lactation

Discuss with your doctor or pharmacist first if are pregnant or breastfeeding because Pharmaniaga Cephalexin Suspension crosses the placenta and small quantities are found in the milk of nursing mothers.

-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.

This is because Pharmaniaga Cephalexin Suspension can affect the way some other medicines work. Also, some other medicines can affect the way

Pharmaniaga Cephalexin Suspension works.

- Probenecid, a medicine for gout
- Cytotoxic, drug for leukemia
- Bacteriostatic antibiotics
- Oral anticoagulants, drug to prevent blood clot
- Metformin, drug for type 2 diabetes
- Oral contraceptive, drug to prevent pregnancy

If you need any advice, talk to your doctor or pharmacist.

How to use Pharmaniaga Cephalexin Suspension

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 of 4 g daily.

Common dosage regimen is:

Children age,
5 to 12 years – 250 mg three times daily.
1 to 5 years – 125 mg three times daily.
Under 1 year – 62.5 mg to 125 mg twice daily.

-When to use it

Use 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

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 or pharmacist has told you.

- Tell your doctor or pharmacist if you have allergies to cephalosporins, penicillins or any other antibiotics.
- Tell your doctor or pharmacist what other prescription and non-prescription medicines that you are taking.
- Tell your doctor if you have or have had kidney or liver problems, ulcer or stomach problems.
- Tell your doctor if are pregnant, planning to get pregnant or breastfeeding. If you are pregnant when taking Pharmaniaga Cephalexin Suspension, contact your doctor.
- 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.

-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 Pharmaniaga Cephalexin Suspension to anyone else even if they have the same symptoms or condition as you.

-Things to be careful of

If allergic reaction occurs, stop using it and inform your doctor or pharmacist.

Side Effects

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

Side effect of Pharmaniaga Cephalexin Suspension includes nausea, vomiting, indigestion, diarrhea, abdominal pain, swelling or inflammation of the large intestine (colon) due to an overgrowth of *Clostridioides difficile* bacteria, abnormally low levels of platelets, abnormally low concentration of white and red blood cell, rises in liver enzyme (ALT and AST), liver disorder, allergic reactions such as skin rashes, skin reddening, blister, vaginal inflammation and abnormal discharge, muscle stiff or joint disorder such as pain, swelling and tenderness, kidney disorder, dizziness, tiredness, headache, anxiety, confusion, hallucinations, hyperactivity, nervousness, sleep disturbances or seizure.

Pharmaniaga Cephalexin Suspension may cause severe allergy and serious skin reactions. Stop using Pharmaniaga Cephalexin 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 visiting the website npra.moh.gov.my (Public Reporting Side Effects to medicines (ConSERF)/ Vaccine (AEFI)).

Storage and Disposal of Pharmaniaga Cephalexin Suspension

-Storage

Store the medicines below 30°C. Keep container tightly closed. Protect from light.

Keep out of reach and sight of children.

Do not take Pharmaniaga Cephalexin Suspension after the expiry date stated on the label. 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

Pharmaniaga Manufacturing Berhad
(198001006232),
No. 11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650, Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad
(198001006232),
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