

SOFILEX POWDER FOR ORAL SUSPENSION

Cephalexin (125mg/5ml)

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What Sofilex is used for

It is used to treat bacterial infection in ear, respiratory tract, urinary tract, skin and soft tissues.

How Sofilex works

Cephalexin is the antibiotic which kills bacteria in human body.

Before you use Sofilex

- When you must not use it

Do not use *Sofilex* if you are allergic to Cephalexin, cephalosporin group of antibiotics, penicillin or any other ingredients in this medicine.

- Before you start to use it

Tell your doctor or pharmacist before using *Sofilex* if you:

- are pregnant or plan to pregnant.
- are breast-feeding or plan to start breast-feeding.
- have kidney problem

• Taking other medicines

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

In particular, tell your doctor if you are taking any of the following:

- Other antibiotics
- Diuretics (water tablet) such as Furosemide
- Probenecid for a treatment of gout

How to use Sofilex

- How much to use

- *Children 6-12 years old:*
10ml (250mg) every 8 hours.
- *Children 1-5 years old:*
5ml (125mg) every 8 hours
- *Children under 1 year old:*
5ml (125mg) every 12 hours

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.

- When to use it

To be taken with or without food.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Sofilex* for as long as your doctor recommends. Ask your doctor or pharmacist before prolonged use of this medicine.

- 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.

Taking too many tablets may cause abdominal discomfort, nausea, diarrhoea, vomiting and blood in the urine.

While you are using it

- Things you must do

- Always wash your hand before handle the medicine.
- Reconstitute the powder with water up to 60ml marking on the bottle. Shake well to wet and disperse the powder. Store the medicine in the refrigerator upon reconstitution.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking *Sofilex*.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take the medicine after 7 days of reconstitution.

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give *Sofilex* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Tell your doctor or pharmacist if you:

- are allergic to Cephalexin or any other ingredients in this medicine.
- are pregnant or breast-feeding.
- have problems with liver and/or kidney.
- have bacterial, fungal or viral infection.

Side Effects

- Skin itchiness with swollen and pale red patches and bumps.
- Skin rashes.
- Diarrhoea, nausea, vomiting
- Fever
- Colon inflammation
- Blood disorders

Sofilex may cause severe allergy and serious skin reactions. Stop using *Sofilex* and seek medical assistance immediately if you experience any of the following symptoms: Skin reddening, blisters, rash, fever, sore throat or eye irritation

Like all medicines, *Sofilex* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects or allergic reactions after taking this medicine.

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.gov.my [Consumers→Reporting Side Effects to Medicinal (ConSERF) or Vaccine (AEFI)].

Storage and Disposal of Sofilex

-Storage

Store below 30°C. Protect from light. Keep out of the reach of the children. Do not use this medicine after expiry date.

-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

• Before reconstitution:

White, free flowing powder with blackcurrant odour.

• Upon reconstitution with water:

Very pale yellow colour suspension with blackcurrant flavor.

- Ingredients

- Active ingredients(s)

Cephalexin Monohydrate

- Inactive Ingredients

Sodium Benzoate, Blackcurrant Flavour, Sodium Carboxy Methyl Cellulose, Saccharin Sodium, Colloidal Silicon Dioxide, Lactose Anhydrous.

- MAL number

MAL19984839AZ

Manufacturer and Product Registration Holder

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