Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about cephalexin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Cephalexin. It contains the active ingredient cephalexin monohydrate.

It is used to treat infections in different parts of the body caused by bacteria, such as:

- respiratory tract (chest, lungs, tonsils, throat)
- sinuses
- ears (middle ear infection)
- skin
- genitourinary tract (kidney, bladder, prostate).

Cephalexin will not work against infections caused by viruses such as colds or the flu.

How it works

Cephalexin belongs to a group of antibiotics called cephalosporins that are closely related to penicillins.

Cephalexin works by killing the bacteria causing your infection or by stopping its growth.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed cephalexin for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if you have had an allergic reaction to cephalexin, other cephalosporins, or any of the ingredients listed at the end of this leaflet.

Do not take this medicine if you have had a serious allergic reaction to penicillins.

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.

Do not take this medicine if you are intolerant or allergic to lactose. These capsules contain lactose.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if:

- 1. You have allergies to:
- cephalosporins, penicillins or any other antibiotics.

You may have an increased chance of being allergic to cephalexin if you are allergic to any of these medicines.

- · any other medicines
- any other substances, such as foods, preservatives or dyes.
- 2. You are intolerant or allergic to lactose.
- 3. You have or have had any medical conditions, especially the following:
- · kidney disease
- · severe bowel conditions/disease
- liver disease.
- 4. You plan to become pregnant or breastfeed

Your doctor will discuss with you the risks and benefits involved.

Cephalexin passes into breast milk.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and cephalexin may interfere with each other. These include:

- 1. probenecid, a medicine used to treat gout or to prolong the action of certain antibiotics
- 2. metformin, a medicine used to treat diabetes.

These medicines may be affected by cephalexin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Talk to your doctor about whether you need additional contraception while taking cephalexin.

Some antibiotics decrease the effectiveness of some birth control pills, although this has not been shown with cephalexin.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking cephalexin.

Other interactions not listed above may also occur.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many capsules you will need to take. This depends on your infection, your condition and whether or not you are taking any other medicines.

Adults

The usual adult dose is one 250 mg capsule taken every six hours. Your doctor may recommend a different dose depending on your condition.

Children

Your child's doctor will tell you how much cephalexin your child should take. This will depend on your child's age, weight and the type of infection.

How to take it

Swallow the capsules with a glass of water.

When to take it

Take it at about the same times each day, spaced evenly apart.

Taking your medicine at the same times each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days, unless told otherwise by your doctor.

If you stop taking this medicine too soon, the infection may not clear completely or your symptoms may return.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much cephalexin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much cephalexin, you may have diarrhoea or feel sick.

While you are taking this medicine

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking cephalexin.

Tell your doctor immediately if you become pregnant.

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after cephalexin 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 get a sore white mouth or tongue while taking or soon after stopping Cephalexin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have fungal infection called thrush. Sometimes the use of Cephalexin allows fungi to grow and the above symptoms occur. Cephalexin does not work against fungi.

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

Things you must not do

Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful while driving or operating machinery until you know how cephalexin affects you.

Cephalexin generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, cephalexin may cause dizziness or tiredness in some people.

Children may also be affected so they should be carefully watched if riding bikes or climbing.

Possible side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking cephalexin.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

While taking it

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- oral thrush white, furry, sore tongue and mouth
- vaginal thrush sore and itchy vagina and/or discharge
- · itching in the genital or anal areas
- mild diarrhoea
- mild stomach upsets, such as indigestion, feeling sick and/or being sick (vomiting)
- · dizziness, tiredness or headache
- · aching or swollen muscles or joints.

The above list includes the more common side effects. Mostly, these are mild.

Tell your doctor as soon as possible if you notice any of the following:

- feve
- itching or any type of skin rash or blistering, peeling or flaking skin
- severe vomiting and/or diarrhoea, stomach pain
- yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice)
- bleeding or bruising more easily than normal, frequent infections such as fever, severe chills, sore throat or mouth ulcers
- feeling agitated, confused or seeing or hearing things that are not there.

These may be 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 Accident and Emergency at your nearest hospital:

- signs of an allergic reaction, such as hives, a severe skin reaction, fainting, swelling of the limbs, face, lips, mouth or throat, difficulty swallowing or breathing
- · skin rash with joint pain and fever.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with cephalexin:

- · severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects and may mean that you have a serious condition affecting your bowel. Cephalexin can cause bacteria, which is normally present in the bowel and normally harmless, to multiply and cause the above symptoms. You may need urgent medical attention.

Do not take any medicine for diarrhoea without first checking with your doctor or pharmacist.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place, protected from light and moisture, where the temperature will stay below 25° C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What APO-Cephalexin Capsules look like

APO-Cephalexin 250 mg capsules:

Dark green and white, self-locked hard gelatin capsules of size 2, imprinted with RX656 in black ink, containing white to off-white granular powder/pellets.

Blister packs of 20 capsules.

APO-Cephalexin 500 mg capsules:

Dark green and light green, self-locked hard gelatin capsules of size 0, imprinted with RX657 in black ink, containing white to off-white granular powder/pellets.

Blister packs of 20 capsules.

Ingredients

Each capsule contain cephalexin monohydrate equivalent to 250 mg or 500mg of cephalexin as the active ingredient.

It also contains the following inactive ingredients:

- magnesium stearate
- lactose
- · gelatin
- · iron oxide yellow
- brilliant blue FCF
- sunset yellow FCF
- titanium dioxide
- purified water
- TekPrint SW-9008 black ink.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Cephalexin 250 mg capsules Blister packs

AUST \bar{R} Number: 73870

APO-Cephalexin 500 mg capsules Blister packs

AUST R Number: 133852

Sponsor Apotex Pty Ltd 16 Giffnock Avenue Macquarie Park, NSW 2113

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