[CEPHALEX 250 mg and 500 mg (Cephalexin BP 250 mg and 500 mg Capsules)]*

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CEPHALEX?

CEPHALEX contains the active ingredients Cefalaxin monohydrate. CEPHALEX used to treat infections caused by bacteria in different parts of the body.

For more information, see Section 1. Why am I using CEPHALEX? in the full CMI.

2. What should I know before I use CEPHALEX?

Do not use if you have ever had an allergic reaction to CEPHALEX or any of the ingredients listed at the end of the CMI. Do not take CEPHALEX if you are pregnant, taking medicines similar to CEPHALEX or have serious allergic reaction to penicillin.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use CEPHALEX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CEPHALEX and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CEPHALEX?

- Continue taking CEPHALEX 250 mg and 500 mg for as long as your doctor tells you.
- It is important to complete the full course prescribed by your doctor, even if you begin to feel better after a few days. If you do not, the bacteria causing your infection may not clear completely or your symptoms may return.

More instructions can be found in Section 4. How do I use CEPHALEX? in the full CMI.

5. What should I know while using CEPHALEX?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using CEPHALEX Tell your doctor if you become pregnant while taking CEPHALEX.
Things you should not do	 Do not take a double dose to make up for the dose that you missed. Do not stop taking your medicine or change the dosage without first checking with your doctor.
Driving or using machines	CEPHALEX may cause dizziness or tiredness in some people.
Drinking alcohol	There are no known interactions between CEPHALEX and alcohol.
Looking after your medicine	Keep it in a cool dry place where the temperature stays below 30°C

For more information, see Section 5. What should I know while using CEPHALEX? in the full CMI.

6. Are there any side effects?

Common side effects include: dizziness, fainting, light-headedness, cough, headache, diarrhoea, feeling sick, stomach pain, tiredness, weakness. Serious side effects include: swelling of the face, lips, tongue and/or

any side effects, see	y breathing and/or sw e Section <u>6. Are there</u>	e any side effects?	in the full CMI.	riading what to do	II you navi
CEDITAL EXT					

[CEPHALEX 250 mg and 500 mg (Cephalexin BP 250 mg and 500 mg Capsules)]*

Active ingredient(s): (Cefalaxin monohydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using CEPHALEX You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CEPHALEX.

Where to find information in this leaflet:

- 1. Why am I using CEPHALEX?
- 2. What should I know before I use CEPHALEX ?
- 3. What if I am taking other CEPHALEX?
- 4. How do I use [CEPHALEX]?
- 5. What should I know while using CEPHALEX?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using CEPHALEX?

CEPHALEX 250 mg and 500 mg contains cephalexin monohydrate as the active ingredient. It is used to treat infections caused by bacteria in different parts of the body, including infections of the:

- respiratory tract (throat, tonsils, chest and lungs)
- nose (sinusitis)
- ears (otitis media)
- skin and soft tissue
- kidneys and bladder (genitourinary tract).

This medicine belongs to a group of medicines called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

2. What should I know before I use CEPHALEX?

Warnings

When you must not take it

Do not take CEPHALEX 250 mg and 500 mg if you have an allergic reaction to:

- any medicine containing cephalexin monohydrate
- other cephalosporins
- 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 penicillin.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver disease
- kidney disease
- bowel disease.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell them before you start taking CEPHALEX 250 mg and 500 mg.

3. What if I am taking other medicines?

Taking other medicines

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

Some medicines and CEPHALEX 250 mg and 500 mg may interfere with each other.

These include:

- probenecid (e.g. Pro-Cid), a medicine commonly used to treat gout
- metformin, a medicine used in the treatment of diabetes.

These medicines may be affected by CEPHALEX 250 mg and 500 mg or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking CEPHALEX 250 mg and 500 mg.

4. How do I use CEPHALEX?

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton or bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much and how often you should take CEPHALEX 250 mg and 500 mg.

This will depend on the type of infection. The dose varies from patient to patient.

How to take it

CEPHALEX 250 mg and 500 mg capsules: Swallow the capsules whole with a full glass of water.

When to take it

It does not matter if you take this medicine with or without food.

How long to take it

Continue taking CEPHALEX 250 mg and 500 mg for as long as your doctor tells you.

It is important to complete the full course prescribed by your doctor, even if you begin to feel better after a few days. If you do not, the bacteria causing your 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.

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 Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CEPHALEX 250 mg and 500 mg. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling sick in the stomach, diarrhoea, blood in the urine, unusually increased reflexes, convulsions or hallucinations.

5. What should I know while using CEPHALEX?

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you are taking CEPHALEX 250 mg and 500 mg, especially if you are about to be started on any new medicines.

Tell your doctor if you become pregnant while taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking CEPHALEX 250 mg and 500 mg.

It may interfere with the results of some tests.

If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.

CEPHALEX 250 mg and 500 mg may affect the results of some of these tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take CEPHALEX 250 mg and 500 mg to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

If you stop taking it, your condition may worsen.

Things to be careful of

Be careful driving or operating machinery until you know how CEPHALEX 250 mg and 500 mg affects you.

It may cause dizziness or drowsiness in some people. Children should be careful when riding bicycles or climbing trees.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CEPHALEX 250 mg and 500 mg.

This medicine helps most people with infection but it may have unwanted side effects in a few people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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

- sore or white mouth or tongue (oral thrush)
- sore and itchy vagina and/or discharge (another form of thrush)
- diarrhoea
- nausea
- vomiting
- dizziness
- unusual tiredness/weakness
- abdominal pain
- headache.
- severe body rash
- swelling of face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- fever
- swelling of the joints
- yellowing of the skin or eyes
- joint pain
- confusion and hallucinations
- seizure potential
- bleeding or bruising more easily than normal.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your doctor immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with CEPHALEX 250 mg and 500 mg:

- severe stomach cramps or pain
- severe, watery or bloody diarrhoea
- fever, in combination with one of the above.

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

You may have a serious condition affecting your bowel requiring urgent medical attention.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

• sudden signs of allergy such as rash, itching or hives on the skin with swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

This is a very serious side effect. You may need urgent medical attention or hospitalisation. This side effect is very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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

7. Product details

Storage

CEPHALEX 250 mg and 500 mg capsules:

Keep the capsules in the blister pack until it is time to take them.

If you take the capsules out of the blister pack, they may not keep as well.

Keep it in a cool dry place where the temperature stays below 30°C (for the 250 mg and 500 mg capsules).

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.

Do not store it 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.

Disposal

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

What it looks like

CEPHALEX 250 mg

White to off white powder filled in dark green cap and dark green body with printing "CEP" on cap and "250" on body with black ink. They are available in packs of 20 capsules.

CEPHALEX 500 mg

White to off white powder filled in light green cap and light green body with printing "CEP" on cap and "500" on body with black ink. They are available in packs of 20 capsules.

Ingredients

CEPHALEX 250 mg and 500 mg capsules:

Capsules:

CEPHALEX 250 mg and 500 mg capsules contain cephalexin (as monohydrate) equivalent to 250 mg

or 500 mg of cephalexin anhyrdrous as the active ingredient.

They also contain the inactive ingredients:

- Lactose Anhydrous
- Silicon Dioxide
- Magnesium Stearate

The capsule shell consists of titanium dioxide, allura red, brilliant blue, quinoline yellow, gelatin, sodium lauryl sulphate, and water. Traces of printing black Ink contain shellac, dehydrated alcohol, Isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, potassium hydroxide and water.

Sponsor

Pharmacor Pty Ltd. Chatswood, NSW 2067, Australia

Australian Registration Numbers for CEPHALEX 250 mg and 500 mg products are:

250 mg capsule: 204535 500 mg capsule: 204534

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