

PACKAGE LEAFLET: INFORMATION FOR THE USER**Cefaclor 250 mg Capsules**
Cefaclor 500 mg Capsules
Cefaclor

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cefaclor Capsules are and what they are used for
2. What you need to know before you take Cefaclor Capsules
3. How to take Cefaclor Capsules
4. Possible side effects
5. How to store Cefaclor Capsules
6. Contents of the pack and other information

1. What Cefaclor Capsules are and what they are used for

Cefaclor capsules contain the active ingredient cefaclor, which is an antibiotic.

Cefaclor capsules are used to treat the following infections caused by bacteria that can be killed by cefaclor:

- Bronchitis
- Infection of lung tissue (pneumonia)
- Bladder (cystitis) and kidney infections
- Throat infections including tonsillitis and pharyngitis
- Middle ear infections (otitis media)
- Skin and soft tissue (e.g. muscle) infections
- Infection of the sinuses (sinusitis)

2. What you need to know before you take Cefaclor Capsules**Do not take Cefaclor Capsules if:**

- you are allergic (hypersensitive) to cefaclor, any cephalosporin (other similar antibiotics) or any of the other ingredients of Cefaclor capsules (these are listed in Section 6 of this leaflet).
An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and Precautions**Talk to your doctor before taking Cefaclor capsules if you**

- have had an allergic reaction to penicillins or other drugs in the past
- have a history of gastrointestinal disease, especially inflammation of the colon (colitis)
- have severe kidney problems

Tell your doctor if you are having blood or urine tests. Cefaclor capsules may interfere with these tests.

Other medicines and Cefaclor capsules

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important for the following, as they may interact with your Cefaclor capsules:

- warfarin (a blood thinner)
- probenecid (a treatment for gout)

It may still be all right for you to be given Cefaclor capsules and your doctor will be able to decide what is suitable for you

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Cefaclor capsules should not affect your ability to drive or use machines.

3. How to take Cefaclor Capsules

Always take Cefaclor Capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Adults and the elderly:

The usual dose is 250 mg three times a day. Your doctor will tell you if you need to take a higher dose.

Patients undergoing regular dialysis: The usual dose is 250 mg to 1 g prior to dialysis. A dose of 250 mg to 500 mg every 6 to 8 hours is recommended between periods of dialysis.

Use in children:

Cefaclor capsules are not recommended for children.

If you take more Cefaclor Capsules than you should

Go to the nearest accident and emergency department or tell your doctor straight away.

If you forget to take Cefaclor Capsules

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. **Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face, lips or limbs, rash or itching (especially affecting your whole body).**

Serious side effects

The following side effects are serious. You should stop taking this medicine and contact your doctor immediately if you experience them:

- serious peeling or blistering of the skin
- severe diarrhea, possibly with blood or mucus.

The following side effects have been reported

- diarrhea
- feeling sick (nausea)
- vomiting
- measles-like rash, (alone)
- itching
- red wheals on the skin (urticarial) (alone)
- rash with wide spread joint pain and / or stiffness, swollen lymph glands, fever and, possibly, cloudy urine
- swollen arms or legs
- breathlessness
- changes in blood counts, which may show up as bruising or a very tired feeling. You will need a blood test to confirm this.
- damage to your liver or kidneys which can only be detected by a blood and / or urine test
- jaundice (yellow skin and eyes)
- weakness
- pins and needles in the hands or feet
- fainting
- abnormally excitable behavior
- agitation
- nervousness
- sleeplessness
- confusion
- tight muscles
- dizziness
- seeing or hearing things (hallucinations)
- itching of the vagina caused by thrush (candidiasis).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cefaclor Capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cefaclor Capsules contain

The active substance is cefaclor (as cefaclor monohydrate). Each 250 mg capsule contains 250 mg of cefaclor (as cefaclor monohydrate). Each 500 mg capsule contains 500 mg of cefaclor (as cefaclor monohydrate). The other ingredients are sodium starch glycollate (type A), silica colloidal anhydrous and magnesium stearate. The capsule shell is made of gelatin. The colouring agents used are indigo carmine (E132), titanium dioxide (E171) and iron oxide (E172).

What Cefaclor Capsules look like and contents of the pack

Cefaclor 250 mg Capsules are blue and green. Cefaclor 500 mg Capsules are grey and green. They come in packs of 8, 10, 16, 20, 24, 30, 32, 40, 48, 50, 56, 60, 64, 70, 72, 80, 88, 90, 96 or 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder and manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.

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