

Patient package insert according to the Pharmacist's Regulations (Preparations) - 1986

This medicine can be sold by a physician's prescription only

Cefovit 250, capsules

Composition:

Cefovit 250:

Each capsule contains:

Cephalexin (as monohydrate) 250 mg

Inactive ingredients and allergens in the medicine- see section 6 "Additional information".

Read this leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is as same as yours.

1. What is the medicine intended for?

This antibiotic medicine is intended for treatment of infections caused by micro-organisms sensitive to cephalexin.

Therapeutic group: first generation cephalosporins.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (cephalexin), other antibiotics of the cephalosporins group, or to any of the other ingredients this medicine contains (see section 6 "Additional information"). An allergic reaction may include: rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Special warnings regarding the use of this medicine

Before using this medicine, tell the doctor if:

- You have ever developed a severe skin rash or skin peeling, blistering and/ or mouth sores after taking cephalexin or other antibacterials.
- You have had allergic reaction to cephalexin, cephalosporins, penicillins, or other medicines in the past.
- You develop severe or prolong diarrhoea during or after taking cephalexin.
- You suffer from severe kidney disorder (you may need a reduced dose).

Additional special warning

Acute Generalised Exanthematous Pustulosis (AGEP) has been reported with the use of cephalexin. AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk, and upper extremities. The highest risk of occurrence of this serious skin reaction is within the first week of treatment. If you develop a serious skin rash or another of these skin symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately.

Tests and follow up

Tell your doctor if you are about to have blood and/ or urine tests. The medicine may interfere with these tests.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Any other antibiotics (e.g. gentamicin, tobramycin, cefuroxime).
- Potent diuretics medicines e.g. furosemide (used to treat high blood pressure or edema- water retention).
- Probenecid (used to treat gout).
- Metformin (used to treat diabetes).
- Medicines used to treat leukemia.

Even if you are taking one or more of the medicines listed above, treatment with **Cefovit 250/ Cefovit Forte 500** may still be the right treatment for you, as your doctor will be able to decide what is suitable for you.

Use of the medicine and food

Cefovit 250 / Cefovit Forte 500 may be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this medicine.

Driving and use of machines:

This medicine is not expected to affect your ability to drive or use machines.

3. How to use this medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

The usual dosage is:

For adults and adolescents above 12 years of age:

The daily dosage is 1-4 grams, administered in divided doses (2-8 capsules of **Cefovit Forte 500**, or 4-16 capsules of **Cefovit 250**), according to the type and severity of infection.

For children below 12 years of age:

The doctor will calculate the exact dosage for your child according to body weight. The usual dosage is 25-50 mg/ kg body weight per day, administered in divided doses every 8 or 12 hours.

Capsules of **Cefovit 250/ Cefovit Forte 500** are intended for swallowing. For patients who cannot swallow or require treatment with low doses, there are suitable registered preparations available in Israel (such as suspension).

Do not exceed the recommended dose.

Duration of treatment-

If your condition does not improve within a few days, refer to the doctor again. Use the medicine at fixed intervals, as determined by the doctor.

Method of administration:

Do not chew! Swallow the medicine whole with a glass of water, with or without food.

There is no information regarding opening and dispersing the contents of the capsule.

If you have accidentally taken a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, take a dose as soon as you remember; but if it is almost time to take the next dose, skip the missed dose and continue treatment as usual. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

Cefovit Forte 500, capsules

Cefovit Forte 500:

Each capsule contains:

Cephalexin (as monohydrate) 500 mg

Cefovit 250, capsules

If you stop taking the medicine

Even if the symptoms have disappeared, it is important to complete the treatment as recommended by the doctor. Discontinuing the treatment before the recommended time could lead to development of bacterial resistance to the medicine and recurrence of the infection.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have additional questions regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, using this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer any of them.

Contact your doctor immediately if you experience any sudden wheezing, difficulty breathing, swelling of the eyelids, face or lips, 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 one or more of the following:

- Serious peeling or blistering of the skin.
- Severe diarrhoea.
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (Acute Generalised Exanthematous Pustulosis - AGEP). See also in section 2 "Additional special warning".

Additional side effects:

- Diarrhoea
- Feeling sick (Nausea)
- Vomiting
- Indigestion
- Stomach pain
- Measles-like rash (alone)
- Itching
- Red wheals on the skin (urticaria) (alone)
- Rash with wide spread joints pain and/ or stiffness, swollen lymph glands, fever and possibly cloudy urine.
- Changes in blood counts, which may show up as bruising or very tired feeling. You will need a blood test to confirm this.
- Damage to the liver or kidneys, which can be detected by a blood and/ or a urine test.
- Jaundice (yellow skin and eyes).
- Weakness
- Fainting
- Abnormally excitable behaviour
- Agitation
- Tiredness
- Headache
- Confusion
- Dizziness
- Seeing or hearing things (hallucinations)
- Encephalopathy (non-inflammatory brain disease)
- Convulsions
- Myoclonus (muscle-twitching)
- Itching of the vagina or anus caused by thrush (candidiasis).

If a side effect appears, if one of the side effects worsens, or if you experience a side effect that is not mentioned in this leaflet, consult the doctor.

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects problems associated with medication and drugs" on the Ministry of Health homepage (www.health.gov.il), which links to an online form for reporting side effects, or by following the link:

<https://sideeffects.health.gov.il>

5. How should this medicine be stored?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use this medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store in a dry place below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Capsule content:

Starch, Talc, Magnesium Stearate.

Capsule shell:

Gelatine, Titanium Dioxide (E 171), Quinoline Yellow (E 104).

Printing Ink on capsule shell:

Shellac, Propylene Glycol, Strong Ammonia Solution, Potassium Hydroxide, Black Iron Oxide (E 172).

What the medicine looks like and what the package contains:

Cefovit 250: Yellow capsules with the text "CEFOVIT VITAMED" imprinted in black.

Cefovit Forte 500: Yellow capsules with the text "CEFOVIT FORTE VITAMED" imprinted in black.

Approved package sizes:

Cefovit 250: 10, 12, 20, 250, 500, and 1000 capsules.

Cefovit Forte 500: 10, 12, 20, 250, 500, and 1000 capsules.

Not all package size may be marketed.

Manufacturer and registration holder:

Vitamed Pharmaceutical Industries Ltd.,

6 Hatahana St., P.O. Box 114, Binyamina 3055002, Israel.

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Drug registration number at the national drug registry of the Ministry of Health:

Cefovit 250: 026-84-25145-00

Cefovit Forte 500: 026-85-25146-00