

Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is dispensed with a doctor's prescription only

Cefovit 250 capsules

Cefovit Forte 500 capsules

The active ingredient and its quantity:

Cefovit 250: Each capsule contains Cephalexin (as monohydrate) 250 mg

Cefovit 500: Each capsule contains Cephalexin (as monohydrate) 500 mg

For the list of inactive ingredients, please see Section 6 – "Additional information".

Read this leaflet carefully in its entirety 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 to treat your condition. Do not pass it on to others. It may harm them even if you think their condition is similar.

It is important to finish the treatment as recommended by your doctor, even if the symptoms have resolved. Stopping the treatment early could cause development of bacterial resistance to the drug and recurrence of the infection.

1. What is the medicine intended for?

An antibiotic for treating illnesses caused by bacteria that are susceptible to cephalexin.

Therapeutic group: first generation cephalosporins.

2. Before using this medicine:

Do not use this medicine if:

- You are allergic to the active ingredient or to any of the other ingredients that the medicine contains, see Section 6 – Additional information.
- You are allergic to cephalexin, or to other antibiotics of the cephalosporin or penicillin families. An allergic reaction could include: rash, itch, breathing difficulties or swelling of the face, lips, throat or tongue.
- You suffer from porphyria – a hereditary metabolic disease.

Special warnings regarding the use of this medicine:

Before treatment with Cefovit 250 / Cefovit Forte 500, tell the doctor if:

- You suffer, or have suffered in the past, from an allergic reaction to cephalexin, an antibiotic of the cephalosporin or penicillin family, or other medicines.
- You are suffering from kidney dysfunction (you may need a reduced dose).
- You are developing diarrhea. This could be a symptom of colitis. Other symptoms include pain and fever.

Tell your doctor if you are about to have blood or urine tests. Cefovit 250 / Cefovit Forte 500 could interfere with these tests.

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

- Other antibiotics, especially: amphotericin, capreomycin, vancomycin, gentamicin or neomycin.
- Diuretic medicines such as furosemide, bumetanide.
- Probenecid for treating gout.
- Metformin for treating diabetes.
- Medicines for treating leukemia.

Even if you are taking the above medicines, treatment with Cefovit could still be the correct treatment for you, as per the attending doctor's decision.

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 nursing, or if you think that you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

Driving and use of machinery

This medicine is not expected to affect the ability to drive or to operate machinery.

3. How should this medicine be used?

Always use according to the doctor's instructions. If you are not sure about how to use it, consult your doctor or pharmacist.

The dose and manner of treatment will be determined by the doctor only.

The usual dosage is:

For adults and for children over the age of 12:

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

For children under the age of 12:

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, in divided doses every 8 or 12 hours.

Do not exceed the recommended dose.

How to use this medicine: Do not chew!

The medicine may be taken with or without food. It should be swallowed with water.

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 attending doctor.

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

If you have forgotten to take the medicine at the required time,

take a dose as soon as you remember, but do not take two doses together under any circumstances!

If you wish to stop taking the medicine:

Even if the state of your health has improved, do not stop taking the medicine without consulting your doctor.

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 your doctor or pharmacist.

4. Side effects:

As with any medicine, using Cefovit 250 / Cefovit Forte 500 may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

You must stop using this medicine and refer to a doctor immediately if you experience:

- A rash.
- Fever.
- Skin irritation.
- Swelling of the lips, eyelids, tongue.
- Breathing difficulties or sudden wheezing when breathing.

All these effects are signs of an **allergic reaction**. **You must stop using this medicine immediately.**

Dangerous side effects:

The following side effects are dangerous. You must stop using this medicine and contact the doctor immediately:

- Extensive peeling or blisters on the skin.
- Acute diarrhea.

Additional side effects:

- Diarrhea, abdominal pain, heartburn, indigestion.
- Lower abdominal pain, colitis, acute diarrhea containing mucus and blood.
- Nausea or vomiting.
- Measles-like rash.
- Itching.
- Red bruises on the skin (urticaria – hives).
- Pus in the eyes.
- Blisters in the nose or mouth.
- Rash with extensive pain in the joints and/or stiffness of joints, swollen lymph nodes, fever and possibly cloudy urine.
- Changes in blood cell counts, which may manifest as skin bruising or fatigue. Blood tests are needed to verify this.
- Damage to the liver or kidneys. This may be detected by a blood test and/or a urine test.
- Yellowing of the skin and eyes (jaundice).
- Weakness, fainting.
- Feeling of confusion or irritability, hearing or seeing things that do not exist (hallucinations), extreme restlessness.
- Dizziness, fatigue, headaches, sleep disorders, tension.
- Irritation around the anus or genitalia, vaginal swelling, vaginal discharge due to yeast infection (caused by candida).

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 your doctor.

Side effects can be reported to the Ministry of Health by selecting the link "Report of side effects due to medication" on the home page of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects, or by accessing the URL: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How should this medicine be stored?

- **Avoid poisoning!** This medicine, and all other medicines, must be stored in a closed place out of the reach of children and/or infants, to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this medicine after the expiry date indicated on the package. The expiry date refers to the last day of that month.
- Store in a dry place below 25°C.
- Do not dispose of medicines in the toilet or trash. Ask the pharmacist how to destroy unused medicines. This will help protect the environment.

6. Additional information:

- In addition to the active ingredient, Cefovit 250 / Cefovit Forte 500 also contains: Starch, talc, magnesium stearate, gelatin, titanium dioxide (E-171), Quinoline Yellow (E-104).

Ink composition:

Shellac, propylene glycol, strong ammonia sol., pot. hydroxide, black iron oxide.

Quantity of ink: 150 mcg per capsule.

- What the medicine looks like and what the package contains
Cefovit 250: Yellow capsule with the text CEFOVIT VITAMED appearing in black.

Cefovit Forte 500: Yellow capsule with the text CEFOVIT FORTE VITAMED appearing in black.

Name and address of the manufacturer:

Vitamed Pharmaceutical Industries Ltd.,
P.O. Box 114, 3055002 Binyamina, Israel.

This leaflet was reviewed and approved by the Ministry of Health in: August 2017.

The medicine registration number in the National Drug Registry at the Ministry of Health:

Cefovit 250 268425145

Cefovit Forte 500 268525146