Patient package insert according to Pharmacists' Regulations (Preparations)- 1986
This medicine can be sold by a physician's prescription only

Cefovit Forte Suspension, 250 mg/ 5 ml, Powder for Suspension

Composition:
Each 5 ml contains:
Cephalexin (as monohydrate) 250 mg.
Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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 the same as yours.

1. What is this 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 Cefovit Forte Suspension, 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 prolonged 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 **Cefovit Forte Suspension** 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. **Cefovit Forte Suspension** 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 diuretic 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 leukaemia.

Even if you are taking one or more of the medicines listed above, treatment with **Cefovit Forte Suspension** may still be the right treatment for you, as your doctor will be able to decide what is suitable for you.
Use of this medicine and food
Cefovit Forte Suspension 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 using machines:
This medicine is not expected to affect your ability to drive or use machines.
Important information about some of the ingredients of this medicine
- This medicine contains sucrose. If you have been told by the doctor that you or your child has an intolerance to some sugars, contact the doctor before taking or giving your child this medicine.
- This medicine contains 25 mg sodium benzoate in each 5 ml **Cefovit Forte Suspension**. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- This medicine contains less than 1 millimole of sodium (23 mg) per 5 ml, that is to say essentially "sodium- free".

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 doses of 500 mg, or 4-16 doses of 250 mg), according to the type and severity of the 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.
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.
How to prepare the suspension
Prepare the suspension according to the preparation instructions that appear on the bottle label:
The pharmacist will add 36 ml of distilled water to the bottle to prepare 60 ml of suspension and shake well until homogenous suspension is obtained.
Method of administration:
- Shake the bottle well before each use.
- Make sure to measure the dose of suspension using the measuring cup provided.

• The medicine may be taken with or without food.

If you have accidentally taken a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed 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.

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 <u>each time</u> you take a medicine. Wear glasses if you need them.

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

<u>4. Side effects</u>

As with any medicine, the use of **Cefovit Forte Suspension** 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 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 suffer from a side effect which 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

<u>5. How to store the medicine?</u>

• 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:**
• **<u>Dry powder:</u>** Store the powder in a dry place, below 25°C.
• **<u>Prepared suspension:</u>** Store the prepared suspension in a refrigerator (2-8°C) and use it within 14 days.
• 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.

<u>6. Additional information</u>

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

Sucrose, Sodium Benzoate, Xanthan Gum, Strawberry Flavour, Simethicone, Citric Acid Anhydrous, Yellow Iron Oxide (E 172), Banana Flavour, Peach Flavour, Disodium Edetate.

What the medicine looks like and what the package contains:

A bottle with a child-resistant cap containing an orange to yellow powder and a measuring cup.
After adding distilled water, an orange to yellow suspension with a fruity scent will be obtained.

Approved package size: 60 ml.

Manufacturer and registration holder:

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

Revised in October 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health: 026-83-25148-00