

Patient package insert in accordance with the Pharmacist's Regulations (Preparations) – 1986

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

AMOXI CARE FORTE 250 SUSPENSION

The active ingredient and its amount:

Each 5 ml contains: Amoxycillin 250 mg (as trihydrate)

For a list of the inactive ingredients, please see Section 6.

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 illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

It is important to complete the full course of treatment as recommended by the doctor, even if your symptoms have passed. Stopping the treatment early may cause the development of bacterial resistance to the medicine, and lead to recurrent infection.

Prepare the suspension according to the preparation instructions shown on the label of the bottle, and shake well before each use.

1. What is this medicine intended for?

This medicine is intended to treat infections caused by bacteria sensitive to Amoxycillin.

Therapeutic group: Semi-synthetic penicillin-group antibiotics.

2. Before using this medicine

Do not take this medicine if:

- You have a known sensitivity to Amoxycillin or to any of the medicine's ingredients.
- You have a known sensitivity to other medicines from the cephalosporin or penicillin groups.
- You are suffering from mononucleosis.

Special warnings regarding the use of this medicine:

- If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medicine.
- You must inform your doctor if you are suffering from any type of allergic disease.
- During prolonged treatment, you should undergo periodic kidney, liver, and blood function tests.
- While taking this medicine, you must inform your doctor before taking tests to measure glucose levels in the blood or urine, because treatment with this medicine may cause false positive results in those tests.

Before treatment with Amoxi Care Forte 250 Suspension, tell your doctor if:

- You are pregnant or breastfeeding.
- You are suffering, or have suffered in the past, from impaired function of:
 - The kidneys.
 - The liver.
 - The digestive system (e.g. enteritis).
 - The blood system (e.g. coagulation, etc.).
- If you are currently being treated for a kidney problem.
- If you are not passing water regularly.
- If you suffer from reduced urination and do not drink enough fluids.
- If you have suffered in the past from an allergic reaction to any type of antibiotic.
- If you suffer from mononucleosis, including symptoms of fever and swollen glands.

If you are taking, or have recently taken another medicine, including non-prescription medicines or food supplements, inform the doctor or pharmacist. Inform the doctor if you are taking:

- Antibiotics from the following groups: tetracyclines, chloramphenicol, erythromycin, sulfonamide.
- Probenecid or Allopurinol (for gout).
- Birth control pills – Amoxycillin may decrease the effectiveness of the pills, and it is therefore recommended to use an additional method of contraception, such as a condom or a diaphragm with a spermicide, during this treatment.
- Oral anticoagulants, such as warfarin.

Use of this medicine and food: Amoxi Care Forte 250 Suspension may be taken with or without food.

Pregnancy and breastfeeding: Consult a doctor if you are pregnant or breastfeeding.

Driving and the use of machinery: This medicine is not expected to affect your ability to drive or to operate machinery.

Important information about some of the ingredients of the medicine: Each 5 ml of suspension contains 1.939 grams of sugar and 5.6mg of sodium.

3. How should this medicine be used?

This medicine must always be used according to doctor's instructions only. Check with the doctor or pharmacist if you are unsure.

Suspension preparation instructions:

For the 60 ml packaging: The pharmacist will add 41 ml distilled water to the bottle and shake well until homogenous suspension is obtained.

For the 100 ml packaging: The pharmacist will add 70 ml distilled water to the bottle and shake well until homogenous suspension is obtained.

The dosage and the method of treatment will be determined by the doctor only.

The attending physician will determine the required dosage and length of treatment with this medicine in accordance with the type and severity of infection from which you suffer.

Do not exceed the recommended dosage.

Directions for use: Shake the bottle well before each use.

Make sure to measure the dose of the suspension using the enclosed measuring cup. This medicine may be taken with or without food.

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

If you forget to take this medicine at the required time, take the next dose as soon as you remember and continue the normal dosage schedule, but never take two doses at the same time in order to make up for a missed dose. Complete the full course of treatment as recommended by your doctor.

If you discontinue the treatment with this medicine

Even if there is an improvement in your health, do not discontinue the treatment with this medicine without consulting your doctor or pharmacist.

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 further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, the use of Amoxi Care Forte 250 Suspension may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

Stop the treatment and refer to your doctor immediately in the following cases:

Extremely rare side effects (Side effects with an incidence of less than 1 in 10,000 patients):

- A severe allergic reaction which includes a rash or itching, swelling of the face, lips, tongue, or body, difficulty breathing. This side effect is severe and in some cases has even led to death.
- An allergic reaction which causes inflammation of the blood vessels and includes symptoms of a rash or red spots under the skin, or signs of bruising. This reaction may be accompanied by joint pain and kidney problems.
- A delayed allergic reaction may appear 7-12 days after taking the medicine. Symptoms may include a rash, fever, joint pain, swelling of the lymph nodes (especially under the arms).
- An allergic reaction known as erythema multiforme, which includes itchy, reddish-purple patches on the skin, especially on the hands and feet, prominent lesions on the skin; sensitivity in the mouth, eyes, or other parts of the body, fever and fatigue.
- Other severe dermatological reactions, including: changes in skin color, skin protuberances, itching, flaky skin, peeling, blisters, redness, and pain, occasionally accompanied by fever, headache and body aches.
- Fever, chills, sore throat and other signs of inflammation, easily caused bruises. These may indicate a problem with the blood cells.
- Inflammation of the large intestine accompanied by diarrhea, at times with blood in the stools, pain and fever.
- Serious side effects related to the liver that usually occur in cases of prolonged treatment with the medicine, in men or in the elderly. These side effects are usually reversible. Consult your doctor immediately in the following cases:
 - Severe diarrhea with bleeding.
 - Blisters, redness or bruises on the skin.
 - Dark urine or pale stools.
 - Yellowing of the skin or eyes (jaundice). (This symptom may also occur as a sign of anemia. See below.)

These side effects may occur during the treatment or several weeks after the end of the treatment.

Additional side effects:

Common side effects

(Side effects with an incidence of 1-10 in 100 patients):

- Diarrhea or abdominal pain, nausea.
- Rash.

Rare side effects

(Side effects with an incidence of 1-10 in 1,000 patients):

- Vomiting.
- An itchy rash.

Very rare side effects

(Side effects with an incidence of less than 1 in 10,000 patients):

- Oral, vaginal or skin fungal infection.
- Tooth discoloration (temporary).
- Excessive movement of the muscles (hyperkinesia).
- Dizziness.
- Convulsions – especially in patients with kidney problems or who are taking high doses.
- Kidney infection.
- Hyperactivity.
- Hepatitis or jaundice due to cholestasis.
- Crystals in the urine – the urine appears cloudy, or there is difficulty or discomfort upon urination. Make sure to drink plenty of fluids in order to avoid this side effect.
- Yellow, brown or black discoloration of the tongue, which may be accompanied by a coating on the tongue.
- Anemia – signs include fatigue, headache, shortness of breath, dizziness, pallor, and yellowing of the skin and eyes.
- The blood coagulation time may be increased (in case of a nosebleed or an injury).

If any of the side effects appears or worsens, or if you experience any side effects not mentioned in this leaflet, you must consult your doctor.

Side effects may be reported to the Ministry of Health by clicking 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.

5. How should the medicine be stored?

- **Avoid poisoning!** This medicine, and all other medicines, must be stored in a safe 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 a doctor.
- Do not use this medicine after the expiry date shown on the package. The expiry date refers to the last day of that month.
- Store in the carton box, protected from light in a dry place below 25°C.
- Store the prepared suspension at room temperature and use within 14 days.
- Do not dispose of medicines in household sewage or garbage. Ask the pharmacist how to dispose of unused medicines. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Each 5 ml contains: Sucrose (1.939 gr), sodium benzoate, strawberry flavor, xanthan gum, sodium citrate, simethicone, banana flavor, EDTA sodium, (sodium content 5.6 mg).

What the medicine looks like and what the package contains:

A bottle containing white powder.

Amoxi Care Forte 250 Suspension after adding distilled water: a white to pale yellow liquid with a fruity scent.

Manufacturer and license holder: Vitamed

Pharmaceutical Industries Ltd., POB 114, 3055002 Binyamina, Israel.

Medicine registration number in the national medicine registry of the

Ministry of Health: Amoxi Care Forte 250 Suspension: 1551734692

This leaflet was reviewed and approved by the Ministry of Health in December 2015