

Patient Information Leaflet (PIL)

Zamur™ 250mg, film-coated tablets

Zamur™ 500 mg, film-coated tablets

Cefuroxime

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

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1. What Zamur is and what it is used for

Zamur is an antibiotic that, when taken, kills infectious bacterial microorganisms. Zamur is suitable to treat of infections of:

- the tonsils, the throat, the sinus, and the middle ear
- the lungs or chest
- the urinary tract
- the skin and soft tissues.

Zamur is also used to treat:

- Lyme disease (an infection spread by parasites called ticks)
- Genital infection

It must not be taken unless prescribed by a doctor.

Your doctor should test for the type of bacteria responsible for your infection and monitor their susceptibility to Zamur during the course of treatment.

2. Before you take Zamur

a. Do not take Zamur

Zamur must not be taken in cases of known or suspected hypersensitivity to cephalosporin antibiotics. If you have – or suspect you have – an allergy to penicillin, you must inform your doctor. For example, an allergy or hypersensitivity can manifest as symptoms such as skin blotches, fever, asthma, shortness of breath, blood circulation problems, swelling of the skin (e.g. hives) and mucous membranes, rash or painful tongue.

b. Take special care with

Your doctor must be informed if you have previously suffered from an allergy to penicillin or you are generally prone to allergies.

When experiencing difficulty breathing, tightness of the chest, swelling of the eyelids, face or lips, rash (red spots), skin swelling, hives or very severe diarrhea, or symptoms of liver inflammation or jaundice such as tiredness, weakness, malaise during treatment, loss of appetite, nausea, vomiting, yellowing of the eyes (conjunctiva), skin or discolored stools, you should tell your doctor immediately before proceeding with Zamur.

If diarrhoea occurs, you must not take any medicines that prevent bowel peristalsis (bowel movements).

Inform your doctor, if you have kidney dysfunction, may need to adjust the dose of Zamur.

In patients with diabetes, urine sugar tests may show a false-positive result if methods based on copper reduction are used (e. g. Fehling, Benedict, Clinitest); enzyme tests should therefore be used.

If the disorder being treated with Zamur is not cured or has not significantly improved after one pack, you should tell your doctor immediately.

After your treatment is completed, please return the pack with any remaining contents to your doctor or pharmacist for proper disposal.

Further information may be obtained from your doctor or pharmacist. These persons have the detailed prescribing information at their disposal.

c. Taking other medicines

Medications taken to treat excessive production of stomach acid may alter the effect of Zamur. If you are taking an oral contraceptive (the pill), it may become less effective during treatment with antibiotics. This also applies to Zamur. For this reason, you should take additional

contraceptive measures.

Please tell your doctor or pharmacist if you are taking or using the following medicines: strong water-repellent medicines (diuretics), medicines used to treat gout that contain probenecid, medicines that reduce acidity in the stomach, oral contraceptives or other antibiotics (in particular antibiotics from the group of so-called aminoglycosides).

Tell your doctor or pharmacist if you

- suffer from other illnesses
- have any allergies or
- are taking any other medicines (including those purchased without a prescription).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

d. 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. Zamur should not be used during pregnancy unless clearly necessary.

e. Driving and using machines

This medicine may cause dizziness, affecting the ability to react, drive, and use tools or machines.

3. How to take Zamur

Always take Zamur exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

The usual duration of treatment is 7 (5-10) days, depending on the severity and course of the infection.

Always keep to the dosage and length of treatment stated by your doctor and do not stop treatment under any circumstances without your doctor's consent.

Zamur should be taken with food.

Due to their bitter taste, the film-coated tablets should be swallowed whole with liquid.

Adults and adolescents over 12 years of age

Normally 1 × 250 mg film-coated tablet every 12 hours (morning and evening). For certain infections (otitis media and severe infections): 1 × 500 mg film-coated tablet every 12 hours (morning and evening).

Lyme disease: 2 x daily (every 12 hours) 500 mg for 20 days.

Uncomplicated gonorrhoea: one single dose of 1 g.

Children aged 5 years and older (weighing at least 15 kg) up to 12 years of age:

Normally 125 mg = $\frac{1}{2} \times 250$ mg film-coated tablet every 12 hours (morning and evening).

In children aged 5 years and older (weighing at least 20 kg) up to 12 years of age, Zamur film-coated tablets can be used to treat middle-ear infections or severe infections.

For middle-ear infections or severe infections, the dosage is 1 × 250 mg film-coated tablet, twice daily. This dosage must not be exceeded.

Children under 5 years of age

Zamur film-coated tablets are not suitable for treating children under 5 years of age.

In some cases, the doctor may prescribe a different dosage for you.

Do not change the prescribed dosage yourself. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

If you take more Zamur than you should

If you take too much Zamur you may have cerebral disorders, which may manifest as seizures. Don't delay. Contact your doctor or your nearest hospital emergency department immediately. If possible, show them the Zamur pack.

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

4. Possible side effects

Like all medicines, Zamur can cause side effects, although not everybody gets them

The following side effects may occur when taking Zamur:

Common: fungal infections (such as oral thrush), headache, dizziness, gastrointestinal disorders such as diarrhea, abdominal pain and nausea.

Uncommon: vomiting, rashes.

Rare: severe diarrhea (see also "Take special care with").

Very rare: heartburn, jaundice, hepatitis, itching, nettle rash, severe rash, allergic reactions, or even anaphylactic shock (see also "Take special care with").

Also, changes in the numbers of white or red blood cells and platelets, prolonged bleeding times, and liver abnormalities have been reported.

If one or more of the following symptoms occur, stop taking Zamur and inform your doctor as soon as possible:

Severe nausea, severe diarrhoea or severe stomach pain, bleeding from the anus, initial yellowing of the skin or eyes.

If you develop breathing difficulties, tightness in the chest, swelling of the eyelids, face or lips, rash (red spots), skin swelling or hives (signs of hypersensitivity/allergy), you should tell your doctor immediately and not continue taking Zamur unless expressly instructed to do so by the doctor.

Some patients may get a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with Zamur for Lyme disease. This is known as the Jarisch-Herxheimer reaction. Symptoms usually last a few hours or up to one day.

Other side effects which may occur when taking Zamur:

Common side effects (may affect up to 1 in 10 people)

- an increase in a type of white blood cell (eosinophilia)
- an increase in liver enzymes (ALT [SGPT], AST [SGOT], LDH)

Uncommon side effects (may affect up to 1 in 100 people)

- positive Coombs' test
- a decrease in the number of blood platelets (cells that help blood to clot)
- a decrease in the number of white blood cells (leukopenia, neutropenia)
- an increase in liver tests (alkaline phosphatase, bilirubin)

Rare side effects (may affect up to 1 in 1,000 people)

- urticaria, pruritus (itching)

Very rare side effects (may affect up to 1 in 10,000 people)

- haemolytic anaemia (red blood cells destroyed too quickly)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Zamur

Keep out of the reach and sight of children.

Do not store above 30 °C.

Zamur may be used only up to the date marked with "EXP" on the pack.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

a. What Zamur contains

The active substance is cefuroxime as cefuroximum axetil.

The other ingredients are:

Table core: croscarmellose sodium, crospovidone, sodium laurilsulfate, castor oil, hydrogenated, methylcellulose, silica, precipitated.

Film-coating: hypromellose, cellulose, microcrystalline, macrogol 8 stearate, talcum, titanium dioxide.

b. What Zamur looks like and content of the pack

Film-coated tablets (with a score line) of 250 mg and 500 mg cefuroxime (as 300.72 mg and 601.44 mg cefuroxime axetil).

Zamur 250 mg, film-coated tablets (with a score line): 10, 14 and 10x14

Zamur 500 mg, film-coated tablets (with a score line): 10, 14 and 10x14.

Not all presentations may be marketed.

c. Marketing Authorisation Holder and Manufacturer

Manufactured by Steiner, Berlin, Germany for Acino Pharma AG, Liesberg, Switzerland.

d. Date of revision of the text

Jan 2019

To report any side effect(s):

● **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

a. Council of Arab Health Ministers

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists