

Package leaflet: Information for the patient

Cefuroxim Mylan 250 mg, filmomhulde tabletten Cefuroxim Mylan 500 mg, filmomhulde tabletten cefuroxime

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called *cephalosporins*.

[Invented name] is used to treat infections of:

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

[Invented name] can also be used:

- to treat Lyme disease (an infection spread by parasites called ticks).

Your doctor may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to [Invented name] during your treatment.

2. What you need to know before you take

Do not take [Invented name]:

- if you are allergic to cefuroxime axetil or any cephalosporin antibiotics or any of the other ingredients of this medicine (listed in section 6).
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after treatment with cefuroxime or any other cephalosporin antibiotics.
- if you have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).

- if you think this applies to you, don't take [Invented name] until you have checked with your doctor

Warnings and precautions

Talk to your doctor or pharmacist before taking [Invented name]

Take special care with [Invented name]

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with cefuroxime treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children and adolescents

[Invented name] is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

You must look out for certain symptoms, such as allergic reactions, fungal infections (such as candida) and severe diarrhoea (pseudomembranous colitis) while you are taking [Invented name]. This will reduce the risk of any problems. See 'conditions you need to look out for' in section 4.

If you need a blood test

[Invented name] can affect the results of a test for blood sugar levels, or a blood screen called the Coombs test. If you need a blood test:

Tell the person taking the sample that you are taking [Invented name]

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Medicines used to reduce the amount of acid in your stomach (e.g. antacids used to treat heartburn) can affect how [Invented name] works.
- Probenecid (used to treat gout)
- Oral anticoagulants (e.g. warfarin)

Pregnancy and breast-feeding and fertility

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.

Driving and using machines

[Invented name] can make you dizzy and have other side effects that make you less alert. Don't drive or use machines if you do not feel well.

[Invented name] contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'

3. How to take [Invented name]

Always take this medicine as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take [Invented name] after food. This will help make the treatment more effective. Swallow the tablets whole with some water. Don't chew, crush or split the tablets-this may make the treatment less

effective. Other more suitable formulations e.g. oral suspension may be available for patients who are unable to swallow the tablets.

The recommended dose is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Use in children and adolescents

The recommended dose of [Invented name] is 10 mg/kg (to a maximum of 125 mg) to 15 mg/kg (to a maximum of 250 mg) twice daily depending on:

- The severity and type of infection

[Invented name] is not recommended for children under 3 months, as safety and effectiveness are not known in this age group

Depending on the illness or how you or your child responds to treatment, the initial dose may be changed or more than one course of treatment may be needed.

Patients with kidney problems

If you have a kidney problem, your doctor may change your dose.

Talk to your doctor if this applies to you.

If you take more [Invented name] than you should

If you take too much [Invented name] you may have neurological disorders, in particular you may be more likely to have fits (seizures).

- Don't delay. Contact your doctor or your nearest hospital emergency department immediately. If possible, show them the [Invented name] pack.

If you forget to take [Invented name]

Do not take a double dose to make up for a forgotten tablet. Just take your next dose at the usual time.

If you stop taking [Invented name]

Don't stop [Invented name] without advice

It is important that you take the full course of [Invented name]. Don't stop unless your doctor advises you to- even if you are feeling better. If you don't complete the full course of treatment, the infection may come back.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions you need to look out for

A small number of people taking [Invented name] get an allergic reaction or potentially serious skin reaction. Symptoms of these reactions include:

- **severe allergic reaction.** Signs include **raised and itchy rash, swelling**, sometimes of the face or mouth causing **difficulty in breathing**.
- **skin rash**, which may **blister**, and looks like **small targets** (central dark spot surrounded by a paler area, with a dark ring around the edge).
- **a widespread rash with blisters and peeling skin.** (These may be signs of *Stevens-Johnson syndrome* or *toxic epidermal necrolysis*).
- **widespread rash, high body temperature** and **enlarged lymph nodes** (DRESS syndrome or drug hypersensitivity syndrome).
- **chest pain** in the context of **allergic reactions**, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

Other conditions you need out look out for while taking [Invented name] include:

- **fungal infections.** Medicines like [Invented name] can cause an overgrowth of yeast (*Candida*) in the body which can lead to fungal infections (such as thrush). This side effect is more likely if you take [Invented name] for a long time.
- **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like [Invented name] can cause inflammation of the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain, fever
- **Jarisch-Herxheimer reaction.** Some patients may get a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with [Invented name] for Lyme disease. This is known as the *Jarisch-Herxheimer reaction*. Symptoms usually last a few hours or up to one day

Contact a doctor or nurse immediately if you get any of these symptoms.

Other possible side effects

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

- fungal infections (such as *Candida*)
- headache
- dizziness
- diarrhoea
- feeling sick
- stomach pain.

Common side effects that may show up in blood tests

- an increase in a type of white blood cell (*eosinophilia*)
- an increase in liver enzymes.

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

- being sick
- skin rashes.

Uncommon side effects that may show up in blood tests:

- a decrease in the number of blood platelets (cells that help blood to clot)
- a decrease in the number of white blood cells
- positive Coomb's test.

Not known: (frequency cannot be estimated from the available data)

- severe diarrhoea (pseudomembranous colitis)
- allergic reactions
- skin reactions (including severe)

- high temperature (fever)
- yellowing of the whites of the eyes or skin
- inflammation of the liver (hepatitis).

Side effects that may show up in blood tests:

- red blood cells destroyed too quickly (haemolytic anaemia)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Invented name] contains

[Invented name] 250 mg film-coated tablets contain 250 mg cefuroxime (as cefuroxime axetil)

[Invented name] 500 mg film-coated tablets contain 500 mg cefuroxime (as cefuroxime axetil)

The other ingredients are. microcrystalline cellulose, sodium croscarmellose, sodium lauril sulfate (E487), colloidal anhydrous silica, , hydrogenated vegetable oil, hypromellose, titanium dioxide (E171), macrogol

What [Invented name] looks like and contents of the pack

[Invented name] 250 mg film-coated tablets white to off-white, film-coated capsule shaped tablets (approximately 16.1 mm x 6.6 mm) with 'A 33' stamped into the tablet on one side and plain on the other side.

[Invented name] 250 mg film-coated tablets are available in blister packs of 8, 10, 12, 14 and 16 tablets.

[Invented name] 500 mg film-coated tablets white to off-white, film-coated capsule shaped tablets (approximately 20.1 mm x 8.6 mm) with 'A 34' stamped into the tablet on one side and plain on the other side.

[Invented name] 500 mg film-coated tablets are available in blister packs of 6, 10, 14, 16 and 24 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Registratiehouder:

Mylan Pharmaceuticals Ltd
Damastown Industrial Park
Mulhuddart
Dublin 15
Dublin, Ireland

Voor informatie en inlichtingen:

Mylan B.V.
Krijgsman 20
Amstelveen

Manufacturer

McDermott Laboratories trading as Gerard Laboratories trading as Mylan Dublin
35/36 Baldoyle Industrial Estate
Grange Road, Dublin 13
Ireland

Mylan Hungary Kft.
H-2900 Komárom
Mylan útca.1
Hongarije

In het register ingeschreven onder:

Cefuroxim Mylan 250 mg, filmomhulde tabletten	RVG 123282
Cefuroxim Mylan 500 mg, filmomhulde tabletten	RVG 123283

This medicinal product is authorised in the Member States of the EEA under the following names:

Tsjechië	Cefuroxim Mylan
Italië	Cefuroxima Mylan
Nederland	Cefuroxim Mylan 250 mg, 500 mg, filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in mei 2023