

Package leaflet: Information for the patient

Cefadroxil Mylan 500mg Capsules, hard Cefadroxil Mylan 1g Film-coated Tablets Cefadroxil Mylan 100mg/ml Powder for Oral Suspension Cefadroxil

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

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1. What Cefadroxil Mylan is and what it is used for

Your medicine contains the active ingredient cefadroxil. Cefadroxil is an antibiotic and belongs to a group of medicines called cephalosporin's.

Cefadroxil Mylan is used to treat bacterial infections of the upper respiratory tract, the skin and soft tissue, and the urinary system.

2. What you need to know before you take Cefadroxil Mylan

Do not take Cefadroxil Mylan:

- if you are allergic, or think you may be allergic, to cefadroxil, any other cephalosporin antibiotic, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cefadroxil Mylan:

- if you are allergic to penicillin antibiotics
- if you use chemical tests to check for sugar in your urine. Cefadroxil may cause a false positive reaction. This does not occur with dipstick type tests.
- If you are having a test called a Coombs test, which looks at red blood cells in your blood.

Other medicines and Cefadroxil Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines or any other medicine including those obtained without a prescription:

- antibiotics such as tetracycline, erythromycin, sulfonamides (e.g. sulfamethoxazole/trimethoprim), chloramphenicol, polymyxin B, vancomycin, colistin, aminoglycosides e.g. gentamicin

- Probenecid, (for gout)
- high doses of a diuretic (water tablet) such as furosemide
- medicine to thin the blood.

Taking Cefadroxil with food and drink

Cefadroxil should be taken with food preferably during or after meals.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Low levels of cefadroxil can pass into breast milk, however the swallowed amounts are lower than the prescribed doses. Breast-feeding is possible when taking cefadroxil, although breast-feeding (or treatment) should be discontinued if the infant develops diarrhoea, thrush or skin eruptions.

Driving and using machines

Cefadroxil should not affect your ability to drive or use machines.

Cefadroxil Mylan oral suspension contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

1 ml of Cefadroxil Mylan oral suspension contains approximately 0.62 g of sucrose. This should be taken into account when doses of 8 ml or above are given to patients with diabetes mellitus.

3. How to take Cefadroxil Mylan

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

Capsules and tablets

Adults and children weighing more than 40kg:

The recommended dose for adults and children weighing more than 40 kg is 500 mg to 1g twice a day.

Capsules and tablets should not be given to children under 6 years.

Patients with kidney problems should take 500 mg every 12 to 36 hours depending on the severity of the kidney problem. Follow your doctor's instructions carefully.

How to take capsules and tablets:

- Take this medicine during or after meals.
- The capsules and tablets should be swallowed with plenty of liquid.
- Swallow the capsules whole.
- For the tablets only, the score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Oral suspension

Adults and children weighing more than 40kg:

The recommended dose for adults and children weighing more than 40 kg is 500 mg to 1g twice a day.

Children weighing less than 40 kg:

The oral suspension may be given to children weighing less than 40 kg. The amount of suspension and the number of times a day you should give the suspension to your child will depend on your child's

weight and the type of infection that is being treated. Your doctor will tell you exactly how to give the suspension.

If you, or your child, have kidney problems, your doctor will tell you exactly how much of the suspension should be taken. The suspension should be taken every 12 to 36 hours depending on the severity of the kidney problem.

How to take the oral suspension:

- The oral suspension should be **shaken well before use**.
- Take this medicine during or after meals.

If you take more Cefadroxil Mylan than you should

If you take more Cefadroxil Mylan than you should contact your nearest hospital emergency department immediately. Remember to take the container and any remaining medicinal product with you. Symptoms of overdose include allergic reaction causing difficulty breathing or dizziness, a fall in blood pressure, and increase or decrease in heart beat, nausea, vomiting, skin eruptions, diarrhoea cramps, reduced consciousness, muscular contractions or coma.

If you forget to take Cefadroxil Mylan

Take the next dose as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cefadroxil Mylan

Do not stop taking Cefadroxil Mylan without talking to your doctor, even if you feel better. It is important that you take the full course of Cefadroxil Mylan prescribed by your doctor. You will need to take it for 2 or 3 days after your symptoms have gone or for a minimum of 10 days for certain types of infections.

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.

If any of the following happen, **stop taking** Cefadroxil Mylan and tell your doctor **immediately** or go to your nearest hospital emergency department. **You may need medical attention.**

- cefadroxil may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.
- if you develop symptoms of a severe allergic reaction (angioedema or anaphylaxis) such as swollen face, tongue or pharynx, difficulty to swallow, hives and/or difficulties to breathe, tightness of the chest
- if you notice blood in the urine or cloudy urine, if you produce little or no urine or have lower back pain. This could be symptoms of kidney problems.

The above mentioned side effects are rare and may affect up to 1 in 1,000 people.

You should also contact your doctor promptly if you experience any of the following symptoms:

- severe diarrhoea (colitis), which may have blood in it

- severe skin reactions with blistering of the skin, mouth, eyes and genitals
- if you notice your skin is unusually pale or yellow and you experience weakness or breathlessness. These symptoms can indicate a reduced amount of red blood cells in your blood.

The frequency of the above mentioned symptoms is not known.

Other side effects:

Common (may affect up to 1 in 10 people):

- nausea
- vomiting
- diarrhoea
- indigestion
- abdominal pain
- severe itching
- rash
- allergic skin eruptions
- hives
- a swollen sore tongue

Uncommon (may affect up to 1 in 100 people):

- vaginal fungal infections or ‘thrush’

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

- unexplained bruising or bleeding, which may be due to reduced platelets in the blood which help the blood to clot
- an increase in certain white blood cells, which may be seen in blood tests
- fever, feeling generally unwell with or without swollen glands in the neck or muscle pains (serum sickness)
- joint pain
- changes in liver enzymes (which show how the liver is working and may be seen in blood tests)

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

- tiredness
- headache
- dizziness
- nervousness
- sleeplessness

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

- a red raised, measles-like rash

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 Cefadroxil Mylan

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

Keep the container or blister packs in the outer carton in order to protect from light.

Store ready prepared oral suspension in a refrigerator (2°C-8°C). The ready prepared Cefadroxil Mylan suspension should be used within 14 days.

Do not use this medicine after the expiry date which is stated on the label, carton or blister after EXP. The expiry date refers to the last day of that month.

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 Cefadroxil Mylan contains

- The active substance is cefadroxil (as the monohydrate). Each capsule contains 500mg of cefadroxil. Each tablet contains 1g of cefadroxil. Each 1ml of ready prepared solution contains 100mg of cefadroxil.
- The other ingredients are:

Capsule: sodium laurilsulfate, magnesium stearate, cellulose microcrystalline, titanium dioxide (E171) and gelatin.

Tablet core: silica colloidal anhydrous, sodium laurilsulfate, magnesium stearate, macrogol 6000, crospovidone, povidone, talc, and cellulose microcrystalline. **Tablet coating:** titanium dioxide (E171), hypromellose and talc.

Oral solution: silica colloidal anhydrous, magnesium stearate, guar galactomannan, saccharin, titanium dioxide (E171), talc, sucrose and peach-apricot flavour.

What Cefadroxil Mylan looks like and contents of the pack

Cefadroxil Mylan 500mg Capsules are hard gelatin capsules with white opaque body and cap.

Cefadroxil Mylan 1g Film-coated Tablets are white to yellowish oval, biconvex tablets with a score-line on both sides.

Cefadroxil Mylan 100mg/ml powder for oral suspension is a white to slightly yellowish powder. The ready to use suspension is a white to slightly yellowish liquid.

Cefadroxil Mylan 500mg Capsules, hard are available in blisters or plastic bottles of 6, 7, 8, 10, 14, 16, 20, 30 and 100 capsules.

Cefadroxil Mylan 1g Film-coated Tablets are available in blisters or plastic bottles of 6, 7, 8, 10, 16, 20 and 100 tablets.

Cefadroxil Mylan 100mg/ml Powder for Oral Suspension is available in 60ml and 100ml amber glass bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

McDermott Laboratories Ltd t/a Gerard Laboratories, Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Sandoz GmbH, Biochemiestraße 10, Kundl, 6250, Austria.

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