

CEFADROXIL

250 mg/5 ml granules 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

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

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

Cefadroxil suspension is an antibiotic. It belongs to a group of antibiotics called cephalosporins. These antibiotics are similar to penicillin.

Cefadroxil suspension kills bacteria and can be used against various types of infections. Like all antibiotics, cefadroxil is only effective against certain types of bacteria. It is therefore appropriate to treat certain types of infections. Cefadroxil suspension can be used to treat:

- infections of the throat;
- uncomplicated infections of the bladder and kidneys;
- uncomplicated infections of the skin and soft tissue.

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

Do not take Cefadroxil suspension:

- if you are allergic to cefadroxil or any of the other ingredients of this medicine (listed in section 6);
 - if you are allergic to any other cephalosporin antibiotic;
 - if you have had a severe allergic reaction to any penicillin antibiotic.
- Not all people allergic to penicillin are allergic to cephalosporins. However, you should not take this medicine if you have ever had a severe allergic reaction to any penicillin, as you may also be allergic to this medicine (a cross-allergy).
- if you are allergic to peanut or soya, do not take this medicinal product.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cefadroxil suspension:

- if you have ever had an allergic reaction to an antibiotic or suffer from asthma;
- if you have been told that your kidneys are not working well or if you are undergoing dialysis (due to problems with the way your kidneys work). You can take cefadroxil, but your doctor will adjust the dose for you;
- if you have ever had an inflammation of the large bowel, called colitis, or any other serious disease that affects the intestines.

If you are being treated with Cefadroxil suspension for an extended period the doctor will perform regular blood tests.

You must look out for certain symptoms of gastrointestinal disorders such as diarrhoea while you are taking cefadroxil. See *Serious side effects* in section 4.

Infants

Cefadroxil should be used with caution in premature and newborn infants, since their enzyme system is not fully developed.

If you need a blood or urine test

Cefadroxil can affect the results of urine tests for sugar and a blood test known as the *Coombs test*. If you are having test:

Tell the person taking the sample that you are taking cefadroxil.

Other medicines and Cefadroxil suspension

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

Cefadroxil may be affected by other medicines which are excreted by the kidneys. Many medicines have this effect, so you should consult your doctor or pharmacist before taking Cefadroxil suspension.

In particular, tell your doctor or pharmacist if you are taking the following medicines:

- **anticoagulants** (used to thin the blood);
- **probenecid** (used for gout). It may delay the elimination of cefadroxil from your body;
- **cholestyramine** (used to reduce high cholesterol).

Never take Cefadroxil suspension together with the following medicines:

- **antibiotics** called aminoglycosides (such as gentamicin), polymyxin B and colistin;
- other antibiotics that stop the growth of bacteria (such as **tetracycline**);
- **water pills** (diuretics) such as furosemide. It may be necessary to frequently check your kidney function during treatment. This can be done through blood and urine tests.

You should allow two to three hours to pass between taking Cefadroxil suspension and any of the above medicines.

Cefadroxil suspension with food, drink and alcohol

Cefadroxil can be taken with or without food.

Pregnancy, 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

You may suffer from headaches, dizziness, nervousness, insomnia and fatigue while taking this medication. This can affect your ability to drive or use machines. If this happens, do not drive or use machines.

Cefadroxil 250 mg/5 ml granules for oral suspension contains sucrose

This medicine contains 2.780 g of sucrose per 5 ml reconstituted suspension. This should be taken into account by patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars (fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency), contact your doctor before taking this medicinal product.

Cefadroxil 250 mg/5 ml granules for oral suspension contains Soy-Lecithin.

If you are allergic to peanut or soya, do not use this medicinal product. (see Section 2 "Do not take Cefadroxil suspension")

3. How to take Cefadroxil suspension

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

The dose prescribed by your doctor depends on the nature and severity of the infection. It also depends on how well your kidneys are working. Your doctor will explain this. Your doctor will calculate the exact dose.

Cefadroxil granules for oral suspension is intended for use in children \geq 5 kg.

It may also be used in adults and older children who have difficulty swallowing capsules.

The following table helps to define the recommended doses:

| Indications | Adults and adolescents weighing more than 40 kg with normal kidney function |
|--|---|
| Uncomplicated infections of the bladder and kidneys | 1000 mg twice daily |
| Uncomplicated infections of the skin and soft tissue | |
| Infections of the throat | 1000 mg once a day for at least 10 days |

Adults

For adults and adolescents the doctor may prescribe a more appropriate pharmaceutical form, Cefadroxil capsules.

Use in children

The daily dose is calculated according to the weight of the child. Your doctor will calculate the exact dose.

| Indications | Children weighing less than 40 kg, with normal kidney function |
|--|--|
| Uncomplicated infections of the bladder and kidneys | 30-50 mg/kg/day divided into two daily doses |
| Uncomplicated infections of the skin and soft tissue | |
| Infections of the throat | 30 mg/kg/day once a day over at least 10 days |

| Body weight (kg) | General dosing recommendations based on 30-50 mg/kg/day administered <u>twice daily</u> | General dosing recommendations for pharyngitis and tonsillitis based on 30 mg/kg/day administered <u>once daily</u> |
|------------------|---|---|
| 5-6 | 2.5 to 3.75 ml twice daily | 3.75 ml once daily |
| 7-8 | 2.5 to 5 ml twice daily | 5 ml once daily |
| 9-10 | 3.75 to 5 ml twice daily | 6.25 ml once daily |
| 11-12 | 3.75 to 6.25 ml twice daily | 7.5 ml once daily |
| 13-14 | 5 to 7.5 ml twice daily | 8.75 ml once daily |
| 15-16 | 5 to 8.75 ml twice daily | 10 ml once daily |
| 17-18 | 6.25 to 10 ml twice daily | 11.25 ml once daily |
| 19-20 | 6.25 to 10 ml twice daily | 12.5 ml once daily |
| 21-22 | 7.5 to 11.25 ml twice daily | 13.75 ml once daily |
| 23-25 | 7.5 to 12.5 ml twice daily | 15 ml once daily |
| 26-27 | 8.75 to 13.75 ml twice daily | 16.25 ml once daily |
| 28-29 | 8.75 to 15 ml twice daily | 17.5 ml once daily |
| 30-31 | 10 to 16.25 ml twice daily | 18.75 ml once daily |
| 32-33 | 10 to 17.5 ml twice daily | 20 ml once daily |
| 34-35 | 11.25 to 17.5 ml twice daily | 20 ml once daily* |
| 36-37 | 11.25 to 18.75 ml twice daily | 20 ml once daily* |
| 38-40 | 12.5 to 20 ml twice daily | 20 ml once daily* |

*The single dose should not exceed 1000 mg.

- Children should not use Cefadroxil suspension if they weigh less than 40 kg and have kidney problems or are undergoing hemodialysis (a procedure to remove waste from the blood).

Elderly and patients with kidney problems

The dosage should be adjusted.

Patients undergoing hemodialysis

The doctor may adjust the dose during hemodialysis. Patients undergoing hemodialysis are treated with one additional dose of cefadroxil at the end of hemodialysis.

Instructions for reconstitution

Directions for making up the suspension using a graduated plastic measuring cup

Warning:

- A graduated plastic measuring cup is provided; this serves only to measure the amount of water needed to prepare the suspension.
- After preparing the suspension, throw away the plastic measuring cup.
- Never use the graduated plastic measuring cup to give the medicine.

1. Shake the bottle to loosen the granules and remove the cap.
2. Add 60 ml purified water to the bottle, using the plastic measuring cup, and replace the cap. Shake well the bottle to obtain a uniform suspension. The reconstituted suspension is a light lemon yellow viscous liquid with pleasant orange odour.
3. The reconstituted suspension may be stored for 7 days below 30°C or 21 days in a refrigerator (5°C ± 3°C).

Method of administration

Use the plastic graduated oral syringe provided to measure the dose needed. The plastic oral syringe is graduated on 1.25 ml, 2.5 ml, 3.75 ml and 5 ml.

1. Shake the bottle before use and remove the bottle cap.
2. Check how much medicine needs to be taken.
3. Remove cap from the syringe.
4. While the bottle is sitting on a firm, flat surface, insert the syringe into the bottle.
5. Slowly pull back the plunger of the syringe up to the graduation mark on the syringe corresponding to the quantity in milliliters (ml) prescribed by the doctor.
6. Remove the syringe from the bottle.
7. Make sure your child is supported in an upright position.
8. Put the tip of the syringe carefully into your child's mouth. Point the tip of the syringe towards the inside of your child's cheek.
9. Slowly push down the plunger of the syringe: **Do not squirt it out quickly.** The medicine will trickle into your child's mouth.
10. Allow your child some time to swallow the medicine.
11. Repeat steps 4-10 in the same way until the whole dose has been given.
12. Replace the cap on the bottle. Wash the syringe as instructed below.

Cleaning and storing the syringe

1. Pull the plunger out of the syringe and wash both parts thoroughly in fresh drinking water.
2. Allow the plunger and the barrel to dry naturally. Push the plunger back into the syringe. Keep it in a clean safe place with the medicine.

Duration of treatment

Treatment should be continued for at least 2-3 days after the acute symptoms disappear. In case of streptococcal infections, the minimum duration of treatment is 10 days.

If you take more Cefadroxil suspension than you should

If you use more Cefadroxil suspension than prescribed, immediately contact your doctor or hospital. Symptoms of overdose may include: nausea, hallucinations, increased reflexes, decreased consciousness or even coma, problems with the way your kidneys work.

If you forget to take Cefadroxil suspension

If you forget to use this medicine, continue with your normal dosage schedule recommended by your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cefadroxil suspension

It is important that you take the medicine as prescribed by your doctor. Do not suddenly stop using this medication without first talking to your doctor. Otherwise, the symptoms may return.

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 occurs, **stop taking this medicine and consult your doctor immediately or go to the emergency department of the nearest hospital:**

Serious side effects that require emergency care:

Very rare (may affect up to 1 in 10,000 users):

- severe allergic reactions (anaphylaxis) such as:
 - Sudden onset of wheezing and tightness in the chest;
 - Swelling of eyelids, face or lips;
 - Loss of consciousness (fainting).
- severe rash associated with blistering, involving eyes, mouth and throat, or genitals (Stevens-Johnson syndrome).
- severe diarrhea, or if you have blood in your stool, which is an indication of an inflammation of the intestines, called pseudomembranous colitis.

Rare (may affect up to 1 in 1,000 users):

- yellowing of the eyes or skin, changes in blood tests for liver function;
- swelling of the face, tongue and throat;
- decrease in the number of different types of blood cells (symptoms may include fatigue, new infections, fever, sudden sore throat and mouth ulcers), increased number of certain types of white blood cells, decrease in the number of blood cells that are necessary for blood clotting that may result in bruising or bleeding.

If you think you have any of these signs, stop taking this medicine and contact your doctor or the emergency department of the nearest hospital.

Other possible side effects:

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

- feeling or being sick, upset stomach, abdominal pain, swelling of the tongue with redness and pain and diarrhea;
- itching, rash, hives.

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

- thrush, vaginal thrush.

Rare (may affect up to 1 in 1,000 users):

- allergic reactions (which include skin rash, allergic reactions less severe than those mentioned above, hives, itching);
- changes in the way your kidneys work;
- joint pain;
- fever.

Very rare (may affect up to 1 in 10,000 users):

- a type of anemia which can be severe and is caused by the breakdown of red blood cells;
- headache, sleeplessness, dizziness, nervousness;
- tiredness;
- abnormal blood tests.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cefadroxil suspension

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

The product as granules should be stored below 25°C.

Once water is added to the granules to make the viscous liquid suspension, it may be stored for 7 days below 30°C or 21 days in a refrigerator (5°C + 3°C).

Do not use this medicine after the expiry date which is stated on the carton, bottle after "Expiry date:". The expiry date refers to the last day of that month.

After the course of treatment has finished discard any unused suspension. 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 suspension contains

- The active substance is cefadroxil monohydrate.

5 ml oral suspension contains 250 mg cefadroxil, corresponding to 262.39 mg cefadroxil monohydrate.

1 ml oral suspension contains 50 mg cefadroxil, corresponding to 52.478 mg cefadroxil monohydrate

- The other ingredients are: microcrystalline cellulose and carmellose sodium, sucrose, xantan gum E415, sodium benzoate E211, citric acid monohydrate, sodium citrate dihydrate, polysorbate 80, flavour powder orange (flavouring ingredients, maltodextrin, sucrose, soy-lecithin E322, silicon dioxide E551), quinoline yellow al.lake E104.

What Cefadroxil suspension looks like and contents of the pack

Cefadroxil granules for oral suspension are light yellow granules with visible dark yellow granules and pleasant-orange odour.

The granules for oral suspension are packed in a 150 ml brown neutral glass bottle, supplied with an aluminium cap with a polyethylene seal.

Cardboard box contains one (1) bottle, one plastic measuring cup graduated on 60 ml for reconstitution only, one plastic oral 5 ml syringe for dosing graduated on 1.25 ml, 2.5 ml, 3.75 ml and 5 ml, and an instruction leaflet. Each bottle contains 65 g granules for preparation of 100 ml oral suspension.

Marketing Authorisation Holder and Manufacturer

ALKALOID-INT d.o.o.

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

| | |
|-----------------|---|
| UK | Cefadroxil 250 mg/5 ml granules for oral suspension |
| Austria | Valdocef 250 mg/5 ml Granulat zur Herstellung einer Suspension zum Einnehmen |
| Bulgaria | Valdocef 250 mg/5 ml granules for oral suspension |
| Czech Republic | Valdocef 250 mg/5 ml granule pro perorální suspenzi |
| Germany | Valdiocef 250 mg/5 ml Granulat zur Herstellung einer Suspension zum Einnehmen |
| France | Cefadroxil Alkaloid-INT 250 mg/5 ml, granulés pour suspension buvable |
| Poland | Valdocef |
| Romania | Valdocef 250 mg/5 ml granule pentru suspensie orală |
| Slovak Republic | Valdocef, 250 mg/5 ml granulát na perorálnu suspenziu |
| Slovenia | Valdiocef 250 mg/5 ml zrnca za peroralno suspenzijo |

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Advice/medical education

Antibiotics are used to cure infections caused by bacteria (bacterial infections). They are ineffective against infections caused by viruses (viral infections).

If your doctor has prescribed antibiotics, you need them precisely for your current illness.

Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosages;
- schedules;
- duration of treatment.

Consequently, to preserve the efficacy of this drug:

- 1 - Use antibiotics only when prescribed by your doctor.
- 2 - Strictly follow the prescription.
- 3 - Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
- 4 - Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
- 5 - After completion of treatment, return all unused medicines to your pharmacist to ensure they will be correctly thrown away.

