Cefadroxil 500mg Capsules

Patient Information Leaflet

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

Your medicine is called Cefadroxil 500mg Capsules and will be referred to as Cefadroxil Capsules throughout the rest of this leaflet.

In this leaflet:

- What Cefadroxil Capsules are and what they are used for
- 2 Before you take Cefadroxil Capsules
- 3 How to take Cefadroxil Capsules
- Possible side effects
- 5 How to store Cefadroxil Capsules
- 6 Further information

What Cefadroxil Capsules are and what they are used for

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

Cefadroxil kills bacteria and it can be used against various sorts of infections.

Like all antibiotics, Cefadroxil Capsules is only effective against some types of bacteria. So, it is only suitable for treating some types of infection. Cefadroxil Capsules can be used to treat:

- * throat infections
- * chest infections such as bronchitis and some types of pneumonia
- * uncomplicated infections of the bladder and kidneys
- * infections in the skin and the layers just under the skin

2 Before you take Cefadroxil Capsules

Do not take Cefadroxil Capsules

- * You are allergic (hypersensitive) to Cefadroxil Capsules or to any of the other ingredients of this medicine (See Further Information in Section 6).
- * You are allergic (hypersensitive) to any other cephalosporin type of antibiotic
- * You have ever had a severe allergic reaction to any sort of penicillin antibiotic

Not all people who are allergic to penicillins are also allergic to cephalosporins. However, you should not take this medicine if you have ever had a severe allergic reaction to any penicillin. This is because you might also be allergic to this medicine (cross-allergy).

If you are not sure about anything, ask your doctor or pharmacist.

Take special care with this medicine if:

- * You have ever had an allergic reaction to any antibiotic or asthma, tell your doctor or pharmacist before you take this medicine.
- * You have ever been told that your kidneys do not work very well. Also, if you are having any sort of treatment (like dialysis) for kidney failure. You may take cefadroxil but you may need a lower dose.
- * If you have ever had inflammation of your bowel, called colitis or any other severe disease affecting your gut.
- * If you are being treated with cefadroxil for a prolonged period.

 The attending physician must check your blood regularly. Infections due to cefadroxil-resistant micro-organisms (bacteria or germs) may develop.
- * This medicine can alter the results of some blood tests (such as cross-matching blood and the Coombs' test). It is important to tell the doctor that you are taking this medicine if you have to have any of these tests
- * This medicine can also alter the results of urine tests for sugar (such as Benedict's or Fehling's tests). If you have diabetes and routinely test your urine, tell your doctor. This is because other tests may have to be used to monitor your diabetes while you are having this medicine.

Talk to your doctor or pharmacist if any of the above apply to you.

Taking other medicines

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

This medicine can be affected by other medicines that are removed by the kidneys. This is especially so if these other medicines also affect how well kidneys work. There are many medicines that can do this, so check with your doctor or pharmacist before taking this medicine.

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

- * Oral contraceptives (the Pill). These may not work while you are getting Cefadroxil Capsules. You must use another type of contraception while you are receiving this medicine.
- * Anticoagulants (medicines for blood-thinning)
- * Probenecid (for gout). This can delay the time it takes for cefadroxil to leave your body.
- * Cholestyramine (medicine to lower elevated cholesterol levels)

Do not take Cefadroxil Capsules at the same time as:

- * Antibiotics called aminoglycosides (such as gentamycin), polymyxin B and colistin
- * Other antibiotics that inhibit growth of bacteria (such as tetracycline)
- * Water tablets or injections (diuretics) such as furosemide. It might be necessary to check your kidneys often during treatment. This can be done with blood and urine tests.

Leave two or three hours after taking this medicine before taking any of these other medicines.

Taking Cefadroxil Capsules with food and drink

Cefadroxil Capsules may be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding do not take Cefadroxil Capsules before consulting your doctor.

Driving and using machines

You may get headache, dizziness, nervousness, sleeplessness and exhaustion when taking this medicine. This may affect your ability to drive or operate machinery. If this happens, do not drive or use machines.

How to take Cefadroxil Capsules

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

The dispensing label will tell you how much of this medicine you should take and how often you should take. Please read it carefully. The dose your doctor prescribes depends on the type of infection and how bad the infection is. It also depends on how well the kidneys are working. Your doctor will explain this to you.

Children:

- * Children who weigh below 40 kg and need treatment with cefadroxil are usually given liquid oral formulations.
- * In children the dose may be increased up to 100 mg/kg/day
- * For children who weigh below 40 kg and have kidney problems or haemodialysis Cefadroxil Capsules must not be taken.

Elderly and patients with kidney problems or on haemodialysis Adjustment of the dosage is necessary.

Patients with haemodialysis

Patients with haemodialysis are treated with 500 mg to 1000 mg cefadroxil capsules at the end of haemodialysis.

The exact dose will have been worked out by the doctor and shown on the label.

Cefadroxil 500mg Capsules

Patient Information Leaflet (continued)

The following table provides a guide to usual doses:

Indications	Adults and young people who weigh more than 40 kg and have normal renal function
Lower respiratory tract infections	
Urinary tract infections	1000 mg twice a day
Skin and soft tissue infections	
Upper respiratory tract infections (pharyngitis, tonsillitis)	Dosage may be reduced to 1000 mg once a day over at least 10 days

Method of administration

The capsules should be swallowed whole with a glass of water.

Duration of treatment

The treatment should be continued for at least 2-3 days after acute symptoms have disappeared.

In the case of streptococcal infections the minimum duration of therapy should be 10 days.

If you take more of this medicine than you should

If you have taken too much of this medicine, contact your doctor or hospital as soon as possible. Symptoms of overdosage may be nausea, hallucinations, increased reflexes, clouding of consciousness or even coma, disorders of kidney function.

If you forget to take this medicine

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

If you stop taking this medicine

It is important that you take your medicine in accordance with the doctor's instructions. Do not suddenly stop using this medicine without discussing it first with your doctor. Otherwise symptoms may return.

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

Possible side effects

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

Serious side effects

If any of the following happens, stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital:

Very rare serious side effects (affects less than 1 patient in 10,000): Severe allergic reactions (anaphylactic shock) to this medicine are. These can include:

- * Sudden wheeziness and tightness of chest
- * Swelling of eyelids, face or lips
- * Severe skin rashes that can blister and may involve the eyes, mouth and throat and genitals.
- * Loss of consciousness (fainting).

All of these allergic reactions need urgent medical attention. If you think you are having any of these types of reaction, stop taking this medicine and contact your doctor or your nearest hospital accident and emergency department.

Other possible side effects:

Common side effects (affects 1 to 10 patients in 100) include:

- * nausea, vomiting, stomach discomfort, abdominal pain, diarrhoea and swollen, red, sore tongue; If you have severe diarrhoea or if you see blood in your diarrhoea you should stop taking this medicine and talk to your doctor immediately.
- * itching, itchy rash;

Uncommon side effects (affects 1 to 10 patients in 1,000) include: Having a course of Cefadroxil Capsules can temporarily increase the chance that you can get infections caused by other sorts of germs. For example, thrush may occur.

Rare side effects (affects 1 to 10 patients in 10,000) include:

- * anaemia, drops in the numbers of different cells in the blood (symptoms can include tiredness, new infections, fever and easy bruising or bleeding), increases in some types of white blood cells, decreases in the numbers of small cells that are needed for clotting of the blood;
- * hypersensitivity reactions (These are skin rashes that are less severe allergic reactions than mentioned above, lumpy rash (hives), itching);
- * yellow eyes or skin, changes in blood tests that check how your liver is working;
- * changes in kidney function;
- * joint problem;
- * fever, feeling or being sick, weakness and a feeling of generally being

Very rare side effects (affects less than 1 patient in 10,000) include:

- * anaphylactic reactions (e.g. bronchospasms, purpura and edema of the face and extremities);
- * a type of anaemia that can be severe and is caused by red blood cells breaking up; If you are having a blood test for any reason, tell the person who is taking your blood sample that you are taking this medicine as it may affect your result.
- * headaches, sleeplessness, dizziness, nervousness;
- * inflammation of the gut called pseudomembranous colitis;
- * rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever;
- * abnormal blood tests:

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

How to store Cefadroxil Capsules

- * KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Store in the original package.
- Do not take use Cefadroxil Capsules after the expiry date shown on the carton and blister label. If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- If your medicine becomes discoloured or show any other signs of deterioration, ask your pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Further information

What Cefadroxil Capsules contains:

The active substance is cefadroxil. One capsule contains 500 mg cefadroxil (as monohydrate).

The other ingredients are: magnesium stearate, sodium lauryl sulfate, microcrystalline cellulose, titanium dioxide (E171), gelatine.

What Cefadroxil Capsules looks like and contents of the pack Each capsule is white, opaque containing white to light yellow powder.

Avaliable in blister packs of 20 capsules.

Manufacturer and Licence Holder

This medicine is manufactured by Sandoz GmbH, Biochemiestrasse 10. A-6250 Kundl, Austria and is procured from within the EU. Product Licence Holder LTT Pharma Limited, B98 0RE and repackaged by Lexon (UK) Limited Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 33723/0189

Cefadroxil 500mg Capsules

Blind or partially sighted? Is this leaflet hard to see or read? Phone Lexon (UK) Limited, Tel: 01527 505414 for help.

Revision date: 09/12/14