

NORMOCEF 500 mg film-coated tablets

cefuroxime

Read this leaflet carefully before using the medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if the signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

- 1. What NORMOCEF is and what it is used for**
- 2. What you need to know before you take NORMOCEF**
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1. What NORMOCEF is and what it is used for

Cefuroxime 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.

Antibiotics are used to treat bacterial infections and are not used to treat viral infections (like a flu or a cold). It is important to follow the dose related instructions, the administration interval and the duration of the treatment indicated by your doctor.

Do not keep or reuse this medicine. Once finish your treatment, you have left antibiotics, return it to the pharmacy for its correct disposal. Do not throw away any medicines via wastewater or household waste.

NORMOCEF is used to treat infections of:

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

NORMOCEF can also be used:

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

2. What you need to know before you take NORMOCEF

Do not take NORMOCEF

- If you are allergic (hypersensitive) to any cephalosporins antibiotics or any of the other ingredients of this medicine (see Section 6).
- 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 NORMOCEF until you have checked with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking NORMOCEF

NORMOCEF 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 NORMOCEF. 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

NORMOCEF 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 NORMOCEF

Other medicines and NORMOCEF

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

Medicines used to **reduce the amount of acid in your stomach** (e.g. antacids used to treat **heartburn**) can affect how NORMOCEF works.

Probenecid

Oral anticoagulants

- **Tell your doctor or pharmacist** if you are taking any medicine like this.

Contraceptive pills

NORMOCEF may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with NORMOCEF you also need to use a barrier method of contraception (such as condoms). Ask your doctor for advice.

Pregnancy, breast-feeding and fertility

Tell your doctor before you take NORMOCEF:

- If you are pregnant, think you might be pregnant or are planning to become pregnant
- If you are breast-feeding

Your doctor will consider the benefit of treating you with NORMOCEF against the risk to your baby.

Driving and using machines

NORMOCEF **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.

3. How to take NORMOCEF

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

Take NORMOCEF after food. This will help to make the treatment more effective.

Swallow NORMOCEF tablets whole with some water.

Don't chew, crush or split the tablets. This may make the treatment less effective.

The usual dose

Adults

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

Children

The usual dose of NORMOCEF 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.

NORMOCEF is not recommended for children aged under **3 months**, as the 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 NORMOCEF than you should

If you take too much NORMOCEF 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 NORMOCEF pack.

If you forget to take NORMOCEF

Do not take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

Don't stop NORMOCEF without advice

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

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 NORMOCEF 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 dark ring around the edge).
- **a widespread rash with blisters and peeling skin.** (These may be the signs of *Stevens-Johnson syndrome* or *toxic epidermal necrolysis*).
- **fungal infections.** Medicines like NORMOCEF 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 NORMOCEF for a long time.
- **severe diarrhoea (*pseudomembranous colitis*).** Medicines like NORMOCEF 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 NORMOCEF 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.**

Common side effects

This may affect **up to 1 in 10** people:

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

Common side effects may show up in blood tests:

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

Uncommon side effects

These 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

Other side effects

Other side effects have occurred in a very small number of people, but their exact frequency is unknown:

- severe diarrhoea (*pseudomembranous colitis*)
- allergic reactions
- skin reaction (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 the blood tests:

- red blood cells destroyed too quickly (*haemolytic anaemia*)

If you get any side effects

→ **Tell your doctor or pharmacist.** This includes any possible side effects not listed in this leaflet.

5. How to store NORMOCEF

Keep NORMOCEF out of the sight and reach of children.

Store below 30°C. Store in its original package. Protect from humidity.

Do not use this medicine after the expiry date stated on the carton. 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 NORMOCEF contains

The active substance is cefuroxime (I.N.N.) (axetil).

NORMOCEF 500 mg film-coated tablets: Each coated tablet contains 500 mg of cefuroxime (axetil).

The other components (excipients) are: microcrystalline cellulose, sodium croscarmellose, sodium laurilsulphate, colloidal silica, hydrogenated vegetable oil, hypromellose, and titanium dioxide (E-171).

What NORMOCEF looks like and contents of the pack

NORMOCEF is presented in white or almost white, elongated, biconvex, scored and marked film-coated tablets.

NORMOCEF 500 mg film-coated tablets: The tablets are white or almost white, elongated, biconvex and screen-printed. Each package contains 10, 15, 20 or 500 tablets.

Not all the pack sizes are marketed in all countries.

Marketing authorisation holder and manufacturer:

LABORATORIOS NORMON, S.A.

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This leaflet was last reviewed in January 2014