

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ceporex Capsules 250mg and 500mg (cefalexin)

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

What is in this leaflet:

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

1. WHAT CEPOREX IS AND WHAT IT IS USED FOR

This medicine is called Ceporex Capsules. Ceporex Capsules contain the active substance cefalexin, which belongs to a group of medicines called cephalosporin antibiotics.

Cefalexin is used to kill bacteria that cause infections in your body. These include ear, nose, throat and chest infections, urinary tract infections, infections of the bone, skin and soft tissue and genital infections, for example gonorrhoea or infections resulting from childbirth. Ceporex may also be prescribed to treat dental infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEPOREX CAPSULES

Do not take Ceporex Capsules

- if you are allergic (hypersensitive) to any cephalosporin antibiotic, such as cefalexin, cefuroxime, cefradine or cefaclor

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine:

- if you are allergic to any penicillin antibiotic, such as penicillin, ampicillin, amoxicillin or flucloxacillin
- if you suffer from any kidney problems
- if you are on kidney dialysis
- if you are diabetic (cefalexin can interfere with some urine sugar tests)-

- If you develop diarrhoea

If any of the above apply to you, it is important that you tell your doctor or pharmacist before taking Ceporex Capsules and they will decide what to do. It may still be safe for you to take Ceporex Capsules.

If you are having a blood test, it is important to tell your doctor that you are taking this medicine as it may affect the result.

Other medicines and Ceporex Capsules

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

This is especially important if you are taking:

- gentamicin (an antibiotic used to treat severe infections)
- a medicine called probenecid (used to treat gout)
- metformin (used in the treatment of diabetes)
- diuretic “water” tablets (medicines which reduce water retention by increasing the volume of urine, e.g. furosemide, ethacrynic acid)
- Anticoagulants (medicines that prevent the clotting of blood (e.e warfarin)
- Any other antibiotics (e.g. aminoglycosides, polymyxin, colistin)
- combined oral contraceptives. Ceporex Capsules may reduce the effectiveness of combined oral contraceptives. Therefore, a second non-hormonal form of contraception, such as a condom, should be used while taking Ceporex Capsules and for seven days after the course of Ceporex has stopped. You should discuss this with your doctor or pharmacist. The advice differs when the course of Ceporex lasts for three weeks or more; discuss with your doctor or pharmacist.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, or are breast-feeding, you should ask your doctor or pharmacist for advice before taking Ceporex or any other medicine.

Driving and using machines

Ceporex may make cause side effects such as dizziness, fatigue and confusion and may affect your ability to drive or operate machinery. If affected, do not drive or operate machines

3. HOW TO TAKE CEPOREX CAPSULES

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

Ceporex Capsules should be taken by mouth (orally).

The usual dose for adults and children over 12 years old is 1g twice a day. In more severe infections the dosage may be increased to 1g three times a day or 3g twice a day, depending on the severity of the infection. The usual dose for children will depend on the child’s weight.

For patients suffering from kidney disease and/or undergoing dialysis, your doctor will tailor your dosing schedule and dose amount to suit your condition.

It is important to read the label on your medicine, as it will tell you precisely what dose to take.

If you take more Ceporex Capsules than you should

If you take too many capsules contact your nearest hospital casualty department or tell your doctor or pharmacist immediately. Take this leaflet and any remaining capsules with you.

If you forget to take Ceporex Capsules

If you forget to take your medicine, just take your normal dose as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ceporex Capsules

Keep taking the medicine until you have finished the full course of treatment that your doctor has prescribed for you. Do not stop taking the medicine, even if you feel better. This will make sure that the infection has completely cleared.

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

4. POSSIBLE SIDE EFFECTS

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

If you get any of the following side effects you should **stop taking Ceporex** and tell your doctor immediately or go to the casualty department of your nearest hospital, as these may be signs of a serious allergic reaction:

- a skin rash resembling hives or nettle rash
- itchy and/or scaly skin
- red or purple patches on the skin
- joint pain
- difficulty breathing or wheezing
- fever
- swelling of the tongue, face, lips or throat
- feeling faint accompanied by one or some of the other reactions above.

Tell your doctor immediately if you notice the following as you may require urgent medical attention:

- diarrhoea which becomes severe or contains blood or mucus

Other side effects of Ceporex Capsules include:

- diarrhoea (which may be bloody)
- dizziness

- feeling sick or being sick
- stomach discomfort
- headache
- kidney problems
- jaundice (yellowing of the skin and the whites of the eyes)
- liver problems
- seeing and hearing things which are not there (hallucinations)
- Itching
- Red wheals on the skin (Urticaria) (alone)
- nervousness
- confusion, agitation, tiredness
- difficulty sleeping
- muscle tightness
- hyperactivity
- irritation or inflammation of the vagina, including thrush or discharge
- dyspepsia
- Itching around the genitals or anus
- Pain or swelling in the joints

Very rarely this medicine may lower the levels of certain blood cells, these will return to normal when you stop taking Ceporex Capsules (symptoms may include sore throat, mouth ulcers or feeling weak).

Reporting of side effects

If you get any side effects, talk to your doctor or 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.

5. HOW TO STORE CEPOREX CAPSULES

Keep out of the sight and reach of children.

Do not use Ceporex Capsules after the expiry date, which is stated on the label and carton. The expiry date refers to the last day of that month.

Store your capsules below 30°C. Store in the original packaging in order to protect the capsules from light.

Do not use Ceporex Capsules if you notice that the pack or any of the capsules are damaged.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ceporex Capsules contain

The active substance in Ceporex Capsules is called cefalexin. The capsules contain either 250mg or 500mg of cefalexin. The capsules also contain magnesium stearate. The capsule shells are made of gelatin and contain red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172) and titanium dioxide (E171) as colouring

agents. The printing ink on the capsule shells contains shellac glaze 45%, titanium dioxide (E171), purified water, 2-ethoxyethanol, lecithin (soya) and simethicone.

What Ceporex Capsules look like and the contents of the pack

Ceporex Capsules 250mg are caramel and grey coloured hard gelatin capsules with ‘Ceporex 250 Galen’ printed in white.

Ceporex Capsules 500mg are caramel and grey coloured hard gelatin capsules with ‘Ceporex 500 Galen’ printed in white.

Ceporex Capsules 250mg and 500mg are available in packs containing 20, 28, 100 and 500 capsules. Not all pack sizes may be marketed. (Delete this section as appropriate.)

Marketing Authorisation Holder

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