

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Ceporex Tablets 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 Tablets. Ceporex Tablets 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 TABLETS**

#### **Do not take Ceporex Tablets**

- 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 Tablets and they will decide what to do. It may still be safe for you to take Ceporex Tablets.

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 Tablets**

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 Tablets 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 Tablets 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 drive or operate machines

## **3. HOW TO TAKE CEPOREX TABLETS**

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

Ceporex Tablets 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 Tablets than you should**

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

**If you forget to take Ceporex Tablets**

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 Tablets**

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 Tablets include:

- diarrhoea (which may be bloody)
- 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)
- dizziness
- 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 Tablets (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](http://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 TABLETS**

Keep out of the sight and of children.

Do not use Ceporex Tablets 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 tablets below 30°C. Store in the original packaging in order to protect the tablets from light.

Do not use Ceporex Tablets if you notice that the pack or any of the tablets 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 Tablets contain**

The active substance in Ceporex Tablets is called cefalexin. The tablets contain either 250mg or 500mg of cefalexin. The tablets also contain magnesium stearate,

microcrystalline cellulose, hydroxypropyl methylcellulose, macrogol 400, erythrosine (E127), indigo carmine (E132) and titanium dioxide (E171).

**What Ceporex Tablets look like and the contents of the pack**

Ceporex Tablets 250mg are pink film-coated tablets with ‘Ceporex 250’ engraved on one side.

Ceporex Tablets 500mg are pink film-coated tablets with ‘Ceporex 500’ engraved on one side and ‘Galen’ on the other side.

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

**Marketing Authorisation Holder**

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