PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CeporexTM tablets 1g

(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.

If this medicine was prescribed by your DENTIST, please read **dentist** wherever you see **doctor** in this leaflet.

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 Tablets
- 3. How to take Ceporex Tablets
- 4. Possible side effects
- 5. How to store Ceporex Tablets
- 6. Contents of the pack and other information

1. WHAT CEPOREX IS AND WHAT IT IS USED FOR

Ceporex tablets contain cefalexin which is an antibiotic belonging to the cephalosporin class. Antibiotics are used to kill the bacteria or "germs" which cause infections. Ceporex is used to treat infections of the chest, ear, nose, throat, urinary systems, bone, flesh and skin. Genital infections, e.g. gonorrhoea and those resulting from childbirth, are also treated with Ceporex. Your doctor has prescribed this medicine because he has found that you have one of these infections.

You may also be prescribed Ceporex by your dentist 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 flucloxicillin
- 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 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:

- gentamycin (an antibiotic used in severe infections) taken with cefalexin can cause a reduction of potassium in the blood. Low blood potassium can cause muscle weakness or cramps.
- probenecid, usually used in the treatment of gout; taking probenecid with cefalexin increases the action of the cefalexin and the length of time the drug stays in your system.
- 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. If you answer "YES" to any of these questions, check with your doctor first BEFORE you take any of your medicine. Your doctor may decide that the benefits of taking Ceporex outweigh any risks that there may be.

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.

Look at the label - it should say WHO should take it, HOW MANY tablets and WHEN. If it does not say all this or you are not sure, ask your doctor or pharmacist. If prescribed for a CHILD, make sure the medicine is taken as the label says.

Swallow each tablet **whole** with a drink of water.

The usual doses are as follows:

adults and children over 12 years of age - 1g (1000mg) twice daily. For some infections higher doses of 1g three times a day or 3g twice a day may be required

children 7 to 12 years - 500mg to 1g twice daily. children 1 to 6 years - 250mg to 500mg twice daily. children less than 1 year - 62.5mg to 125mg twice daily.

Your dose, number of times a day, and length of time you need to take the medicine varies depending on your infection. It is important therefore, that you follow the instructions on the label carefully.

For most infections, treatment should continue for at least two days **after** everything has returned to normal, but for more complicated infections treatment for two weeks is recommended.

If you have kidney disease your dose may be lowered.

If you are receiving intermittent dialysis, you should be given an additional dose of Ceporex after each dialysis.

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:

- sudden wheezing or difficulty breathing
- swelling of your eyelids, face, lips, mouth or throat
- a rash resembling hives or nettle rash
- if your skin becomes itchy, red or swollen or you develop blisters
- pain or swelling in your joints or swollen glands
- fever
- 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. 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.

Ceporex tablets should be stored below 30°C and protected from light.

If your doctor stops your treatment, return any unused tablets to your pharmacist for safe disposal. Only keep your tablets if your doctor tells you to.

Do not take the tablets after the expiry date on the label or carton.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ceporex tablets contain

The active ingredient is cefalexin 1gram

The active ingredient in this medicine is cefalexin. This is the new name for cephalexin.

The ingredient itself has not changed.

Other ingredients include magnesium stearate and microcrystalline cellulose. The tablet coating consists of hydroxypropyl methylcellulose, macrogol-400 and Opadry OY-S-6927 which contains erythrosine (E127), indigo carmine (E132) and titanium dioxide (E171).

What Ceporex Tablets look like and the contents of the pack

Ceporex Tablets are pink film-coated tablets.

Ceporex tablets come in packs of 4/14/20/28/100/500 tablets

Not all pack sizes may be marketed

Marketing Authorisation holder

Co-Pharma Limited

Unit 4, Metro Centre.

Tolpits Lane

Watford

Herts, UK

WD18 9SS

Manufacturer

Almac Pharma Services Limited, Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, UK.

The information in this leaflet was last revised in April 2016.

The information provided applies only to CEPOREX TABLETS.