PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Ceporex syrup 250mg

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

1. WHAT CEPOREX SYRUP IS AND WHAT IT IS USED FOR

Ceporex syrup contains cefalexin which is an antibiotic belonging to the cephalosporin class. Antibiotics are used to kill the bacteria or "germs" which cause infections. Ceporex syrup is used to treat infections of the chest, ear, nose, throat, urinary systems, bone, flesh and skin. Genital infections, eg gonorrheoa 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, or if you have heart disease you may be given this medicine before a more complicated dental procedure to prevent further heart problems.

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

Do not take Ceporex Syrup

- 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 Syrup

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

Ceporex Syrup contains sunset yellow (E110)

Ceporex Syrup contains sunset yellow colouring (E110) which may cause an allergic reaction including asthma, although this allergy is more common in people allergic to aspirin.

- If you have been told by your doctor that you have an intolerance to some sugars (hereditary fructose intolerance, glucose-galactose malabsorption syndrome, or sucrose-isomaltase deficiency). You should talk to your doctor before taking this medicine. Ceporex 250mg contains 2.830g of sucrose per 5ml of suspension.

3 HOW TO TAKE CEPOREX SYRUP

Always take Ceporex Syrup 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 5ml spoonfuls 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.

Use the 5ml spoon that the pharmacist has given you to measure the amount of medicine to take. It is best to take the syrup as it is. Do NOT add water or other drinks to the bottle, that may stop it working properly.

The usual doses to be taken by mouth are as follows: adults and children over 12 years of age - 1g (1000mg) twice daily. 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.

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 syrup after each dialysis.

If you forget to take Ceporex Syrup

If you forget to take a dose, it is important to take another as soon as you remember. Then go on as before.

If you take more Ceporex Syrup than you should

It is important to stick to the dose on the label of your medicine. Taking more than this dose is unlikely to be dangerous unless a lot of the syrup is taken at once. In that case, don't delay; ask your doctor what to do or contact your nearest hospital emergency department.

If you stop taking Ceporex Syrup

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 Syrup (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 SYRUP

Keep out of the sight and of children.

Your Ceporex will have already been made up by the pharmacist before it was given to you. Store the made up syrup at 2°C - 8°C in a refrigerator.

Once dispensed by your pharmacist, the syrup will only keep for 10 days. Any syrup remaining after this time should be given back to your pharmacist for safe disposal.

The pack should not be dispensed after the expiry date printed on the bottle label or carton.

If for any reason you have been given Ceporex still in its granule form, it should be stored at room temperature (below 25°C).

If your doctor stops your treatment, return any unused medicine to your pharmacist for safe disposal.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What your Ceporex syrup contains

When made up with water, each 5ml spoonful contains:

The active ingredient - cefalexin 250mg.

Other ingredients - sucrose, acacia powder, citric acid, sodium citrate, sodium calcium edetate, sunset yellow colouring (E110) and orange bramble flavouring.

Ceporex Syrup is prepared (usually done by your pharmacist) by adding water to the granules to give an orange-flavoured and coloured suspension.

Each bottle contains granules to make 100ml of syrup.

Marketing Authorisation holder

Co-pharma Limited, Unit 4, Metro Centre, Tolpits Lane, Watford, Herts, UK WD18 9SS.

Manufacturer

PDMS, Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, UK.

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The information supplied applies only to CEPOREX SYRUP.