

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Xorimax

Xorimax 250mg Film-coated tablets

Xorimax 500mg Film-coated tablets

CEFUROXIME AXETIL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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

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### What is in this leaflet?

1. What Xorimax Tablets are and what they are used for
2. Before you take Xorimax Tablets
3. How to take Xorimax Tablets
4. Possible side effects
5. How to store Xorimax Tablets

#### *1. WHAT XORIMAX TABLETS ARE AND WHAT THEY ARE USED FOR*

Cefuroxime is an antibiotic. It belongs to a group of antibiotics that are called cephalosporins. These types of antibiotics are similar to penicillin.

Cefuroxime works by killing some types of bacteria that can cause various sorts of infections in people. Like all antibiotics, cefuroxime is only able to kill some types of bacteria so is only suitable for treating some types of infection.

Cefuroxime is used to treat:

- Throat infections
- Infections of the sinuses
- Ear infections
- Bronchitis and pneumonia
- Infections of the skin and layers just under the skin
- Gonorrhoea (a sexually transmitted disease) when it has not spread from the lower genital organs in men or women

- Infections of the bladder or kidneys
- Lyme disease when it is still in the early stages and to prevent later complications in people who are at least 12 years old

## *2. BEFORE YOU TAKE XORIMAX TABLETS*

### ***Do not take Xorimax Tablets***

- If you are allergic (hypersensitive) to cefuroxime, to any other cephalosporin type of antibiotic or any of the other ingredients
- If you are allergic to penicillin

### ***Take special care with Xorimax Tablets***

#### ***Before you use Xorimax Tablets you should tell your doctor:***

- If you have kidney problems
- If you are having dialysis

You may still be given cefuroxime but you may need a lower dose. You should also be aware that:

- Cefuroxime can alter the results of some blood tests. These include cross-matching blood and the Coombs' test
- Cefuroxime can also alter the results of some blood or urine tests for sugar. If you are a diabetic, other tests may have to be used to monitor your diabetes while you are having cefuroxime
- Cefuroxime reduces efficacy of oral contraceptives in which case you should take other precautions to prevent pregnancy

If any of the above apply to you, you should talk to your doctor who will decide what to do. Please also note that Cefuroxime should not be given to a child under 3 months old. Also, that the tablets are not suitable for children who are unable to take tablets.

### ***Taking other medicines***

Cefuroxime may interact with some other medicines. It is important to tell your doctor or pharmacist if you are taking any other medicine especially the following:

- Probenecid (a medicine used for the treatment of gout and gouty arthritis). This medicine could increase the amount of cefuroxime in your blood so you may need a lower dose if you also take probenecid.

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

### ***Pregnancy and breast-feeding***

Cefuroxime should not be used during pregnancy or if you are breast-feeding unless this has been discussed with your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

### ***Driving and using machines***

Taking this medicine should not affect your ability to drive or use machinery. However, in some people your medicine may cause dizziness, if you are affected do not drive or use machinery.

### 3. How to take Xorimax Tablets

Always take Xorimax Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Please read the label on the carton.

Xorimax Tablets should be taken with food and should be swallowed whole with water. Do not crush the tablets. Keep taking the tablets for as long as your doctor tells you, even if you start to feel better.

#### **Adults, including the elderly**

- The usual dose is 250mg twice daily, for about seven days. However, it can range from 125mg twice daily for urinary tract infections to 500mg twice daily for chest infections
- Gonorrhoea can be treated with a single dose of 1000mg
- Lyme disease in people of at least 12 years old is usually treated with 500mg twice daily for about 20 days Sometimes Xorimax Tablets are given after cefuroxime injections.

#### **Children**

- The usual dose is 125mg twice daily. Sometimes the dose is calculated from the body weight and is 10 milligrams per kilogram of body weight with a maximum of 250mg each day
- For ear infections (otitis media), children under the age of 2 but at least 3 months old are usually given 125mg twice daily or 10 milligrams per kilogram of body weight to a maximum of 250mg daily. Children over the age of 2 are given 250mg twice daily or 15 milligrams per kilogram to a maximum of 500mg daily for ear infections (otitis media)

#### **Patients with reduced kidney function**

Your doctor may choose to use a lower dose.

#### **If you take more Xorimax Tablets than you should**

It is important to stick to the dose on the label of your medicine. If you have taken more tablets than you should have or if someone else has swallowed some of your tablets, contact your doctor, pharmacist or hospital emergency department immediately. Always take any tablets left over with you and also the box, as this will allow easier identification of the tablets. Symptoms of overdose may include fits.

#### **If you forget to take Xorimax Tablets**

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take that dose as soon as you remember. Then take the next dose at the usual time.

Do not stop taking Xorimax Tablets even if you feel better. Continue taking the tablets until you have completed the whole course. If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Xorimax Tablets can cause side effects, although not everybody gets them. Contact your doctor or go to the nearest hospital immediately, and stop taking these tablets, if you experience any of the following side effects:

- Allergic (hypersensitivity) reactions, such as sudden wheeziness and tightness of chest, swelling of eyelids, face or lips, loss of consciousness
- Diarrhoea, especially if severe and/or bloody

- Rashes (rarely peeling or blistered rashes), which may involve the eyes, mouth and throat and genital organs, hives, itching

The following side effects may occur but it is not necessary to contact your doctor immediately: Common side effects (affecting less than 1 in 10 but more than 1 in 100 people):

- An increase in the numbers of a type of white blood cell called eosinophils
- Headache
- A feeling of dizziness or 'spinning'
- Feeling sick
- Abdominal pain, diarrhoea
- Increases in the level of substances (enzymes) in your blood that measure how your liver is working
- Thrush infections

**Uncommon side effects** (affecting less than 1 in 10 but more than 1 in 1000 people):

- A drop in the numbers of white blood cells (with an increased risk of getting other infections) or a drop in the numbers of very small blood cells called platelets (which can cause easy bruising or prolonged bleeding)
- Being sick
- False positive Coombs' test (a blood test)

**Rare side effects** (affecting less than 1 in 1000 people):

- Inflammation of the kidneys that can stop them from working properly

**Very rare side effects** (affecting less than 1 in 10,000 people):

- Anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- Hepatitis (inflammation of the liver), jaundice (yellowing of the skin or the whites of the eyes)
- Pains in the joints with a general unwell feeling
- Fever (raised temperature)

If you are given cefuroxime to treat Lyme disease, it is possible that you could feel generally

unwell, possibly with fevers and body aches for a short period.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE XORIMAX TABLETS**

Keep out of the reach and sight of children.

Do not use the product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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.

***This leaflet was last approved in July 2014.***