Xorimax® 250 mg – tablets

Active ingredient: cefuroxime axetil

SANDOZ

Composition
Medicinally active ingredient:
Xorimax 250 mg - 1 coated tablet contains 300.72 mg cefuroxime axetil, equivalent to 250 mg cefuroxime.
Other ingredients:
aspartame, microcrystalline cellulose, copovidone, croscarmellose sodium, crospovidone, magnesium stearate, mannitol, sodium dodecyl sulphate, colloidal anhydrous silica, soluble starch, talc, titanium(IV) oxide (E171)

Presentation
Xorimax 250 mg is available in packs containing 10, 12 or 24 coated tablets.

Pharmaceutical and therapeutic category or mode of action
Antibiotic
Cephalosporin for oral use.

Marketing authorization holder
Sandoz GmbH, Kundl - Austria

Manufacturer
PenCef Pharma GmbH, Göttingen - Germany

Indications
Infections caused by cefuroxime-sensitive organisms:
- infections of the upper airways including throat and ear infections (otitis media, sinusitis, pharyngitis, tonsillitis)
- infections of the lower airways (acute exacerbation of chronic bronchitis, pneumonia)
- infections of the skin and soft tissue
- infections of the kidneys and/or urinary tract
- acute, uncomplicated gonorrhoea

Contraindications
When must Xorimax 250 mg not be used?
Xorimax 250 mg must not be administered to patients with confirmed hypersensitivity to cefuroxime axetil, other cephalosporins or any of the other ingredients.
Note:
Patients who are allergic to penicillin or other β-lactam antibiotics may also be allergic to cefuroxime axetil.

Xorimax 250 mg is unsuitable for children below the age of 5 years.

Experience with regard to children below the age of 3 months is as yet insufficient. Children of this age group must therefore not be treated with cefuroxime axetil.
This medicine contains a phenylalanine source. In connexion with the hereditary metabolic disease phenylketonuria, it must be taken into account that this medicine contains the sweetener aspartame and that aspartame is converted to phenylalanine. Patients with phenylketonuria must not take Xorimax 250 mg. This medicine contains 0.3 mg aspartame, equivalent to 0.2 mg phenylalanine, per coated tablet.

The safety and efficacy of the use of Xorimax 250 mg have been established only for the dosages mentioned in the section "Dosage instructions, mode and duration of administration".

When may Xorimax 250 mg only be used with particular care?

Particular care is required if Xorimax 250 mg is administered to persons with a history of pronounced allergies or asthma or who have previously developed a shock-type allergic (anaphylactic) reaction to penicillin.

What must be borne in mind in the case of patients with impaired kidney and liver function?

Specific dosage guidelines (see section "Dosage instructions, mode and duration of administration" and section "Overdosage") apply to patients with markedly impaired kidney function (glomerular filtration rate below 10 ml/min).
No particular precautionary measures are required for patients with impaired liver function.

What must be noted during pregnancy and breast-feeding?

Animal experiments yielded no indication of developmental toxicity for cefuroxime axetil.
Cefuroxime passes into breast milk.
Xorimax 250 mg should therefore be used during pregnancy, especially during the first three months, and while breast-feeding only after a careful risk/benefit assessment by the treating physician.

What must be considered in relation to infants, children and the elderly?
Specific dosage guidelines (see section "Dosage instructions, mode and duration of administration") apply to children and infants.
No particular precautionary measures are required for the elderly unless kidney function is severly impaired.

Precautions for use and special warnings

What precautions must be taken?

Patients who are susceptible to allergic reactions (e.g. hayfever, bronchial asthma, nettle rash) are at an increased risk of serious hypersensitivity reactions, for which reason Xorimax 250 mg should be used with particular caution in such cases.

Patients who are treated either at the same time or afterwards with medicines with a potential to damage the kidneys (e.g. aminoglycosides) or with highly effective diuretics (medicines that help reduce the amount of water in the body, such as furosemide, ethacrynic acid) require special monitoring of their kidney function, as it cannot be ruled out that such combinations may adversely affect kidney function.

If therapy exceeds a duration of 10 days, the blood count must be checked (see also section "Side effects").

Any use of antibiotics may lead to the multiplication of organisms which are insensitive to the medicine used.
Attention must be paid to signs which indicate possible secondary infection with such organisms (fungal infection of mucous membranes accompanied by reddening and white coating on the mucous membranes). Secondary infections must be treated appropriately.

Xorimax 250 mg tablets contain a source of phenylalanine. May be harmful for people with phenylketonuria.

What must be borne in mind when driving a vehicle, operating machinery and working in the absence of a secure support?

Previous experience has shown that low to medium doses of Xorimax 250 mg do not influence concentration or speed of reactions. Side effects such as anaphylactic shock and dizziness (see relevant section and also section "Misuse and overdosage"), which make it impossible to accomplish the mentioned activities, have been observed in a few cases.

Interactions with other medicines

What must be borne in mind if other medicines are being used at the same time as Xorimax 250 mg or have been used until recently?

Cefuroxime axetil/probenecid
The simultaneous administration of the anti-gout agent probenecid leads to elevated cefuroxime concentrations in the serum and consequently to a prolongation of effect, as probenecid inhibits the excretion of cefuroxime axetil via the kidneys.

Cefuroxime axetil/contraceptives
The reliability of the contraceptive effect of oral contraceptives ('the pill') may be impaired on treatment at the same time with Xorimax 250 mg. Other contraceptive measures should therefore be taken in addition during treatment with Xorimax 250 mg.

Cefuroxime axetil/potentially kidney-damaging medicines and loop diuretics
Xorimax 250 mg may intensify the potentially kidney-damaging effect of aminoglycosides and of highly effective diuretics (such as furosemide and ethacrynic acid). These medicines may, especially in patients with impaired kidney function, only be used at the same time if kidney function is monitored.

Interference with laboratory diagnostic findings:

The Coombs´ test may yield false-positive results during treatment with Xorimax 250 mg. Interference may likewise occur with nonenzymatic methods used for the determination of sugar levels in the urine and blood, and lead to false-positive or false-negative results. Determination of sugar levels in the urine and blood must therefore be based on enzymatic methods during therapy with Xorimax 250 mg.

Dosage instructions, mode and duration of administration
The following information applies, unless your doctor has prescribed Xorimax 250 mg differently. Please comply with the dosage instructions, as Xorimax 250 mg may otherwise not have the proper effect.

What amounts of Xorimax 250 mg should you take and how often?

Dosage and mode of administration depend on the severity of the infection, the sensitivity of the organism and the patient´s clinical state.

ADULTS and children older than 12 years

Type of infection	Dose and dosing interval
Infections of the upper airways: including the region of the throat and ears (otitis media, sinusitis, pharyngitis, tonsillitis)	2 x 300.72 mg to 2 x 601.44 mg cefuroxime axetil (= 2 x 250 mg to 2 x 500 mg cefuroxime), i.e. 2 x a day 1 Xorimax 250 mg tablet or 2 x a day 2 Xorimax 250 mg tablets
Infection of the lower airways: Acute form of chronic bronchitis	2 x 300.72 mg to 2 x 601.44 mg cefuroxime axetil (= 2 x 250 mg to 2 x 500 mg cefuroxime), i.e. 2 x a day 1 Xorimax 250 mg tablet or 2 x a day 2 Xorimax 250 mg tablets, depending on the severity of the clinical picture and the underlying disorder
Pneumonia	2 x 601.44 mg cefuroxime axetil (= 2 x 500 mg cefuroxime), i.e. 2 x a day 2 Xorimax 250 mg tablets
Infections of the skin and soft tissue	2 x 300.72 mg to 2 x 601.44 mg cefuroxime axetil (= 2 x 250 mg to 2 x 500 mg cefuroxime), i.e. 2 x a day 1 Xorimax 250 mg tablet or 2 x a day 2 Xorimax 250 mg tablets
Infections of the kidneys and/or the urinary tract	2 x 300.72 mg cefuroxime axetil (= 2 x 250 mg cefuroxime), i.e. 2 x a day 1 Xorimax 250 mg tablet
Uncomplicated urinary tract infections in women	2 x 150.36 mg cefuroxime axetil (= 2 x 125 mg cefuroxime), i.e. 2 x a day ½ Xorimax 250 mg tablet
Uncomplicated gonorrhoea	Pulse therapy with 1202.88 mg cefuroxime axetil (= 1 g cefuroxime), i.e. a single dose of 4 Xorimax 250 mg tablets

Children between 5 and 12 years of age
2 x 150.36 mg to 2 x 300.72 mg cefuroxime axetil (= 2 x 125 mg to 2 x 250 mg cefuroxime), i.e. twice a day ½ Xorimax 250 mg tablet or twice a day 1 Xorimax 250 mg tablet.

The higher dose (twice a day 1 Xorimax 250 mg tablet) should be given for otitis media.

Dosage where kidney function is impaired and for elderly patients
Unless the dose for adults and elderly patients does not exceed the respective daily maximum dose, it need not be reduced for mild or moderate impairment of kidney function (creatinine clearance in the region of 30 ml/min). Longer dosing intervals may be required if creatinine clearance is < 30 ml/min as a result of kidney function impairment.

How is Xorimax 250 mg used?
Xorimax 250 mg should be administered at intervals of 12 hours.
The tablets should be taken with ample amounts of liquid (up to 200 ml), preferably water, shortly after a meal, when absorption is best.
The coated tablets have a bitter taste and should therefore not be crushed or chewed.
One oral dose of 1202.88 mg cefuroxime axetil (= 1 g cefuroxime) is administered for the treatment of gonorrhoea in adults.
Treatment with Xorimax 250 mg should be avoided in patients with severe gastrointestinal disturbances accompanied by vomiting and diarrhoea, because adequate absorption cannot be ensured in these cases.
Parenteral administration should be considered alternatively.

Principal incompatibilities
No incompatibilities are known to date.

For how long should Xorimax 250 mg be used?
The duration of treatment (usually 7 to 10 days) depends on the severity and the course of the disease. Treatment should be continued for at least another 2 days after symptoms have disappeared.

In the event of infections caused by beta-haemolytic streptococci (specific type of microbe), a treatment period of at least 10 days is indicated for safety´s sake, to prevent late complications taking the form of rheumatic fever, glomerulonephritis (inflammation of certain areas of the kidneys).

Misuse and overdosage
See also section "Countermeasures in the event of side effects".

What must be done if you have taken too much Xorimax 250 mg?

No acute poisoning with Xorimax 250 mg has been reported to date.
If certain risk factors are present at the same time or very high doses are administered, cephalosporins may cause states of central nervous excitation and lead to convulsions.
In cases of emergency, all necessary intensive care-type measures are indicated.
High serum concentrations can be reduced by haemodialysis.
Anticonvulsants (such as diazepam or barbiturates) may be indicated in the event of motor agitation or convulsive states.

What must you bear in mind if you missed one dose?
A missed dose must be taken as soon as possible before the next regular dose is due.

Side effects

What side effects may Xorimax 250 mg have?

Medicines may also have unwanted effects, called side effects, which, however, do not necessarily occur in all patients. You will find below a listing of unwanted effects observed in conjunction with the administration of Xorimax 250 mg.

Effects on the central nervous system:
Headaches, dizziness.
Especially elderly patients or patients with high-grade fever or serious infections were reported to develop CNS disturbances such as agitation, nervousness, confusion or hallucinations in a few cases.

Hypersensitivity symptoms:
Allergic skin reactions taking the form of skin rash, itching, urticaria (nettle rash), drug-induced fever and serum sickness may occur. As with other cephalosporins, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis (patchy redness of skin and even peeling of the top layer of skin) have been reported in isolated cases.
Severe acute hypersensitivity reactions (anaphylaxis) are possible. Anaphylactic shock is life-threatening and requires appropriate emergency measures (see "Countermeasures in the event of side effects").

Patients with a tendency to allergies are more likely to develop allergic reactions.

Effects on the gastrointestinal tract:
Nausea, vomiting, abdominal pain and diarrhoea have been reported. These side effects occur more frequently on use of higher daily doses.
If severe, persistent diarrhoea occurs during treatment or in the first weeks thereafter, consideration should be given to pseudomembranous colitis (usually caused by Clostridium difficile). This bowel disease, which is caused by antibiotic treatment, may be life-threatening and requires immediate institution of appropriate treatment (see "Countermeasures in the event of side effects").

Effects on the liver and biliary system:
Transient elevations in liver enzymes in the serum (SGOT, SGPT) and in LDH.

A few cases of jaundice were reported.

Effects on blood and blood formation:
Changes in the number of white blood cells (e.g. eosinophilia, leukopenia, neutropenia) and also of platelets (thrombocytopenia) and very rarely of the red blood cells (autoimmune haemolytic anaemia).

Other side effects:
Inflammation of the mucous membranes in the mouth and the vagina, sometimes caused by superinfections with Candida (yeasts).

Any use of antibiotics may lead to the multiplication of organisms which are insensitive to the medicine used. Attention must be paid to signs which indicate a possible secondary infection with such microbes. Secondary infections must be treated appropriately.

What countermeasures must be taken in the event of side effects?

The following side effects which occur extremely rarely (see above for more detailed information on these side effects) may be acutely life-threatening. A doctor must therefore be informed immediately, if such an event occurs suddenly or symptoms unexpectedly take a severe course.

Pseudomembranous colitis:
In this case, the doctor must, depending on the indication, consider discontinuation of therapy with Xorimax 250 mg and immediately institute appropriate treatment where required (e.g. administration of specific antibiotics/chemotherapeutics with clinically established effectiveness). Medicines which inhibit the movement of the intestines (peristalsis) must not be taken.

Severe acute hypersensitivity reactions (e.g. anaphylaxis)

Treatment with Xorimax 250 mg must be discontinued immediately and usual appropriate emergency measures (e.g. antihistamines, corticosteroids, sympathomimetics and ventilation where required) must be instituted.

Occurrence of (epilepsy-type) seizures:

The usual appropriate emergency measures are indicated (e.g. keeping airways clear, anticonvulsants such as diazepam or barbiturates).

What must be done in general if side effects occur?

Please speak to your doctor if you observe any of the side effects listed or other unwanted effects during treatment with Xorimax 250 mg.

Note on expiry date and storage
Do not store above 30°C.
The expiry date of this medicine is printed on the outer carton and the blister strip. Do not use this pack after the date indicated.

Keep medicines out of the reach of children!

Date of information: February 2004

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