

Cefixim Sandoz®

400 mg film-coated tablets

Package leaflet: Information for the user

Cefixim Sandoz® 400 mg film-coated tablets

Active substance: cefixime

Read the entire package leaflet carefully before you start taking this medicine.

x Keep the package leaflet. You may want to read it again later.

x If you have any further questions, please ask your doctor or pharmacist.

x This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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

The package leaflet contains:

1. What is Cefixim Sandoz 400 mg and what is it used for?
2. What should you consider before taking Cefixim Sandoz 400 mg?
note?

4. What side effects are possible?

5. How should Cefixim Sandoz 400 mg be stored?

6. Further information

1. What is Cefixim Sandoz 400 mg and what is it

used for?

applied?

treatment of acute and chronic infections caused by bacteria sensitive to cefixime.

Cefixim Sandoz 400 mg is used for the treatment of acute

and chronic infections of varying severity caused by bacteria sensitive to cefixime and amenable to oral therapy, such as:

x Infections of the ear, nose, and throat area:

x– Middle ear infection (otitis media)

x– Sinus infections (sinusitis)

x– Middle ear infection (Otitis media)

x– Sinus infections (Sinusitis)

x– Tonsillitis (Tonsillitis)

x– Inflammations of the pharynx (Pharyngitis)

x– Inflammations of the larynx (Laryngitis)

- x Infections of the lower respiratory tract
- x Infections of the biliary tract
- x uncomplicated acute and recurrent urinary tract infections including urethritis due to infection by gonococci coccus

400 mg?

Cefixim Sandoz 400 mg must not be taken,

– if you are hypersensitive (allergic) to cefixime, other

cephalosporins, or any of the other ingredients of the medi-

Cephalosporins or any of the other components of the medicinal product parts are.

For cross-allergy, see section "Special caution is required when taking Cefixim Sandoz 400 mg".

Special caution is required when taking Cefixim Sandoz

400 mg

x Proven infections by staphylococci should be treated with cefixime

x Proven infections caused by staphylococci should be treated with cefixime should not be treated, as cefixime is not effective against staphylococci. effective.

x if you suffer from severe allergies or asthma or have previously experienced allergies or asthma.

x if you have ever had an allergy to penicillin,

as there is a possibility that you may also be allergic to cefixime, the active ingredient in Cefixime Sandoz 400 mg (cross-allergy).

x Until further clinical experience is available, Cefixime Sandoz

400 mg should not be administered to premature infants, newborns, and breastfeeding mothers.

x if you have severe renal impairment (creatinine clearance < 10 ml/min/1.73 m²).

x if severe, persistent, even bloody-mucous diarrhea and

cramp-like abdominal pain occur during or after therapy with

Cefixime Sandoz 400 mg. This may indicate a severe, potentially

life-threatening inflammation of the intestinal mucosa (pseudomem-

branous enterocolitis) triggered by antibiotic treatment, which must be treated immediately.

Immediate discontinuation of treatment with Cefixime Sandoz

400 mg depending on the underlying condition is generally

An immediate discontinuation of treatment with Cefixim Sandoz

400 mg depending on the underlying disease is usually

required, a pathogen detection and appropriate treatment

must be initiated by a doctor (e.g., taking special antibiotics/

chemotherapeutics whose effectiveness is clinically proven). Medications

against diarrhea that inhibit bowel movement should

not be taken (see section 4. "What side effects are possible?").

are possible?").

x if you are undergoing long-term therapy with high-dose Cefixime.

In this case, kidney and liver function as well as blood count

monitoring are indicated.

x if you are receiving Cefixime Sandoz 400 mg in combination with certain other antibiotics (aminoglycoside antibiotics, polymyxin B, colistin, viomycin) or with certain high-dose diuretics (loop diuretics such as furosemide).

In these cases, kidney function should be monitored particularly carefully.

This is especially true in the case of already impaired kidney function (see section 4. "What side effects are possible?").

blood pressure at the same time. This can lead to the blood level of Cefixime Sandoz 400 mg being increased by 70%. However, this effect Cefixime Sandoz 400 mg is increased by 70%. However, this effect has no effect on the dosage of the two drugs (see under section "Taking Cefixim Sandoz 400 mg with other medicines").

x if they are simultaneously receiving blood-thinning drugs (anticoagulants) of the coumarin type. In individual cases, patients have been reported to have an extension of coagulation time (prothrombin time) with and without bleeding. This should be taken into account when monitoring coagulation values to consider.

diarrhea, treatment with Cefixim Sandoz 400 mg should be avoided, as adequate absorption of the drug into the body (absorption) is not guaranteed. Here, the doctor must make the decision for an intravenous application (administration via a vein directly into the blood) of a suitable antibiotic.

Any use of antibiotics can lead to the proliferation of pathogens

that are insensitive to the drug used. Pay attention to signs of a possible secondary infection with other pathogens (e.g., fungal infection of the mucous membranes with redness and whitish coatings of the mucous membranes). Secondary infections should be treated accordingly by your doctor. Mucous membranes). Secondary infections should be treated by your doctor accordingly. act.

Influence on laboratory diagnostic findings

In certain methods of urine sugar determination (reduction methods) false positive reactions may occur, but not when using enzymatic methods.

Children under 12 years

For children under 12 years and patients with swallowing difficulties with tablets, liquid oral preparations with the active ingredient cefixime are recommended.

Elderly patients

In general, no dose adjustment is necessary for elderly patients.

When taking Cefixime Sandoz 400 mg with other medicines

Please inform your doctor or pharmacist if you are taking/using other medicines or have recently taken/used them, even if they are non-prescription medicines.

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effect cannot be ruled out, e.g., aminoglycoside antibiotics.

Antibiotics, colistin, polymyxin, viomycin or strongly effective agents for dehydration of the body (diuretics), e.g., with the active ingredient furosemide, there is an increased risk of impaired kidney function.

When nifedipine (an active ingredient for the treatment of heart rhythm disorders and high blood pressure) is administered simultaneously, the availability of the

active ingredient of Cefixim Sandoz 400 mg in the body (bioavailability) is increased by about 70% (see section "Special caution is required when taking Cefixim Sandoz 400 mg").

How does Cefixim Sandoz 400 mg affect the action of other medicines?

When Cefixim Sandoz 400 mg and blood-thinning medicines (anticoagulants) of the coumarin type are administered simultaneously, it can lead to a prolongation of the blood clotting time (prothrombin time) with and without bleeding (see section "Special caution is required when taking Cefixim Sandoz 400 mg").

Please note that this information may also apply to recently used medicines.

Pregnancy and breastfeeding

Pregnancy

There is insufficient data for the use of Cefixim Sandoz 400 mg in pregnant women. Animal studies showed no evidence of teratogenic effects of cefixime. Cefixime reaches the fetus/embryo via the placenta. Due to the lack of clinical experience, Cefixime Sandoz 400 mg, especially in the first 3 months of pregnancy, should only be taken after careful benefit-risk assessment.

Lactation

Lactation

breast milk. A risk to the infant cannot be excluded. Therefore, until further clinical experience is available, Cefixime Sandoz 400 mg should not be administered to breastfeeding mothers. If treatment is necessary, it is advisable to pump and

discard the milk during the therapy period.

Ability to drive and use machines

Based on previous experience, the active ingredient cefixime generally

has no effect on concentration and reaction ability. However, the occurrence of side effects may alter reaction ability and impair the ability to actively participate in road traffic and operate machines.

The same applies to work without a secure hold.

Reaction capacity altered and the ability to actively participate in

May be impaired when driving and operating machinery.

The same applies to work without secure footing.

3. How to take Cefixim Sandoz 400 mg?

Always take Cefixim Sandoz 400 mg exactly as instructed by your doctor. Please consult your doctor or pharmacist if you are not entirely sure.

Unless otherwise prescribed by the doctor, the usual dose is
Dosage and method of administration depend on the severity of the infection, the sensitivity of the pathogen, and the patient's condition and age.

Adults, adolescents over 12 years, and children \geq 50 kg receive 1 film-coated tablet of Cefixim Sandoz 400 mg daily (equivalent to 400 mg Cefixim/day).

The recommended daily dose can be administered either at once or divided into 2 single doses ($\frac{1}{2}$ film-coated tablet each morning and evening).

Children under 12 years or $<$ 50 kg

For children under 12 years or lighter than 50 kg, liquid oral preparations with the active ingredient Cefixim in suitable dosages are available.

Availability.

Dosage for adults and adolescents over 12 years with a

Dosage for adults and adolescents older than 12 years with a single impaired renal function

In patients with significantly impaired renal function, the dose should be reduced to a single daily intake of 200 mg, corresponding to $\frac{1}{2}$ film-coated tablet of Cefixim Sandoz 400 mg.

Method of administration

Please take the film-coated tablets with a glass of water. The intake should be either before or with a meal.

Duration of use

The duration of treatment depends on the course of the infection. In general, the duration of treatment with Cefixim Sandoz

400 mg is 7–10 days.

x For streptococcal infections, a minimum therapy of 10 days should be observed to prevent secondary diseases.

x For uncomplicated lower urinary tract infections in women, a treatment duration of 1–3 days is sufficient.

x In the case of urethritis due to infection by gonococci, a single intake of 1 film-coated tablet of Cefixim Sandoz 400 mg (corresponding to 400 mg Cefixim) is usually sufficient.

The success of the treatment of an infection by gonococci (gonorrhoea) should be confirmed by creating a bacterial culture by the Doctor should be checked 3–4 days after the end of treatment.

The duration of treatment is determined by your doctor.

Please talk to your doctor if you have the impression that the effect of Cefixim Sandoz 400 mg is too strong or too weak.

If you have taken a larger amount of Cefixim Sandoz 400 mg than you should have

Cefixim Sandoz 400 mg is a medication with a wide therapeutic range, i.e., even at high doses, the tolerability is generally good.

Rule good.

so far. Nevertheless, in case of overdose, a doctor should be consulted.

The various forms of blood purification (hemo- or peritoneal dialysis) are not effective measures for removing the drug from the body.

If you forget to take Cefixim Sandoz 400 mg or have taken too few tablets:

If, when prescribed twice daily, a dose of Cefixim Sandoz 400 mg is missed at 12-hour intervals (½ film-coated tablet), it can be made up within 6 hours and then the started intake rhythm can be continued unchanged.

the intake should be made up within 6 hours and then the beg new intake rhythm to be continued unchanged.

If a full daily dose of

1 film-coated tablet of Cefixim Sandoz 400 mg (equivalent to 400 mg/day) was missed during once-daily intake, it can be made up within 12 hours and the usual intake rhythm can be maintained.

If in doubt, please consult your doctor.

If you stop taking it:

Even if the symptoms noticeably improve, the treatment must be completed in any case, as this is the only way to ensure that the pathogens are completely eliminated.

If the treatment is interrupted, e.g., because the side effects seem too severe, consult your doctor.

If you have further questions about the use of the medication, ask your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, Cefixim Sandoz 400 mg can have side effects, but they do not have to occur in everyone.

The following frequency information is used to evaluate side effects:

Very common: more than 1 in 10 treated

Common: 1 to 10 treated out of 100

Common: 1 to 10 treated out of 100

Occasionally: 1 to 10 treated out of 1000

Rare: 1 to 10 treated out of 10,000

Very rare: less than 1 treated out of 10,000

Unknown: Frequency based on available data not assessable

Side effects

After using Cefixim Sandoz 400 mg, the following side effects were observed:

Infections

Rare: With long-term and repeated use, superinfections with resistant bacteria or yeasts are possible.

Blood and lymphatic system disorders

Rare: Increase in eosinophilic blood cells (a certain form of white blood cells) in the blood (eosinophilia).

Very rare: Blood count changes, such as reduction in the total number of white blood cells (leukopenia); severe, potentially developing within hours, reduction of certain forms of white blood cells (granulocytes) in the blood (agranulocytosis); severe reduction of all blood cells (pancytopenia) or reduction in the number of platelets (thrombocytopenia). These blood count changes resolve on their own after the end of therapy.

Blood coagulation disorders.

Reduction in the number of red blood cells (erythrocytes) due to cell-damaging influences (hemolytic anemia).

Disorders of the immune system

Rare: Drug fever

Hypersensitivity reactions of all severity levels – up to anaphylactic shock – have also been observed after oral intake of cephalosporins, although much less frequently than after intravenous (via the vein) or intramuscular administration.

Severe acute hypersensitivity reactions may manifest as:

Facial edema (swelling), tongue swelling, internal laryngeal swelling with narrowing of the airways, palpitations, shortness of breath (dyspnea), drop in blood pressure up to life-threatening shock.

In the event of severe acute life-threatening hypersensitivity reactions, therapy with Cefixim Sandoz 400 mg must be immediately discontinued and the necessary emergency measures must be initiated by a doctor (see section 4.2).

Very rare: Serum sickness-like reactions.

Disorders of the nervous system

Occasionally: Headaches

Rare: Dizziness

Very rare: Temporary increase in activity.

As with other cephalosporins, an increased tendency to seizures cannot be ruled out.

Gastrointestinal disorders

Common: Soft stools, diarrhea

Occasionally: Disorders in the form of abdominal pain, digestive disturbances, nausea, vomiting

Rare: Loss of appetite, flatulence

Very rare: Colitis, which can be triggered by antibiotic therapy and is characterized by severe and persistent diarrhea and must be treated medically (pseudomembranous colitis, see sections "Special precautions when taking Cefixim Sandoz 400 mg are required" and "Countermeasures").

Liver and biliary disorders

Occasionally: Increase in certain liver values (transaminases, alkaline phosphatase) in the blood/serum, which decreases after discontinuation of therapy with Cefixim Sandoz 400 mg.

Very rare: Hepatitis and a certain form of jaundice (cholestatic jaundice).

Diseases of the skin and subcutaneous tissue

Occasionally: Skin rashes (erythema, exanthema)

Rare: Itching, mucosal inflammations

Very rare: Coin-sized, disc-shaped, roundly elevated, occasionally blistered, red skin changes with a bluish center (erythema exsudativum multiforme), blistering detachment of the epidermis (Lyell's syndrome).

Diseases of the kidneys and urinary tract

Rare: Temporary increase in blood urea concentration (urea-containing substance)

Very rare: Increase in blood creatinine concentration (urea-containing substance that indicates the excretory function of the kidney), kidney inflammation (interstitial nephritis)

High-dose treatments with cephalosporins (the antibiotic group to which cefixime, the active ingredient of Cefixime Sandoz 400 mg, belongs) can impair kidney function or lead to

in patients who are simultaneously receiving diuretics (e.g., furosemide) or additional antibiotics that have a kidney-damaging side effect, e.g., aminoglycoside antibiotics.

biotics, to an impairment of kidney function or to the pre-worsening of an already impaired kidney function (see section "Special caution when taking Cefixim Sandoz 400 mg is required").

Countermeasures

The following rare side effects (for further explanations of these side effects see under "What side effects are possible?") can potentially be acutely life-threatening. Therefore, a doctor must be informed immediately if such an event occurs suddenly or develops unexpectedly strongly.

Pseudomembranous enterocolitis (inflammation of the colon)

Here, the doctor must consider discontinuing treatment with Cefixim Sandoz 400 mg and, if necessary, immediately initiate appropriate treatment (e.g., administration of specific antibiotics/chemotherapeutics). Medications that inhibit bowel movement (peristalsis) must not be taken.

Severe acute hypersensitivity reactions (e.g., anaphylaxis)

Here, the treatment with Cefixim Sandoz 400 mg must be stopped immediately and an emergency doctor must be called, who will initiate the recognized emergency measures.

Please inform your doctor or pharmacist if any of the listed

Please inform your doctor or pharmacist if any of the listed if side effects significantly affect you or you notice side effects that are not listed in this package leaflet.

5. How to store Cefixim Sandoz 400 mg?

Keep medicines out of the reach of children.

Do not use the medicine after the expiry date stated on the carton and the blister.

Do not store above 25 °C.

6. Further information

What Cefixim Sandoz 400 mg contains

The active substance is: cefixime trihydrate.

1 film-coated tablet contains 447.63 mg cefixime trihydrate, equivalent to 400 mg cefixime.

The other ingredients are:

Microcrystalline cellulose, croscarmellose sodium, hypromellose, Macrogol 400, magnesium stearate (Ph.Eur.), calcium hydrogen phosphate, sodium lauryl sulfate, talc, titanium dioxide (E171)

What Cefixim Sandoz 400 mg looks like and contents of the pack

Cefixim Sandoz 400 mg are white, oblong film-coated tablets with a score line.
The film-coated tablets can be divided into equal halves.
Cefixim Sandoz 400 mg is available in original packs of 5 (N1), 7 (N1)
Cefixime Sandoz 400 mg is available in original packages with 5 (N1), 7 (N1)
and 10 (N1) film-coated tablets available.

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