

# CEFIXIME TABLETS USP 400 MG

## COMPOSITION:

EACH FILM COATED TABLET CONTAINS:

Cefixime Trihydrate USP	
eq. to cefixime anhydrous	400 mg
Excipients	q.s.
Colour :	Titanium Dioxide

## DESCRIPTION:

Cefixime is a semisynthetic, cephalosporin antibacterial for oral administration. Cefixime Tablets for Oral Suspension is a cephalosporin antibiotic used to treat many different types of infections caused by bacteria.

## INDICATIONS:

CEFIXIME IS USED TO TREAT:

- infection of the middle ear
- infection which may cause green or yellow discharge from your nose and severe pain in your  
cheeks, eyes or forehead (sinus infection)
- throat infection
- infection causing sudden worsening of long-standing bronchitis
- lung infections (pneumonia) which you catch outside of hospital
- infections in the water (urinary) tract including some infections of the kidneys

## DOSAGE AND ADMINISTRATION:

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose your doctor prescribes depends on the type of infection and how bad the infection is. It also depends on how well your kidneys are working. Your doctor or pharmacist will explain this to you.

The recommended dose is

### Adults

The recommended adult dose is one tablet taken once daily. The medicine should always be taken at the same time each day. The tablets should be taken with plenty of water. The tablets can be taken with or without food.

### Patients with kidney problems

In patients with kidney problems, the dosage of cefixime may need to be reduced. Your doctor will calculate the right dose for you according to the results of blood or urine tests that measure how well your kidneys are working.

There is not enough information on the use of cefixime in children and adolescents with kidney problems. Cefixime is therefore not recommended for use in these patients.

### Elderly

No change in dose is needed for elderly patients, provided the kidneys are working normally.

Use in adolescents 12 years of age and older

Adolescents 12 years of age and older may be given the same dose as adults.

Use in children older than 6 months and up to 11 years of age

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

Cefixime is not recommended for use in children less than 6 months of age.

### Method for administration

For oral administration.

**SIDE EFFECTS:**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:

Rare: may affect up to 1 in 1,000 people

- other infections caused by germs that cefixime does not act on (fungal or bacterial super infections). If you start to feel worse, this might be a sign of a new infection.
- increase in the numbers of white blood cells called eosinophils, which may show up in blood tests (hypereosinophilia).
- If left untreated, this can lead to damage to the body.
- You may notice memory loss, feel confused, tired, short of breath, have a fever, cough, mouth sores or feel dizzy.
- sudden severe allergic reactions such as skin rash or hives, itchiness, swelling of the face, lips,
- tongue or other parts of the body which may cause difficulty in swallowing or breathing,
- Tightness of the chest, wheezing and collapse (anaphylactic shock).
- Very rare: may affect up to 1 in 10,000 people
- watery and severe diarrhea that may also be bloody
- severe skin illness with blistering of the skin, mouth, eyes and genitals (Stevens Johnson syndrome, toxic epidermal necrolysis)
- an increased number of infections, pale skin, feeling breathless, bruising or bleeding more easily. These may be signs of reduced numbers of blood cells which help fight infections,
- carry oxygen around the body or help the blood clot.
- feeling breathless with yellowing of the skin and eyes (haemolyticaemia)
- liver problems including jaundice (you may notice yellowing of the skin or whites of the eyes).
- inflammation of the kidney causing lower back pain and difficulty in passing water and
- feeling sick with weight loss, which may lead to kidney failure.
- a delayed allergic reaction. You may notice a rash, swelling of the face, swollen glands, fever
- and in blood tests, changes in how the liver is working and changes in white blood cells called eosinophils.

Other side-effects include:

Common: may affect up to 1 in 10 people

- diarrhea

Uncommon: may affect up to 1 in 100 people

- headache
- nausea (feeling sick)
- vomiting (being sick)
- abdominal (stomach) pain
- changes in blood tests that check how your liver is working
- skin rash

Rare: may affect up to 1 in 1,000 people

- loss of appetite
- dizziness or a feeling of spinning (vertigo)
- flatulence (wind)
- itchy skin
- inflammation of mucus (moist) linings such as the mouth and / or other internal surfaces
- fever
- changes in blood tests that check how well your kidneys are working

Very rare: may affect up to 1 in 10,000 people

- restlessness and increased activity

Not known: frequency cannot be estimated from the available data

- Feeling short of breath
- Indigestion
- Rash with red raised patches
- Puffiness of the face
- Painful joints
- Itching and irritation of the sex organs
- Increased number of blood cells, which help the blood to clot may be seen in blood tests.

#### **OVER DOSE:**

If you or your child have taken more of this medicine than you should, talk to your doctor or contact your nearest hospital emergency department immediately.

#### **CONTRAINDICATIONS:**

Do not take cefixime if you:

- Are allergic to cefixime or any of the other ingredients of this medicine (listed in section 6).
- An allergic reaction may include rash, itching, difficulty breathing or swelling of the face,
- Lips throat or tongue.
- Are allergic to any other cephalosporin type of antibiotic.
- Have ever had a severe allergic reaction to a penicillin antibiotic or to any other beta-lactam type of antibiotic.

#### **DRUG INTERACTIONS:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking:

medicines which are known to be harmful to your kidneys such as:

- antibiotics including aminoglycoside antibiotics e.g. (streptomycin, gentamicin), colistin, polymyxin or viomycin.
- medicines that increase the amount of urine your body produces (diuretics) such asethacrynic acid or furosemide.
- nifedipine, a medicine used for the treatment of high blood pressure or heart problems
- anticoagulants (blood thinning medicines) such as warfarin. In some – medicines which are known to be harmful to your kidneys such as:
- antibiotics including aminoglycoside antibiotics e.g. (streptomycin, gentamicin),

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking:

- antibiotics including aminoglycoside antibiotics e.g. (streptomycin, gentamicin),
- colistin, polymyxin or viomycin
- medicines that increase the amount of urine your body produces (diuretics) such asethacrynic acid or furosemide.
- nifedipine, a medicine used for the treatment of high blood pressure or heart problems
- Anticoagulants (blood thinning medicines) such as warfarin. In some patients, cefixime causesproblems with blood clotting and may increase the time taken for the blood to clot.
- oral contraceptives (the birth control pill)

#### **WARNINGS AND PRECAUTIONS FOR USE:**

Talk to your doctor or pharmacist before taking Cefixime

- if you are allergic to penicillin antibiotics or to any other beta-lactam type of antibiotics. Not
- all people who are allergic to penicillins are also allergic to cephalosporins. However, you
- should not take this medicine if you ever had a severe allergic reaction to any penicillin. This is because you might also be allergic to this medicine.
- sort of treatment (like dialysis) for kidney failure. You may take Cefixime but you may need a lower dose.
- are taking other medicines which are known to be harmful to your kidneys (see "Other medicines and Cefixime"). Your doctor may perform certain test regularly to measure how well your kidneys are working during the treatment.

#### During treatment

- If you have severe or persistent diarrhoea, which may be bloody with stomach pain or cramps,
- during or shortly after treatment with cefixime, stop taking this medicine and contact your doctor immediately. Medicines which may slow or stop bowel movements must not be taken.
- This medicine may increase the risk of infections caused by other sort of germs on which cefixime does not act. For example, thrush (infection caused by a yeast germ called Candida) may occur.
- This medicine may cause severe skin reactions. If you develop a sudden fever with sore throat and tiredness and a burning blister like rash on your skin around your mouth and lips or
- genitals or your skin begins to peel, stop taking this medicine and contact your doctor immediately.
- This medicine may cause kidney problems. If you develop a sudden fever with lower back pain and experience problems when passing water contact your doctor immediately.

#### Pregnancy and Breast-Feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### STORAGE INSTRUCTIONS:

Keep this medicine out of the sight and reach of children.

This medicine product does not require any special temperature storage conditions. Store in the original package.

Do not use this medicine after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### PRESENTATION:



**90 x 180 MM**