

IXIME 400 TABLETS

Cefixime 400mg

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What IXIME 400 is used for

IXIME 400 is an antibiotic that is used to certain bacterial infections of the ear, throat, lungs, or bladder in adults as described further below:

Uncomplicated Urinary Tract Infections caused by *Escherichia coli* & *Proteus mirabilis*

Otitis Media caused by *Haemophilus influenzae* (β lactamase positive & negative strains), *Moraxella catarrhalis* (most of which are β lactamase positive) and *Streptococcus pyogenes*

Pharyngitis and Tonsillitis caused by *Streptococcus pyogenes*

Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis, caused by *Streptococcus pneumoniae* & *Haemophilus influenzae* (β lactamase positive and negative strains)

Uncomplicated Multidrug Resistant and Quinolone Resistant Typhoid
Fever caused by *Salmonella typhi*.

Uncomplicated Gonorrhea

(cervical/urethral) caused by both Penicillinase and Non Penicillinase Producing Strains of *Neisseria*

How IXIME 400 works

Cefixime is a 3rd generation cephalosporin with bactericidal activity. It binds to 1 or more of the penicillin-binding proteins (PBPs) which inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell

wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell lysis and death.

Before you use IXIME 400

-When you must not use it

Do not take IXIME 400 if:

- you are allergic (hypersensitive) to the active ingredient (cefixime) or any ingredients used in this product.
- You are allergic to cephalosporins, penicillin, carbapenems or other beta-lactam agents

-Before you start to use it:

Check with your doctor, nurse or pharmacist before taking your medicine if you have any of the following conditions:

- Kidney disease
- Liver disease
- History of stomach or bowel disease

- Taking other medicines:

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Carbamazepine (medicine for fits or seizures)
- Warfarin and anticoagulants (blood-thinning medicine)
- Probenecid (medicine for gout or hyperuricemia)

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using IXIME 400.

How to use IXIME 400

-How much to use:

Take Cefixime exactly as directed by your doctor or according to the instructions on the label. Do not take more or less than instructed by your doctor.

You may take this medicine with or without food. Try to take it at the same time each day.

The dose of this medicine will be decided by your doctor. Your doctor will advise you on the treatment time frame depending on the type and severity of your infection.

-When to use it:

Take IXIME 400 at regular intervals. Do not skip any doses. You must complete the entire course of this medicine. If you don't, the infection will not be properly controlled.

-How long to use it:

Continue taking IXIME 400 for as long as your doctor recommends.

-If you forget to use it:

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, wait until the usual time to take your medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose):

Contact your doctor immediately or go to the Emergency department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Gastric lavage may be indicated for overdosage; otherwise there is no specific antidote.

Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis.

While you are using IXIME 400

-Things you must do

- Use IXIME 400 exactly as directed by your doctor.
- Tell your doctor immediately if you become pregnant while taking this medication.

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-Things you must not do

- Do not stop using IXIME 400 unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give IXIME 400 to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Pregnancy and breastfeeding

- If you are pregnant or planning to get pregnant, talk to your doctor before using IXIME 400.
- Do not use IXIME 400 unless your doctor tells you to.
- If you get pregnant while using IXIME 400, do not stop using but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using IXIME 400.

Side Effects

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature. If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away. You may need urgent medical treatment:

• **Gastrointestinal Disturbances**

The most frequent side effects seen with Cefixime are diarrhea and stool changes with diarrhea being seen more commonly associated with higher doses.

Some cases of moderate to severe diarrhea have been reported; this has occasionally warranted cessation of therapy. Ixime should be discontinued if marked diarrhea occurs. Other gastrointestinal side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting and flatulence. Pseudomembranous colitis has been reported.

• **Central Nervous System**

Headache and dizziness

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

• **Hypersensitivity Reactions**

Allergies in the form of rash, pruritus, urticaria, drug fever and arthralgia have been observed. These reactions usually subsided upon discontinuation of therapy. Rarely Erythema multiforme, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis have been reported

• **Haematological and Clinical Chemistry**

Thrombocytopenia, leukopenia and eosinophilia have been reported though these reactions were infrequent and reversible. Mild transient changes in liver and renal function tests too have been observed.

• **Hepatic Disorders**

Transient rises in liver transaminases, alkaline phosphatase and jaundice can also occur

• **Miscellaneous**

Other possible reactions include genital pruritus and vaginitis

Cefixime may cause severe allergy and serious skin reactions.

Stop using Cefixime and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of of IXIME 400

Storage:

Store below 25°C.

Disposal:

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicine no longer required. These measures will help to protect the environment.

Product description

-What it looks like:

White to pale yellow film coated capsule shaped tablet with “LUPIN” debossed on one side and scored on the other.

-Ingredient

Active Ingredients:
Cefixime

Inactive Ingredients:

- Pregelatinised starch
- Microcrystalline cellulose
- Magnesium stearate
- Opadry II white
- Dibasic calcium phosphate
- Purified water

-MAL No.

MAL07124617AZ

Manufactured by:

LUPIN LTD.

198-202, New Industrial Area No. 2,
Mandideep-462 046 Dist. Raichur (M.P.)
INDIA.

Product Registration Holder:

Biocare Pharmaceutical (M) Sdn. Bhd.
No 28G, 28-1 & 28-2,
Pusat Dagangan PJCC,
Jalan PJS 5/28,
46150 Petaling Jaya,
Selangor, Malaysia.

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14 September 2023

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