



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **FIXEF 400 mg Film Coated Tablets** **Taken by mouth**

**Active substance:** Each film coated tablet contains 447.67 mg cefixime trihydrate equivalent to 400 mg cefixime.

**Excipients:** Microcrystalline cellulose, prejelatinized starch, calcium phosphate dibasic dehydrate, magnesium stearate, Opadry white OY-D-7233 (hypromellose, titanium dioxide, talc, polyethylene glycol/macrogol, sodium lauryl sulfate)

**Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.**

- *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. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

#### **In this leaflet:**

- 1. What FIXEF is and what it is used for**
- 2. What you need to know before you take FIXEF**
- 3. How to take FIXEF**
- 4. Possible side effects**
- 5. How to store FIXEF**

### **1. WHAT FIXEF IS AND WHAT IT IS USED FOR**

FIXEF contains an active substance called cefixime. This belongs to a group of antibiotics called cephalosporins.

FIXEF is used in the treatment of some infections. FIXEF is used to treat following infections:

- Acute otitis media (sudden inflammation of the middle ear) if caused by susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*.
- Acute sinusitis (sudden inflammation of the sinuses) if caused by susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*,
- Acute bronchitis in the lower respiratory tract (inflammation of the bronchi in the lungs which carry air) if caused by penicillin sensitive *Streptococcus pneumoniae*, *Moraxella catarrhalis* and *Haemophilus influenzae*,
- Acute tonsillopharyngitis (sudden inflammation of tonsils or pharynx) or pharyngitis (inflammation of the throat): Antimicrobial treatment is only indicated if caused by *Streptococcus pyogenes*.
- Acute exacerbations of chronic bronchitis (inflammation of the bronchi) caused by susceptible isolates of *Streptococcus pneumoniae* and *Haemophilus influenzae*
- Uncomplicated urinary tract infections (inflammation of the bladder and the lower parts of the urinary tract)



- Uncomplicated gonorrhoea (a sexually transmitted infection)

### **Appearance and box content of FIXEF**

Each package contains 5 or 10 white, homogenous film coated tablets, scored on one side (this is to help to divide the tablet into two equal parts).

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE FIXEF**

### **DO NOT USE FIXEF**

- If you are allergic (hypersensitive) to cefixime or to any of the other ingredients of FIXEF. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue

### **Take SPECIAL CARE with FIXEF**

- If you have had colitis (inflammation of the large intestines) before.
- If you have kidney failure.

In sudden (acute) otitis media, suspension should not be substituted for tablets as the absorption is higher in the suspension form.

*If these warnings are valid for you, even for a period of time in the past, please consult to your doctor.*

### **Taking FIXEF with food and drink**

FIXEF should be taken with or right after meals.

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine.*

Tell your doctor, if you are or planning to become pregnant.

*If you notice that you are pregnant during your treatment, immediately consult your doctor or pharmacist.*

### **Breastfeeding**

*Consult your doctor or pharmacist before taking this medicine.*

FIXEF was not determined in breast milk, but until sufficient clinical study results have been acquired, a decision should be made whether breast-feeding or FIXEF treatment should be discontinued.

### **Driving and using machines**

There is no information to suggest that cefixime has a direct adverse effect on the ability to drive and use machines. However, the underlying disease or some undesirable effects of cefixime (e.g. gastrointestinal disorders) may affect the ability to drive and use machines.

### **Important information about some of the ingredients of FIXEF**

FIXEF does not contain any excipient requiring any warning.

### **Taking other medicines**

If you are taking the medicines listed below, please tell your doctor:



- Carbamazepine (used in epilepsy patients); FIXEF increases the blood levels of this drug.
- Probenecid (used for chronic gout); FIXEF increases the blood levels of this drug.
- Anticoagulants such as warfarin (helps to thin the blood)

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

### **3. HOW TO TAKE FIXEF**

#### **Instructions for proper use and dose/frequency of administration**

##### Dosage for adults and children over 12 years of age:

FIXEF is taken 1 tablet daily (400 mg). If desired, the total daily dose can be taken in 2 equal parts. FIXEF can be taken on empty or full stomach.

FIXEF should be taken as single 400 mg dosage in uncomplicated gonorrhoea (A sexually transmitted infection).

Treatment for streptococcal tonsillopharyngitis (tonsillitis or pharyngitis) with FIXEF is 10 days.

Adults should use recommended doses and pharmaceutical dosage forms suitable for adults. Oral suspension and sachet forms can be used in patients who have difficulty swallowing solid foods.

#### **Route and method of administration**

FIXEF is taken directly by mouth.

#### **Different age groups**

##### **Use in children**

The safety and efficacy of cefixime has not been established in children less than 6 months.

##### **Use in the elderly**

No special warning is required. Cefixime can be used in the elderly the same as in adults.

#### **Use in special conditions**

##### **Kidney Failure**

Dosage should be decreased in patients with significant renal impairment.

Your doctor will determine the dosage of your drug depending on your illness and will apply it to you.

##### **Liver Failure**

Dose adjustment is not required.

*If you have the impression that the effect of FIXEF is too strong or too weak, talk to your doctor or pharmacist.*

#### **If you take more FIXEF than you should:**

*If you have taken more FIXEF than you should, talk to your doctor or pharmacist.*



**If you forget to take FIXEF**

*Do not take a double dose to make up for missed doses.*

If you forget to take a dose of FIXEF, you should take the next dose in its normal schedule and the same dosage as usual. If you have any questions regarding the use of this medicine, consult your doctor or pharmacist.

**If you stop taking FIXEF**

No negative effect is to be expected after FIXEF therapy.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, side effects may occur in people with sensitivity to ingredients of FIXEF.

Frequencies of undesirable effects are listed as follows:

Very common	: affects at least 1 in 10 patients
Common	: affects 1 to 10 patients in 100
Uncommon	: affects 1 to 10 patients in 1000
Rare	: affects 1 to 10 patients in 10.000
Very rare	: affects less than 1 patient in 10,000
Unknown	: cannot be estimated from the available data.

**If any of the below happens, stop taking FIXEF and IMMEDIATELY tell your doctor and go to the emergency room of the nearest hospital**

**Very rare**

- Hypersensitivity reactions leading up to life threatening shock (e.g. Facial edema, swelling of the tongue, edema of the inner respiratory tract with restriction of respiratory tract, fast heart beat, difficulty breathing, decrease of blood pressure, leading even to shock)
- Erythema multiforme (generally transient hypersensitivity reactions characterized by lace-like redness on the face, hands and feet)
- Stevens-Johnson syndrome (inflammation characterized by severe blisters on the skin and around the eyes, swelling and rash)
- Toxic epidermal necrolysis (severe skin reaction which is seen with big blisters on the skin) have also been seen rarely.

These are all very serious side effects.

If any of these are present in you, it means you are severely allergic to FIXEF. You may need urgent medical treatment or hospitalization.

These very serious side effects are seen very rarely.

**Very common**

- Fullness of stomach
- Nausea
- Vomiting
- Loss of appetite
- Flatulence

**Uncommon:**

- Skin rashes (exanthema, erythema, erythema exidativum multiforme and Lyellus syndrome in isolated cases)

- Pruritus (itching)
- Inflammation of the mucosa

#### **Common**

- Soft stool or diarrhea.

#### **Rare**

- Headache
- Feeling dizzy (vertigo)
- Rise in liver enzymes
- Rise in creatine and urea concentrations in serum

#### **Very rare:**

- Colitis due to antibiotic use [e.g. intestinal inflammation (pseudomembranous enterocolitis) characterized by false membranes]
- Superinfections with resistant bacteria or *Blastomyces*
- Hepatitis (jaundice due to liver infection), obstructive jaundice
- Temporary hyperactivity
- Tendency to contraction type seizure

#### **Unknown:**

- Dyspnea (shortness of breath, difficulty breathing)
- Genital pruritus (itching) and vaginitis (bacterial inflammation of the vagina)

As with other cephalosporins, bleeding-clotting processes can sometimes be affected, so patients undergoing coagulation therapy should be cautious.

#### Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the icon of 'Side Effect Reporting for Medicines' at [www.titck.gov.tr](http://www.titck.gov.tr) or calling +90 800 314 00 08 as the line of side effect reporting. By reporting side effects you can help provide more information on the safety of this medicine.

*If you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.*

### **5. HOW TO STORE FIXEF**

*Keep FIXEF out of the reach and sight of children and in its original package.*

Store at room temperature below 25°C in its original package and protected from light.

#### **Use in accordance with the expiry date.**

*Do not use FIXEF after the expiry date, which is stated on the packaging. Expiry date is the last day of the stated 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.



***Marketing Authorization Holder:***

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Halkalı Merkez Mah. Basın Ekspres Cad. No.: 1  
34303 Küçükçekmece - ISTANBUL/TURKEY

***Manufacturing site:***

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