

## PACKAGE LEAFLET

### **FIXEF 100 mg/5 ml Dry Powder for Pediatric Oral Suspension** **Taken by mouth.**

**Active substance:** Each 5 mL suspension (1 spoon) contains 111.9 mg cefixime trihydrate equivalent to 100 mg cefixime.

**Excipients:** Sucrose, Xanthan gum, sodium benzoate, raspberry flavor, colloidal silicon dioxide.

**Read all of this PACKAGE LEAFLET carefully before you start using 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.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to 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 for this medicine.*

#### **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 a medicine called cefixime, which belongs to a group of antibiotics known as cephalosporins. It is used to treat following infections caused by certain bacteria:

- Acute otitis media (inflammation of the middle ear) if caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*;
- Acute sinusitis (inflammation of the sinuses) if caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis*;
- Acute tonsillopharyngitis or pharyngitis (inflammation of the tonsils and/or pharynx) if caused by *Streptococcus pyogenes*;
- Acute exacerbations of chronic bronchitis (inflammation of the bronchi that carry air in the lungs) if caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*;
- Uncomplicated urinary tract infections (inflammation of the bladder and urethra);
- Uncomplicated gonococcal infections (infection of the outermost part of the urinary tract due to bacteria called Gonococci).

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

FIXEF is a white to off-white powder, which constitutes a white to off-white suspension with raspberry odor when reconstituted. Each package contains dry powder to prepare 50 ml or 100 ml suspension.

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

### **DO NOT USE FIXEF**

- If you are allergic (hypersensitive) to cefixime, other cephalosporins or to any of the other ingredients of FIXEF.

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

- If you 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 pregnant 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.*

Cefixime 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**

Each 5 ml FIXEF (1 spoon) contains 2510.2 mg sucrose. This should be taken into consideration in diabetic patients. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Taking other medicines**

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

- Carbamazepine (used in epilepsy); 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 (a medicine that thins 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 children aged 12 years and under:

The recommended total daily dose is 8 mg/kg. It can be given as a single dose or divided into 2 doses of 4 mg/kg with 12-hour interval.

<b>Bodyweight (kg)</b>	<b>Daily dosage (mg)</b>	<b>Daily dosage (mL)</b>
5 – 7.5	50	2.5
7.6 – 10	80	4
10.1– 12.5	100	5
12.6 – 20.5	150	7.5
20.6 – 28	200	10
28.1 – 33	250	12.5
33.1 – 40	300	15
40.1 – 45	350	17.5
45.1 and over	400	20

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

Daily recommended dose is 400 mg. A single daily dose of 400 mg or divided into two dosages of 200 mg with 12-hour interval can be used. FIXEF can be taken on an empty or full stomach.

For uncomplicated gonococcal infections, a single dose of 400 mg FIXEF should be used.

Treatment of streptococcal tonsillopharyngitis with FIXEF must be 10 days.

It is recommended to use the appropriate doses and pharmaceutical dosage forms for adults. Oral suspension and sachet forms can be used in patients with difficulty swallowing.

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

FIXEF is taken directly by mouth.

#### **Preparation of FIXEF suspension**

FIXEF is supplied as powder and must be reconstituted before use.

Follow the steps below for reconstitution of FIXEF.

Lightly tap on the bottle to loosen all powder.

1. Add water gradually until it fills up to 2/3 of the mark on the bottle and shake vigorously (Boiled and cooled water should be preferred for preparing a suspension).



2. Allow to stand for 5 minutes to ensure full dispersion.
3. Add water up to the mark on the bottle (remaining 1/3) and shake well again (Boiled and cooled water should be preferred for preparing a suspension).
4. The dose recommended by the doctor is given to the patient using a 5 ml measuring spoon that is supplied with the bottle.





Shake the bottle well before each dose.

After use, close the bottle tightly right away.

Each 5 ml of the prepared suspension (1 measuring spoon) contains 100 mg of cefixime.

Prepared suspension can be stored for 14 days at room temperature below 25°C without losing efficacy. After 14 days, the remaining suspension in the bottle cannot be used. Do not put into the refrigerator.

### **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

There is no special warning. Elderly patients can use the same dose as recommended for adults.

### **Use in special conditions**

#### Kidney failure

Dosage should be decreased in patients with significant kidney impairment. Your doctor will determine the dosage of your drug depending on your illness and will apply it to you.

#### Liver failure

No dose adjustment is 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 ending FIXEF therapy.

## **4. POSSIBLE SIDE EFFECTS**

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

**If any of the below happens, stop taking FIXEF and IMMEDIATELY tell your doctor or 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.

Side effects are classified in the following frequencies:

- 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.

Very common:

- Fullness of stomach
- Nausea, vomiting
- Flatulence
- Loss of appetite

Common:

- Soft stool or diarrhea

Uncommon:

- Skin rashes, itching, inflammation of the mucosa (tissue layer that covers the inner surfaces of some organs and produces secretions).

Rare:

- Decreased number of some blood cells (agranulocytosis, pancytopenia, leukopenia, thrombocytopenia)
- Increased number of allergy cells in the blood called eosinophils (eosinophilia)
- Headache
- Dizziness (vertigo)
- Increased liver enzymes
- Increased concentrations of creatinine and urea in the blood

Very rare:

- Blood clotting disorders  
As with other cephalosporins, bleeding-clotting processes can sometimes be affected, so patients undergoing coagulation therapy should be cautious.
- Antibiotic-induced colitis (inflammation of the large intestine) (e.g. pseudomembranous colitis)  
In case of developing intestinal inflammation (pseudomembranous colitis) characterized by pseudo-membranes, your doctor will give appropriate treatments.

- Superinfections (proliferation of microbes that are not susceptible to antibiotics)
- Drug fever
- Reaction like serum sickness (fever, pain and pain in the joints, an allergic reaction that causes skin rash and swelling in the lymph nodes)
- Anemia caused by the breakdown of red blood cells
- Inflammation of the kidney
- Hepatitis (jaundice due to liver infection), obstructive jaundice
- Temporary hyperactivity
- Tendency to contraction type seizure

Not known:

- Genital pruritus (itching) and vaginitis (bacterial inflammation of the vagina)

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

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 via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

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

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

Store the dry powder at room temperature below 25°C.

Store the reconstituted suspension at room temperature below 25°C and use within 14 days.

**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.

If you notice any defects on product and/or its package, do not use FIXEF.

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**

DEVA Holding A.Ş.

Küçükçekmece – İSTANBUL / TÜRKİYE

**Manufacturer**

DEVA Holding A.Ş.

Kapaklı – TEKİRDAĞ / TÜRKİYE

*This package leaflet was approved on 24/06/2024.*