

**Read this leaflet carefully before using the medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any question, consult your doctor or pharmacist.
- This medicine has been prescribed to you personally and you must not give it to others. It can harm them, even if the symptoms are the same as yours.

**This leaflet contains:**

- 1. WHAT IS FIXIM CAPSULES AND WHEN IT IS USED**
- 2. BEFORE USING FIXIM CAPSULES**
- 3. HOW TO USE FIXIM CAPSULES**
- 4. POSSIBLE SIDE EFFECTS**
- 5. STORAGE OF FIXIM CAPSULES**

## **FIXIM 200 mg CAPSULES**

## **FIXIM 400 mg CAPSULES**

The active ingredient is cefixime.

**FIXIM 200 mg CAPSULES:** Each capsule contain 200 mg of cefixime (as trihydrate).

**FIXIM 400 mg CAPSULES:** Each capsule contain 400 mg of cefixime (as trihydrate).

The others components (excipients) are: Colloidal silica, macrogol 40 stearate and magnesium stearate. Components of the capsule: gelatine, iron oxide yellow (E-172) and titanium dioxide (E-171).

### **MARKETING AUTHORIZATION HOLDER AND MANUFACTURER**

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### **1. WHAT FIXIM CAPSULES ARE AND WHAT THEY ARE USED FOR**

FIXIM comes in the form of capsules. FIXIM 200 mg CAPSULES comes in packages of 6 and 12 hard capsules containing 200 mg of cefixime each. FIXIM 400 mg CAPSULES comes in packages of 10 hard capsules containing 400 mg of cefixime each. Cefixime is an antibiotic of the cephalosporin group.

FIXIM CAPSULES are used for the treatment of infectious processes caused by cefixime-sensitive germs, such as: acute sinusitis, pharyngitis, tonsillitis, acute bronchitis, episodes of acute exacerbation of chronic bronchitis, pneumonia, otitis media (infection of the middle ear) and some uncomplicated infections of the urinary tract, such as cystitis and uncomplicated acute pyelonephritis.

### **2. BEFORE TAKING FIXIM CAPSULES**

- **Do not take FIXIM CAPSULES** if you are allergic to cefixime, to other cephalosporins, to cephamycins or any of the other components of the medicine.

- **Take special care with FIXIM CAPSULES:**

If you have previously suffered from some form of allergic reaction to drugs, especially antibiotics such as cephalosporins or penicillin. Treatment with cefixime should be suspended on the appearance of any type allergic reaction.

If severe diarrhoea appears, or if you observe blood, mucus or pus in the faeces, tell your doctor immediately.

Prolonged use of cefixime can lead to greater growth of resistant micro-organisms. In this case, your doctor will decide if treatment should be stopped.

- **Pregnancy:** As there is no information available on the possible negative effects of cefixime administered during pregnancy, its use is not advised during pregnancy, unless your doctor considers it appropriate. Consult your doctor or pharmacist before using any medicinal product.

- **Breastfeeding:** The use of cefixime during pregnancy is not recommended, as there is no data available on the possibility of cefixime passing into breast milk. Consult your doctor or pharmacist before using any medicinal product.
- **Driving and operating machinery:** No effects of this drug on the capacity to drive and use machinery are known.

- **Use of other drugs:** Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicine, including those that do not require a prescription.

Do not take this drug together with other antibiotics without express indication from your doctor.

As with other cephalosporins, it can cause false positive reactions in laboratory tests to determine ketones, glucose in urine and Coombs' reaction.

### 3. HOW TO TAKE FIXIM CAPSULES

Remember to take your medicine. Follow these instructions unless your doctor has indicated otherwise.

If you feel the effect of FIXIM CAPSULES is too strong or too weak, tell your doctor or pharmacist.

FIXIM CAPSULES are administered orally. The capsules should be swallowed without chewing and accompanied by a little liquid.

The recommended daily dose for adults, the elderly and children over the age of 12 years or more than 50 kg of weight is 400 mg per day, during 10 days. These can be taken 400 mg together once a day or 200 mg every 12 hours. The maximum recommended dose should not exceed 12 mg/kg of weight per day.

In cases of women with uncomplicated acute cystitis, a dose of 400 mg daily taken together once a day for 3 days is recommended.

In some cases of advanced kidney disease (renal insufficiency), the dose should be reduced by half. The dose should not exceed 200 mg of cefixime per day if you are on a dialysis programme.

Its administration is not recommended to premature babies, newborns and breast-feeding infants up to 6 months of age.

Your doctor will tell you how long your treatment with FIXIM CAPSULES should last. Do not stop treatment before this, as the symptoms you had before treatment will return.

- If you use more FIXIM CAPSULES than you should: Consult immediately your doctor or pharmacist. In the event of overdose or accidental ingestion, contact the Toxicology Information Service, indicating the product and the amount ingested.
- If you forgot the administration of FIXIM CAPSULES: Do not take a double dose to compensate the forgotten doses

### 4. POSSIBLE ADVERSE EFFECTS

As with all medicines, FIXIM CAPSULES may have adverse effects. Most of them are considered mild and transitory. **Gastrointestinal:** diarrhoea, nausea. **Allergic:** fever, urticaria. **Other reactions:** alterations to kidney function; vaginal pruritus (itching), vaginitis (inflammation of the vagina) and candidiasis (fungal infection). More rarely, cases of headache, alterations to blood cells (eosinophilia) and transitory increases in liver enzymes (transaminases) have been reported.

If any of these reactions or other reactions not described in this leaflet are observed, please consult your doctor or pharmacist.

### 5. STORAGE OF FIXIM CAPSULES

Keep FIXIM CAPSULES out of the reach and sight of children.

Store below 30°C in its original box.

Expiry: Do not take FIXIM CAPSULES after the expiry date shown on the packaging.