

Read this entire leaflet carefully before you start taking FIXIME.

- Keep this leaflet. You may need to read it again.
- If you have more questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

FIXIME 200 mg FILM COATED TABLETS

FIXIME 400 mg FILM COATED TABLETS

WHAT FIXIME CONTAINS:

FIXIME 200 mg Film Coated Tablets contains 200 mg cefixime.

FIXIME 400 mg Film Coated Tablets contains 400 mg cefixime.

The **FIXIME** range of products also contains cellulose microcrystalline, starch, calcium phosphate, magnesium stearate and purified water.

WHAT FIXIME IS USED FOR:

FIXIME is indicated for the treatment of acute and chronic infections when caused by susceptible micro-organisms.

Upper respiratory tract infections e.g. sore throat caused by bacteria, inflammation of the tonsils, middle ear infection, infection of the sinuses.

Lower respiratory tract infections e.g. bronchitis.

Urinary tract infections e.g. acute bladder infection.

Uncomplicated gonorrhoea (sexually transmitted disease).

BEFORE TAKING FIXIME:

Do not take FIXIME if you have the following:

- Hypersensitivity to cefixime, other cephalosporins or to any of the excipients.

Take special care with FIXIME if you have the following:

If you are allergic to penicillin avoid **FIXIME** as there is evidence of cross-allergenicity.

If you have asthma or allergic tendencies.

If you have markedly impaired kidney function.

If you have severe gastrointestinal disturbances involving vomiting and diarrhoea.

Taking other medicines with FIXIME:

If you are taking medicines on a regular basis, concomitant use of FIXIME may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

The concomitant use of **FIXIME** with water tablets, certain antibiotics namely the aminoglycosides or blood thinners are not advised.

Pregnancy and breastfeeding:

You should not use **FIXIME** if you are pregnant. You should not breastfeed if you are taking **FIXIME**.

If you are pregnant or breastfeeding your baby while taking FIXIME, please consult your doctor, pharmacist or other health care professional for advice.

HOW TO TAKE FIXIME:

Your individual dose will be determined by your doctor on the basis of laboratory tests and clinical examinations. Always take **FIXIME** as the doctor has instructed you. You should check with your

doctor or pharmacist if you are unsure.

FIXIME should be taken with plenty of liquid either before or during a meal.

Adults and Children over 12 years:

200 – 400 mg daily given either as a single dose or in two divided doses.

In lower respiratory tract infections e.g. bronchitis, 400 mg daily is recommended.

For upper respiratory tract infections e.g. middle ear infection or sore throat and uncomplicated bladder (urinary tract) infections, 200 mg once daily is usually effective.

Treatment of uncomplicated sexually transmitted disease (gonorrhoea) the recommended dosage is 400 mg as a single dose.

Patients with renal impairment may require a reduction in dose of **FIXIME**.

If you forget to take FIXIME:

Do not take a double dose to make up for the forgotten individual doses.

Do not share medicines prescribed for you with others. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

POSSIBLE SIDE-EFFECTS:

FIXIME can have side-effects.

Speak to your doctor if you get any of the following side-effects:

Immune System Disorders

Less frequent: Allergic reactions of varying degrees such as red skin, perceivable abnormal (fast and strong or irregular) heart beat rates, shortness of breath, low blood pressure, difficulty in breathing due to a tight chest.

Allergic skin disease characterized by patches of circumscribed swelling and hives. Life threatening allergic reactions resulting in shock (loss of consciousness, severely low blood pressure). Allergic reactions similar to those occurring when foreign blood is transfused, manifested by hives and swelling of the skin and tissues.

Skin Disorders

Less frequent: Rashes and red flushed skin, pain, redness, swelling, warm feeling and itching of the inside of the mouth, throat and nose, skin disorders characterized by widespread inflammation (pain, swelling, redness, warmth) of the skin with blisters that rupture (Toxic epidermal necrolysis), severe forms of flushed skin with blisters and areas of raw skin over the whole body and face accompanied by difficulty in breathing (Stevens-Johnson syndrome) and nondescript areas of swelling and redness (Erythema Exudativum Multiforme).

Renal and Urinary Disorders

Less frequent: Transient elevation of body urea concentrations as defined by laboratory test, elevation of blood creatinine and sudden or long-term inflammation of the kidney.

Caution is recommended in patients also treated with water tablets or other medicines which are potentially toxic to the kidney especially in those with diseases which may cause a reduction in blood supply to the kidney.

In these patients, impairment of the function of the kidney and even kidney failure may occur.

In such people, the doctor has to carefully monitor kidney function.

Infections and Infestations Disorders

Less frequent: Infection with other bacteria or even fungi because of a lack of 'beneficial bacteria' as they are also killed by long term use of the antibiotic.

Mouth and/or vaginal thrush (fungal infection) as manifested by sore mouth or tongue, with or without white plaques as and vaginal itching and discharge

Brain, Spinal Cord and Nerves Disorders

Less frequent: Headache, Dizziness, Transient periods where the person becomes hyperactive. An increased tendency for seizures cannot be excluded.

Gastro - Intestinal Disorders

Frequent: Loose stools and diarrhoea

Less frequent: Disturbances in the form of abdominal pain, indigestion, nausea and vomiting, lack of appetite and stomach distension with gas, inflammation of the large intestine due to lack of beneficial bacteria.

General Disorders

Less frequent: Fever caused by taking the medicine.

Blood and Lymphatic Disorders

Less frequent: Abnormal decrease in the amount of certain white blood cells as measured by taking blood and analysis in the laboratory

Abnormal decrease in the bacteria fighting white blood cells in the blood, condition with fever due to suppression of the cells producing white blood cells, which are contained in the bone marrow, abnormal reduction of red blood cells, white blood cells and platelets, abnormal reduction in the amount of blood platelets and other changes of blood cell levels.

These conditions usually return to normal after stopping treatment.

Disorders of blood clotting; decrease in number of red blood cells, due to their destruction in the body.

Liver and Gall Bladder Disorders

Less frequent: Reversible rise in liver enzymes as measured by laboratory test.

Inflammation of the liver as well as jaundice (yellowing of the white of the eyes, skin and inside of the mouth).

Not all side-effects reported for FIXIME are included in this leaflet. Should you general health worsens while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

KEEP OUT OF REACH OF CHILDREN.

Store at or below 30 °C in the original pack or in containers which prevent access of light and moisture.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicine to your pharmacist.

PRESENTATION OF FIXIME TABLETS:

Blister packs containing 1, 3,5 and 10 tablets.

IDENTIFICATION OF FIXIME TABLETS:

FIXIME 200 mg Film Coated Tablets are white, convex, rectangular tablets with rounded corners and bevelled edges and with a divided breakline on each side and EM 72 impressed on the one side.

FIXIME 400 mg Film Coated Tablets are white, convex, rectangular tablets with rounded corners and bevelled edges and with a divided breakline on each side and EM400 impressed on the one side.

REGISTRATION NUMBERS:

FIXIME 200 mg Film Coated Tablets: W/20.1.1/255

FIXIME 400 mg Film Coated Tablets: W/20.1.1/256

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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