PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

FIXINECT 400 mg Tablet

Cefixime

Sugar free

Read all of this leaflet carefully before you start taking FIXINECT

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

1. WHAT FIXINECT IS AND WHAT IT IS USED FOR:

FIXINECT is a medicine used to treat bacterial infections.

- Upper respiratory tract infections (infections of the ear, nose and throat); e.g. inflammation of the tonsils, middle ear infection, infection of the sinuses and sore throat caused by bacteria
- Lower respiratory tract infections; e.g. bronchitis
- Urinary tract infections; e.g. acute bladder infection.
- Uncomplicated gonorrhea (sexually transmitted diseases).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE

Do not take FIXINECT:

If you are hypersensitive to cefixime, other cephalosporins or any of the excipients**.** Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.

Warnings and precautions

Take Special Care with **FIXINECT if:**

- If you are allergic to penicillin
- If you have asthma or allergic tendencies
- If you have impaired kidney function
- If you have severe gastrointestinal disturbances involving vomiting and diarrhoea.

Other medicines and FIXINECT

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

In particular, tell your doctor if you are taking the following:

- Medicines to thin the blood such as warfarin or for pain and inflammation like (NSAIDS) or aspirin as it increases risk of bleeding.
- Antibiotics such as aminoglycosides as they increase the risk of kidney impairment.
- Medicines to treat pressure such as nifedipine or diuretic (water tablets) as they may increase blood levels of **FIXINECT**.

FIXINECT with food

The absorption of **FIXINECT** is not affected by food.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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

Driving and using machines

FIXINECT may have an effect on the ability of patients to drive or operate machines.

3. HOW TO TAKE FIXINECT

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Adults and Children over 12 years:

The usual dose is 200 mg (half tablet) or 400 mg (1 tablet) daily. It is taken orally given either as a single dose or in two divided doses. The tablet must be taken with plenty of liquid either before or during a meal.

Your doctor will tell you how long your treatment with **FIXINECT** will last. Do not stop treatment early because your infection will not be cured. If you have the impression that the effect of **FIXINECT** is too strong or too weak, tell your doctor or pharmacist.

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

FIXINECT should not be given to children < 12 years.

IF YOU TAKE MORE FIXINECT THAN YOU SHOULD:

Symptoms of over dosage include fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

If you forget to take FIXINECT

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

If you stop taking FIXINECT

DO NOT stop taking your tablets until all of your tablets are finished.

4. POSSIBLE SIDE EFFECTS

FIXINECT can have side-effects.

*Not all side effects reported for **FIXINECT** are included in this leaflet. Should your health worsen or if you experience any untoward effects while taking **FIXINECT**, please consult your doctor, pharmacist or other health care professional for advice.*

If any of the following happens, stop taking FIXINECT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- You have an allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also, flu-like symptoms and fever. This may be something called 'Stevens-Johnson' syndrome.
- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally

unwell, fever, chills and aching muscles. This may be something called ‘Toxic epidermal necrolysis’

- You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called ‘erythema multiforme’
- You get infections more easily than usual. This could be because of a blood disorder. This normally gets better after stopping the medicine
- You bruise or bleed more easily than normal. This could be because of a blood disorder. This normally gets better after stopping the medicine
- If your child gets nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), shortness of breath. This may be due to haemolytic anaemia.
- Changes in the way the kidneys are working or blood in your child’s urine
- Fits (convulsions) - Frequency not known
- A brain condition with symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. This may be something called encephalopathy. This side effect is more likely if you have taken an overdose or you already have a problem with your kidneys

  These are all very serious side effects. If you have them, you may have had a serious reaction to ***FIXINECT****. You may need urgent medical attention or hospitalisation*.

  Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called ‘Pseudomembranous colitis’

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following

- Feeling sick (nausea) or being sick (vomiting)
- Stomach pains, indigestion or wind
- Headaches
- Feeling dizzy
- Feeling itchy in the genital or vaginal area

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse drug Reaction reporting Form**”, found online under SAHPRA’s publications : https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **FIXINECT**

5. **HOW TO STORE FIXINECT**

   Store at or below 25 °C in the original pack away from light and moisture.

6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

   What FIXINECT contains

FIXINECT tablets contain the following inactive ingredients:

Calcium hydrogen phosphate dehydrate, microcrystalline cellulose, magnesium stearate, opadry white (hypromellose, titanium dioxide, macrogol, triacetin), pregelatinised starch.

What FIXINECT looks like and contents of the pack

FIXINECT White, to off white, film coated, oblong shaped tablets, with a deep score line on each side, debossed with “A” and “10” on one side and plain on other side.

Contents of pack:

PVC/ Aclar or PVC/PVdC clear film and foil blister pack containing 10 tablets per blister strip. Blister strips are packed in a printed carton.

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) Ltd

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2091

South Africa

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TBI

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Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **FIXINECT.**