PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

AUROXIME TABLETS 125 mg (tablet)

AUROXIME TABLETS 250 mg (tablet)

AUROXIME TABLETS 500 mg (tablet)

Cefuroxime Axetil

Sugar free

Read all of this leaflet carefully before you start taking AUROXIME TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AUROXIME TABLETS** 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.

What is in this leaflet

1 What AUROXIME TABLETS is and what it is used for

AUROXIME TABLETS are used to treat the following:

- Pharyngitis and tonsillitis caused by *Streptococcus pyogenes*.
- Otitis media caused by *Streptococcus pneumoniae, Haemophilus influenzae* (ampicillin-sensitive and resistant strains), *Moraxella (Branhamella) catarrhalis* and *Streptococcus pyogenes*.
- Sinusitis caused by *Streptococcus pneumoniae* and *Haemophilus influenzae.*

- Acute and chronic bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (ampicillin-sensitive strains) and *Haemophilus parainfluenzae* (ampicillin-sensitive strains).
- Acute uncomplicated cystitis caused by *Escherichia coli* and *Klebsiella pneumoniae*.
- Lyme disease caused by *Borrelia burgdorferi*.

2 What you need to know before you take AUROXIME TABLETS

Do not take AUROXIME TABLETS:

- if you are hypersensitive (allergic) to Cefuroxime Axetil or any of the other ingredients of **AUROXIME TABLETS**, (see section 6.1).
- if you are hypersensitive (allergic) to penicillin and other beta-lactam antibiotics.if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with AUROXIME TABLETS:

- If you are having an allergic reaction to **AUROXIME TABLETS,** stop taking **AUROXIME TABLETS** immediately and consult you doctor. You may experience chest pain, which is a severe reaction known as Kounis syndrome.
- If you have a history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.
- If you have kidney problems.
- If you have porphyria: Safety has not been established.
- Pseudomembranous colitis may occur. People who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhea (which may be bloody) and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, **AUROXIME TABLETS** should be stopped immediately and appropriate therapy initiated.
- Tell your doctor if you have syphilis, since a reaction called the “Jarisch-Herxheimer reaction” may occur shortly after starting treatment with **AUROXIME TABLETS**. Symptoms of this reaction include fever, chills and headaches.

- Tell your doctor if you notice any signs and symptoms or other infections such as yeast infections.
- Tell your doctor if you require any blood test or other laboratory tests while taking **AUROXIME TABLETS**.

Children

Do not give **AUROXIME TABLETS** to children under 3 months of age as safety has not been established.

Driving and using machinery:

It is not always possible to predict to what extent **AUROXIME TABLETS** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **AUROXIME TABLETS** affects them.

The ability to drive a motor vehicle or operate machinery may be impaired by **AUROXIME TABLETS**. This applies particularly in combination with alcohol.

Taking AUROXIME TABLETS with food and drink:

Take **AUROXIME TABLETS** half an hour after food.

Pregnancy and Breast-feeding

Safety during pregnancy and lactation is not known.

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.

Taking other medicines with AUROXIME TABLETS:

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

Tell your doctor if you are taking:

- probenecid - this may increase the levels of **AUROXIME TABLETS** in the blood.
- furosemide - this may cause kidney damage.
- aminoglycoside antibiotics (such as amikacin, gentamicin, kanamycin, neomycin, tobramycin) - this may also cause kidney damage.
- contraceptive pill - **AUROXIME TABLETS** may reduce the effectiveness of the contraceptive pill.

3 How to take AUROXIME TABLETS

Do not share medicines prescribed for you with any other person. Always take **AUROXIME TABLETS** exactly as your doctor has instructed you. Your doctor will tell you how long your treatment with **AUROXIME TABLETS** will last. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AUROXIME TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will prescribe an appropriate dose for you according to you condition.

If you take more AUROXIME TABLETS than you should:

Symptoms of overdose may include: seizures, severe abdominal cramps and vomiting.

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

If you forget to take AUROXIME TABLETS:

If you forget to take a dose of your medicine, take it as soon as you remember, and then continue as before. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

4 Possible side effects

Not all side effects reported for **AUROXIME TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **AUROXIME TABLETS**, please consult your health care provider for advice.

AUROXIME TABLETS can have side effects.

If any of the following happens, stop taking **AUROXIME TABLETS** and tell your doctor immediately to go the casualty department of your nearest hospital:

- Anaphylaxis characterised by: Skin rash, hives, difficulty breathing, swelling of your face,
- lips, tongue, or throat and / or shock.
- Pseudomembranous colitis (abdominal cramps, watery, severe diarrhoea, fever).

Tell your doctor if you notice any of the following side-effects:

Frequent:

- Nausea (Uncomfortable sensation in the stomach along with an urge to vomit), stomach cramps and diarrhoea (loose or watery stools),
- Fungal infections in the mouth or vagina (Candidiasis).Headaches or dizziness.

Less frequent:

- Changes in blood count,
- Hearing loss in children with meningitis,
- Porphyria, skin rashes,
- Difficulty breathing, fever,
- Kidney disorders.

Frequency not known:

- Blood disorder called haemolytic anaemia,
- Convulsions,
- Vomiting and diarrhoea with blood in stool,
- Liver disorders such as hepatitis and jaundice,

- Severe skins reactions such as Stevens-Johnson syndrome,
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **AUROXIME TABLETS**

5 How to store AUROXIME TABLETS

Store all medicines out of the reach and sight of children.

Store below 30 °C. Do not remove from blister until required for use.

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

6 Contents of the pack and other information

What AUROXIME TABLETS contains:

The active substance is Cefuroxime Axetil.

AUROXIME TABLETS 125 mg: Each tablet contains Cefuroxime Axetil (Amorphous) equivalent to Cefuroxime 125 mg.

AUROXIME TABLETS 250 mg: Each tablet contains Cefuroxime Axetil (Amorphous) equivalent to Cefuroxime 250 mg.

AUROXIME TABLETS 500 mg: Each tablet contains Cefuroxime Axetil (Amorphous) equivalent to Cefuroxime 500 mg.

The other ingredients are cellulose, microcrystalline; croscarmellose sodium; hydrogenated vegetable oil; silica, colloidal anhydrous and sodium lauril sulfate.

What AUROXIME TABLETS looks like and contents of the pack

1. PVC/ACLAR-ALUMINIUM BLISTER PACKAGING:

Tablets are packed in 250 Micron Clear PVC Film Laminated with 23 Micron Aclar (Width 132 mm) as the forming material and aluminium foil 25 microns (Width 126mm) as the lidding material. Each blister contains 10 tablets.

2. ALU-ALU PACK:

Tablets are packed in Cold Form Laminate: 25 Micron Polyamide / 45 Micron Aluminium Foil / 60 Micron PVC Film (Width 150mm) as the forming material and aluminium foil 25 microns (Width 148mm) as the lidding material. Each blister contains 10 tablets.

AUROXIME TABLETS 125 mg: 10's

AUROXIME TABLETS 250 mg: 10's

AUROXIME TABLETS 500 mg: 10's

Identification of AUROXIME TABLETS

AUROXIME TABLETS 125 mg: White to off-white, uncoated, capsule shaped tablets with ‘A32’ debossed on one side and plain on the other side.

AUROXIME TABLETS 250 mg: White to off-white, uncoated, capsule shaped tablets with ‘A33’ debossed on one side and plain on the other side.

AUROXIME TABLETS 500 mg: White to off-white, uncoated, capsule shaped tablets with ‘A34’ debossed on one side and plain on the other side.

Registration Number/Reference Number

AUROXIME TABLETS 125 mg: A40/20.1.1/0725

AUROXIME TABLETS 250 mg: A40/20.1.1/0720

AUROXIME TABLETS 500 mg: A40/20.1.1/0721

Holder of Certificate of Registration

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