PROFESSIONAL INFORMATION

SCHEDULING STATUS: S4

1 NAME OF THE MEDICINE

AUROXIME TABLETS 125 mg (Tablet)

AUROXIME TABLETS 250 mg (Tablet)

AUROXIME TABLETS 500 mg (Tablet)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

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

Sugar free.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

AUROXIME TABLETS is indicated for the treatment of infections caused by susceptible strains of the following organisms in the following infections:

- 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*.

4.2 Posology and method of administration

Posology

Adults:

Sinusitis and acute or chronic bronchitis:

250 mg twice daily for seven days (Range 5-10 days)

Acute, uncomplicated cystitis:

125 mg twice daily for seven days (Range 5-10 days)

Lyme disease:

Adults and children over 12 years of age: 500 mg twice daily for 20 days

Special populations

Renal function impairment – a reduced dose may be required (see section 4.4).

Paediatric population

There is no experience with **AUROXIME TABLETS** in children under 3 months of age.

- 3 months to 2 years of age: 125 mg twice daily
- Over 2 years of age: 250 mg twice daily

Method of administration

AUROXIME TABLETS should be taken half an hour after food for optimum absorption.

4.3 Contraindications

- Hypersensitivity to cephalosporin antibiotics or to any components of the formulation (see section 6.1).
- Hypersensitivity to penicillin and other beta-lactam antibiotics.
- Pregnancy and breastfeeding (see section 4.6)

4.4 Special warnings and precautions for use

AUROXIME TABLETS should be used with caution in patients with:

- A history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.
- Renal function impairment – A reduced dose may be required.
- Porphyria: Safety has not been established.

Hypersensitivity reactions

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other betalactam antibiotics because there is a risk of cross-sensitivity. As with all beta-lactam antibacterial medicines, serious and occasionally fatal hypersensitivity reactions have been reported. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergiccoronary arteriospasm that can result in myocardial infarction, see section 4.8). In case of severe hypersensitivity reactions, treatment with cefuroxime must be discontinued immediately and adequate emergency measures must be initiated.

Before beginning treatment, it should be established whether the patient has a history of severe hypersensitivity reactions to cefuroxime, to other cephalosporins or to any other type of beta-lactam medicine. Caution should be used if cefuroxime is given to patients with a history of non-severe hypersensitivity to other beta lactam medicines.

Jarisch-Herxheimer reaction

The Jarisch-Herxheimer reaction has been seen following cefuroxime axetil treatment of Lyme disease. It results directly from the bactericidal activity of cefuroxime axetil on the causative bacteria of Lyme disease, the spirochaete Borrelia burgdorferi. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease (see section 4.8).

Overgrowth of non-susceptible microorganisms

As with other antibiotics, use of cefuroxime axetil may result in the overgrowth of Candida. Prolonged use may also result in the overgrowth of other non-susceptible microorganisms (e.g. enterococci and Clostridium difficile), which may require interruption of treatment (see section 4.8).

Antibacterial medicine–associated pseudomembranous colitis have been reported with nearly all antibacterial medicines, including cefuroxime and may range in severity from mild to life threatening. This diagnosis should be considered in patients with diarrhoea during or subsequent to the administration of cefuroxime (see section 4.8).

Discontinuation of therapy with cefuroxime and the administration of specific treatment for Clostridium difficile should be considered. Medicines that inhibit peristalsis should not be given (see section 4.8). 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.

Interactions with Laboratory Tests (see section 4.5)

Paediatric population

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

4.5 Interaction with other medicines and other forms of interaction

Concurrent administration of probenecid increases the area under the mean serum concentration time-curve by 50 %.

Concomitant use of **AUROXIME TABLETS** and furosemide should be avoided when possible, due to enhanced nephrotoxicity. The combined use of cephalosporins and aminoglycosides should be undertaken with caution, due to nephrotoxicity. The efficacy of combined oral contraceptives may be decreased by concomitant use with **AUROXIME TABLETS**.

Interactions with Laboratory Tests:

It is recommended that either glucose oxidase or hexokinase methods be used to determine blood/plasma glucose levels in patients receiving **AUROXIME TABLETS.**

This medicine may give false-negative test results with ferricyanide blood glucose test.

AUROXIME TABLETS does not interfere in the alkaline picrate assay for creatinine.

A false-positive Coombs reaction may appear in patients who receive large doses of **AUROXIME TABLETS.**

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and efficacy in pregnancy has not been established (see section 4.3).

Studies in animals have shown no harmful effects on pregnancy, embryonal or foetal development, parturition or postnatal development.

Breastfeeding

Safety and efficacy in lactation has not been established (see section 4.3). **AUROXIME TABLETS** is excreted in human milk in small quantities. Adverse effects at therapeutic doses are not expected, although a risk of diarrhoea and fungus infection of the mucous membranes cannot be excluded. Breastfeeding might have to be discontinued due to these effects. The possibility of sensitisation should be taken into account.

Fertility

There are no data on the effects of cefuroxime axetil on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

4.7 Effects on ability to drive and use machines

As **AUROXIME TABLETS** may cause dizziness, patients should be warned to be cautious when driving or operating machinery.

4.8 Undesirable effects

Tabulated list of adverse reactions

- Frequency not known- cannot be estimated from the available data.

System Organ Class	Adverse effect	Frequency
Infections and infestations	Candida overgrowth, oral thrush, vaginitis.	*Frequent*
	Clostridium difficile overgrowth	*Frequency not known*
Blood and the lymphatic system disorders	Eosinophilia	*Frequent*
	Thrombocytopenia, leukopenia (sometimes profound), neutropenia,	*Less frequent*
	Haemolytic anaemia	*Frequency not known*
Nervous system disorders	Convulsions	*Frequency not known*
	Headache, dizziness	*Frequent*
Ear and labyrinth disorders	Hearing loss in children with meningitis.	*Less frequent*

Gastrointestinal disorders	Nausea, diarrhoea, abdominal pain.	*Frequent*
	A particular form of enterocolitis is pseudomembranous colitis (see section 4.4).	*Less frequent*
	Vomiting, diarrhoea accompanied by blood in the stools which may be a symptom of enterocolitis.	*Frequency not known*
Hepatobiliary disorders	Transient increases in hepatic enzyme levels, alanine aminotransferase (serum glutamic pyruvic acid transaminase), aspartate aminotransferase (serum glutamic oxaloacetic transaminase), LDH (lactate dehydrogenase) levels, cholestatic jaundice, hepatitis, rise in bilirubin.	*Frequency not known*
Reproductive system and breast disorders	Vaginal candidiasis	*Frequency not known*
Investigations	Transient increase in hepatic enzyme levels	*Frequency not known*
Skin and subcutaneous tissue disorders	Porphyria, skin rashes	*Less frequent*
	Urticarial, pruritus, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic necrolysis) (see Immune system disorders), angioneurotic oedema	*Frequency not known*
	Linear IgA disease	*Frequency not known*
Immune system disorders	Hypersensitivity reactions including skin rashes, cutaneous vasculitis, urticaria, pruritus, bronchospasm, drug fever, serum sickness, anaphylaxis, Jarisch-Hexheimer reaction	*Less frequent*
Cardiac disorders	Kounis syndrome	*Frequency not known*
Renal and urinary disorders	Acute interstitial nephritis, nephrotoxicity when **AUROXIME TABLETS** is used in combination with aminoglycosides or furosemide.	*Less frequent*

Investigations	Positive antiglobulin (Coombs') test.	*Frequency not known*

Cephalosporins as a class tend to be absorbed onto the surface of red cells membranes and react with antibodies directed against the medicine to produce a positive Coombs test (which can interfere with crossmatching of blood) and very rarely haemolytic anaemia. Transient rises in serum liver enzymes have been observed which are usually reversible.

Paediatric population

The safety profile for cefuroxime axetil in children is consistent with the profile in adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

(See section 4.8)

Symptoms of overdose:

Seizures have been reported.

Treatment of overdose:

Treatment is symptomatic and supportive. Serum levels of **AUROXIME TABLETS** can be reduced by haemodialysis or peritoneal dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 20.1.1 Broad and medium spectrum antibiotics

Pharmacotherapeutic group: Antibacterials for systemic use, second generation cephalosporins

ATC Code: J01DC02

Cefuroxime is a bactericidal second-generation cephalosporin. The antibacterial action of cefuroxime results from inhibition of bacterial cell wall synthesis by binding to essential target proteins in bacterial cytoplasmic membranes. Cefuroxime has bactericidal activity against a wide range of bacterial organisms, including beta-lactamase producing strains.

5.2 Pharmacokinetic properties

Cefuroxime axetil is an oral prodrug of cefuroxime. After oral absorption, cefuroxime axetil is hydrolyzed in the intestinal mucosa and blood to release cefuroxime into the plasma. Oral absorption is optimal when administered with food. Peak serum levels of cefuroxime occur approximately 2 to 3 hours after oral dosing, when taken with food. Protein binding is approximately 33% to 50%. Cefuroxime is not metabolised and is excreted unchanged in the urine by glomerular filtration and tubular secretion. The elimination half-life is between 1 and 1.5 hours after oral dosing. The elimination half-life is prolonged with renal impairment. Serum levels of cefuroxime are reduced by dialysis.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Cellulose Microcrystalline
- Croscarmellose Sodium
- Sodium Lauryl Sulfate
- Silica Colloidal Anhydrous

- Hydrogenated Vegetable Oil

Film Coating Ingredients

- Hypromellose
- Titanium dioxide
- Macrogol 400
- Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

1. PVC/ACLAR-ALIUMINIUM 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 126 mm) 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

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)

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

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

05 October 2007

10 DATE OF REVISION OF THE TEXT

08 January 2026