PROFESSIONAL INFORMATION

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

ZEFURIME 250 mg (film-coated tablet)

ZEFURIME 500 mg (film-coated tablet)

COMPOSITION

Each film-coated tablet of ZEFURIME 250 mg contains 250 mg cefuroxime as cefuroxime axetil.

Excipients:

Colloidal silicon dioxide, croscarmellose sodium, hydrogenated vegetable oil, hydroxypropyl methylcellulose, microcrystalline cellulose, polyethylene glycol, propylene glycol, sodium lauryl sulphate, talc, titanium dioxide

Sugar free

Each film-coated tablet of ZEFURIME 500 mg contains 500 mg cefuroxime as cefuroxime axetil.

Excipients:

Colloidal silicon dioxide, croscarmellose sodium, hydrogenated vegetable oil, hydroxypropyl methylcellulose, microcrystalline cellulose, polyethylene glycol, propylene glycol, sodium lauryl sulphate, talc, titanium dioxide

Sugar free

CATEGORY AND CLASS

A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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.

Pharmacokinetic properties

Cefuroxime axetil is an oral prodrug of cefuroxime. After oral absorption, cefuroxime axetil is hydrolysed 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.

INDICATIONS

ZEFURIME 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*.

CONTRAINDICATIONS

Hypersensitivity to cephalosporin antibiotics or to any components of the formulation.
Hypersensitivity to penicillin and other beta-lactam antibiotics.

WARNINGS AND SPECIAL PRECAUTIONS

ZEFURIME 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.

Pseudomembranous colitis may occur. Patients who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhoea (which may be bloody), and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, ZEFURIME should be stopped immediately and appropriate therapy initiated.
Prolonged use of ZEFURIME may result in the overgrowth of non-susceptible organisms (e.g. Candida, enterococci or *Clostridium difficile*).

The Jarisch-Herxheimer reaction has been reported following treatment with ZEFURIME for Lyme disease. This reaction is a common and usually self-limiting consequence of antibiotic treatment for Lyme disease.

INTERACTIONS

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

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 ZEFURIME.
This medicine may give false-negative test results with ferricyanide blood glucose test.
ZEFURIME does not interfere in the alkaline picrate assay for creatinine.
A false-positive Coombs reaction may appear in patients who receive large doses of ZEFURIME.

HUMAN REPRODUCTION

Safety and efficacy in pregnancy and lactation have not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults:

Sinusitis and acute or chronic bronchitis:

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

Acute, uncomplicated cystitis:

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

Lyme disease:

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

Children:

There is no experience with ZEFURIME 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.

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

SIDE EFFECTS

Heamatological:

Frequent: Eosinophilia

Neurological:

The following side effect has been reported and frequency is unknown: Headache

Gastrointestinal:

Less frequent: Nausea, vomiting, diarrhoea, in some cases accompanied by blood in stools, which may be a symptom of enterocolitis. A particular form of enterocolitis is pseudomembranous colitis (see WARNINGS AND SPECIAL PRECAUTIONS).

The following side effect has been reported and frequency is unknown: Abdominal pain

Kidney/Genitourinary:

The following side effect has been reported and frequency is unknown: Vaginal candidiasis

Liver:

The following side effect has been reported and frequency is unknown: Transient increases in hepatic enzyme levels

Skin:

Less frequent: Erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis

Other:

Frequent: Hypersensitivity reactions including skin rashes, urticaria, pruritus, drug fever, serum sickness, anaphylaxis

The following side effect has been reported and frequency is unknown: Bronchospasm

PROFESSIONAL INFORMATION

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS (See SIDE EFFECTS)

Symptoms

Seizures have been reported.

Treatment

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

IDENTIFICATION

ZEFURIME 250 mg: White to off-white capsule shaped film-coated tablet with "LUPIN" debossed on one side and "302" on the other side.
ZEFURIME 500 mg: White to off-white capsule shaped film-coated tablet with "LUPIN" debossed on one side and "303" on the other side.

PRESENTATION

ZEFURIME 250 mg and 500 mg: tablets are packed in clear, colourless polyvinylchloride/Aclar blister packs and sealed with an aluminium foil backing. Ten (10) or 60 tablets are packed in an outer cardboard carton. Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.
Keep blisters in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

ZEFURIME 250 mg: 41/20.1.1/0721
ZEFURIME 500 mg: 41/20.1.1/0722

[DATE OF APPROVAL: 23 JANUARY 2023]

PROFESSIONAL INFORMATION

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

Adcock Ingram Limited
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Erand Gardens,
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Customer Care:0860ADCOCK/ 232625

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: 12 June 2009
Date of the most recent amendment to the professional information as approved by the Authority: 23 January 2023

Namibia: NS2 ZEFURIME 500mg: 11/20.1.1/0006

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