PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE
RICIFUR 250 (Film-coated tablet)
RICIFUR 500 (Film-coated tablet)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
RICIFUR 250: Each tablet contains cefuroxime 250 mg (as cefuroxime axetil).
RICIFUR 500: Each tablet contains cefuroxime 500 mg (as cefuroxime axetil).

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Film-coated tablet.
RICIFUR 250: Off-white coloured, capsule shaped, biconvex, film-coated tablets plain on both the sides.
RICIFUR 500: White to off-white, caplet shaped, film-coated tablets, debossed with "C4" on one side and plain on other side.

4 CLINICAL PARTICULARS
Therapeutic indications
RICIFUR 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 influenza* (ampicillin-sensitive and resistant strains), *Moraxella (Branhamella) catarrhalis* and *Streptococcus pyogenes.*
- Sinusitis caused by *Streptococcus pneumoniae* and *Haemophilus influenza.*
- Acute and chronic bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenza* (ampicillin-sensitive strains) *Haemophilus parainfluenzae* (ampicillin-sensitive strains).
- Acute uncomplicated cystitis caused by *Escherichia coli* and *Klebsiella pneumoniae.*
- Lyme disease caused by *Borrelia burgdorferi.*

4.1 Posology and method of administration
Posology
RICIFUR should be taken half an hour after food for optimum absorption.

Adults:
Sinusitis & 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.

4.2 Special populations
Paediatric population
There is no experience with **RICIFUR** 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.

Patients with renal impairment
A reduced dose may be required.

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.

4.4 Special warnings and precautions for use
RICIFUR 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 blood) and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, **RICIFUR** should be stopped immediately and appropriate therapy initiated.

Paediatric population
There is no experience with **RICIFUR** in children under 3 months of age (see section 4.2).

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 %.

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

4.6 Fertility, pregnancy and lactation
Pregnancy
Safety and efficacy in pregnancy has not been established.
Breastfeeding
Safety and efficacy in breastfeeding has not been established.
Fertility
No data on fertility is available.

4.7 Effects on ability to drive and use machines
RICIFUR has no influence on the ability to drive and use machines.

4.8 Undesirable effects
a. Summary of the safety profile
Prolonged use of **RICIFUR** may result in the overgrowth on non-susceptible organsisms (e.g. Candida, Enterococci or Clostridium difficile).
Pseudomembranous colitis has been reported with the use of **RICIFUR**. 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. The Jarish-Herxheimer reaction has been reported following treatment with **RICIFUR** for Lyme disease. This reaction is a common and usually self-limiting consequence of antibiotic treatment for Lyme disease.
b. Tabulated summary of adverse reactions

MedDRA system organ class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Frequent	Eosinophilia
Nervous system disorders	Frequent	Headache
Gastrointestinal disorders	Frequent	Nausea, abdominal discomfort, diarrhoea, vomiting
	Frequency unknown	Pseudomembranous colitis
Renal and urinary disorders	Frequent	Vaginal Candidiasis
Hepato-biliary disorders	Frequent	Transient elevations in liver enzymes levels
Skin and subcutaneous tissue disorders	Frequency unknown	Erythema multiforme, Steven's-Johnson syndrome, toxic epidermal necrolysis
Immune system disorders	Frequency unknown	Hypersensitivity reactions, including skin rashes, urticarial, pruritus, bronchospasm, drug fever, serum sickness, anaphylaxis.

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 asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8
The applicant can be reached at the following contact number: 010 045 2500.

4.9 Overdose
Symptoms: Seizures have been reported.
Management: Treatment is symptomatic and supportive. Serum levels of **RICIFUR** can be reduced by haemodialysis or peritoneal dialysis.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological classification: A20.1.1 Broad and medium spectrum antibiotics.
Pharmacotherapeutic group: antibacterials for systemic use, second-generation cephalosporins, ATC-Code: J01DC02
Mechanism of action
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
Absorption: 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.
Distribution: 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 %.
Biotransformation: Cefuroxime is not metabolised and is excreted unchanged in the urine by glomerular filtration and tubular secretion.
Elimination: 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.

Preclinical safety data
Not applicable.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
RICIFUR 250:
Croscarmellose sodium
Colloidal silicon dioxide
Hydrogenated Castor Oil
Hypromellose
Microcrystalline cellulose
Sodium lauryl sulphate
Talc
Titanium dioxide (E 171)
RICIFUR 500:
Colloidal Silicon Dioxide
Croscarmellose Sodium
Hydrogenated Vegetable Oil
Hypromellose (HPMC-E 15)
Hypromellose (HPMC-E5)
Microcrystalline cellulose (PH-102)
Opadry White
Pregelatinized Starch
Sodium Lauryl Sulphate

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 years.
Store at or below 25 °C.

6.4 Special precautions for storage
This medicine does not require any special storage conditions.

6.5 Nature and contents of container
RICIFUR 250: Aluminium blister strips of 10, packed in a carton.
RICIFUR 500: Aluminium blister strips of 10, packed in a carton.

6.6 Special precautions for disposal and other handling
No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION
Strides Pharma SA (Pty) Ltd.
106 16th Road,
Building 2, Midrand
1686

8 REGISTRATION NUMBER(S)
RICIFUR 250: 38/20.1.1/0132
RICIFUR 500: 38/20.1.1/0131

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
03 June 2005

10 DATE OF REVISION OF THE TEXT
N.A

Strides

Tel: 010 594 5610.Email: PV@kahmagroup.co.za