Arocef®

Cefadroxil Capsule / Powder for Suspension BP

DESCRIPTION

Arocef® is the preparation of Cefadroxil. Cefadroxil is an orally active first generation Cephalosporin. It is bactericidal in vitro against both Gram-positive and Gram-negative microorganisms. Sensitive Gram-Positive organisms include: penicillinase and non-penicillinase producing *Staphylococci, β-haemolytic streptococci, Streptococcus pneumoniae* and *Streptococcus pyogenes*. Sensitive Gram-negative organisms include *Escherichia coli, Klebsiella species, Proteus mirabilis, Moraxella catarrhalis* and *Bacteroides spp.* and some strains of *Haemophilus influenzae.*

INDICATIONS

Respiratory tract infections: Tonsillitis, Pharyngitis, lobar and bronchopneumonia, acute and chronic bronchitis, pulmonary abscess, empyema, pleurisy, sinusitis, laryngitis.
Skin and soft tissue infection: Lymphadenitis, abscess, cellulitis, decubitus ulcers, mastitis, furunculosis, erysipelas.
Genitourinary tract infection: Pyelonephritis, cystitis, urethritis, gynaecological infections.
Other infections: Osteomyelitis, septic arthritis.

DOSAGE AND ADMINISTRATION

Adults : 500 mg -1 g in single or divided doses, depending upon the severity of infection.
Children:
Under one year: 25 mg /kg daily in divided doses
1- 6 years: 250 mg twice daily.
Over 6 years: 500 mg twice daily.
Elderly: Same as adult dose. No specific dosage recommendations or precautions for use in the elderly except to monitor those patients with impaired renal function.
Renal impairment: In patient with renal impairment, doses may be administered according to the following table.

Creatinine clearance	Initial dose	Maintenance dose	Dose interval
0-10 ml/min/1.73 m^2	1000 mg	500 mg	36 hrs
11-25 ml/min/1.73 m^2	1000 mg	500 mg	24 hrs
26-50 ml/min/1.73 m^2	1000 mg	500 mg	12 hrs

CONTRAINDICATIONS

Arocef® is contraindicated in patients with a history of hypersensitivity to Cefadroxil or any other cephalosporins.

USE IN PREGNANCY & LACTATION

Although animal studies & clinical experience have not shown any evidence of teratogenicity, the safe use of **Arocef®** during pregnancy has not been established. Cefadroxil is excreted in breast milk and should be used with caution in lactating mothers.

PRECAUTION

In patients with a history of penicillin allergy, **Arocef®** should be used with caution. There is evidence of partial cross-allergenicity between the penicillins and the cephalosporins. If an allergic reaction to **Arocef®** occurs, the drug should be discontinued and patient should be treated with the usual agents (pressor amines, corticosteroids or antihistamines), depending on the severity of the reaction. Cefadroxil can be removed from the body by haemodialysis. As experience in premature infants and neonates is limited, the use of **Arocef®** in these patients should only be undertaken with caution. As with all antibiotics, prolonged use may result in overgrowth of non-susceptible organisms.

SIDE EFFECTS

The most commonly reported side-effects are gastrointestinal disturbances and hypersensitive phenomena. Rash, pruritus, urticaria, angioneurotic oedema have been observed infrequently. Serum sickness, vomiting, diarrhoea, dyspepsia, abdominal discomfort, fever, dizziness, headache, arthralgia and genital candidiasis may also occur. Reversible neutropenia may occur rarely, as may leucopenia, thrombocytopenia, agranulocytosis & minor elevation in serum transaminase & Stevens-Johnson Syndrome. Colitis, including rare instances of pseudo-membraneous colitis, has been reported.

PHARMACEUTICAL PRECAUTION

Store in a cool (below 30 °C) and dry place, away from light. Keep out of the reach of children.

PACKAGING

Arocef® 500 Capsule	: Box containing 6 strips of 4 capsules each. Each capsule contains Cefadroxil Monohydrate BP equivalent to Cefadroxil 500 mg.
Arocef® Powder for Suspension	: Bottle containing powder for the preparation of 100 mL suspension. After reconstitution each 5 mL suspension contains Cefadroxil Monohydrate BP equivalent to Cefadroxil 125 mg.

SK+F
Manufactured by
ESKAYEF BANGLADESH LTD.
400, Tongi Industrial Area, Squibb Road,
Tongi, Gazipur, Bangladesh.
® REGD. TRADEMARK
PM00055 V03