POLYCEF®

Cephradine

(Capsule, Suspension & Injection)

Presentation :

POLYCEF® 250mg Capsules : Pink/red capsules imprinted with "Renata"; each capsule contains cephradine BP 250 mg.

POLYCEF® 500 mg Capsules : Light Blue/ash capsules imprinted with "Renata"; each capsule contians cephradine BP 500 mg.

POLYCEF® Suspension : Bottles containing powder for preparation of 100 ml of yellow coloured, banana/orange flavored suspension ; when reconstituted each 5 ml contains cephradine BP 125 mg.

POLYCEF® DS : Bottles containing powder for preparation of 100 ml of yellow coloured tutti-frutti/vanilla flavoured suspension; when reconstituted each 5 ml contains cephradine BP 250 mg.

POLYCEF® Paediatric Drops : Bottles containing powder for preparation of 15 ml of yellow coloured orange/banana flavoured suspension; when reconstituted each 1.25 ml contains cephradine BP 125mg.

POLYCEF® 250mg Injection : Powder in vials containing sterile cephradine equivalent to 250 mg cephradine USP.

POLYCEF® 500mg Injection : Powder in vials containing sterile cephradine equivalent to 500 mg cephradine USP.

POLYCEF® 1gm Injection : Powder in vials containing sterile cephradine equivalent to 1gm cephradine USP.

MICROBIOLOGY :

The wide range of micro-organisms that have shown 'in vitro' sensitivity to cephradine include :

Gram-positive	Gram-negative
Staphylococcus aureus	*Escherichia coli*
Staphyloccus epidermidis	*Proteus mirabilis*
Streptococcus pneumoniae	*Neisseria gonorrhoeae*
Streptococcus pyogenes	*Klebsiella spp.*
Streptococcus pneumoniae	*Neisseria gonorrhoeae*
Streptococcus viridans	*Haemophilus influenzae*
Streptococcus faeaclis	*Shigella spp.*
Peptococcus	*Salmonella spp.*
Peptostreptococcus	*Gardnerella vaginalis*

Cephradine is relatively more resistant to hydrolysis by beta-lactamases and hence many strains of both Gram-positive and Gram-negative bacteria capable of producing beta-lactamase are susceptible to cephradine but resistant to many other broad spectrum antibiotics.

USES :

POLYCEF® is a broad spectrum bactericidal antibiotic of the cephalosporin group active against a wide range of infections caused by susceptible Gram-positive and Gram-negative organisms.

POLYCEF® is indicated for the treatment of the following bacterial infections :

Upper respiratory tract, ENT infections : Pharyngitis, Tonsillitis, Laryngo-Tracheitis, Sinusitis, Otitis media.

Lower respiratory tract infections : Acute and chronic bronchitis, Lobar and broncho-pneumonia.

Urinary tract infections : Cystitis, Urethritis, Pyelonephritis, Prostatitis, Epididymitis.

Skin and soft tissue infections : Abscess, Cellulitis, Furunculosis, Impetigo.

Gastro-intestinal tract infections : Bacillary dysentery, Enteritis, Peritonitis, *Infections in the bones and joints.*
Septicaemia, Endocarditis.

POLYCEF® is also of value for the prophylaxis of post-operative infections, in patients undergoing surgical procedures associated with a high risk of infection.

As in the case of any antimicrobial agent, before instituting therapy with cephradine, necessary bacteriological studies should be performed to identify the causative organisms and their sensitivity to cephradine.

DOSAGE AND ADMINISTRATION :

Adults :

Oral : The usual dosage range is 1-2 g daily in two or four equally divided doses. Servere or chronic infections may require larger doses upto 4 g daily in divided doses or as advised by the physician.

Specific dosage recommendations : Respiratory tract infections : 250 mg to 500 mg four times daily or 500 mg to 1g twice daily.

Urinary tract infections : 500 mg four times daily or 1g twice daily.

Skin and soft tissue infections : 250 mg four times daily or 500 mg to 1g twice daily.

Gastro-intestinal tract infections : 500 mg three to four times daily.

Parenteral : The usual dosage range is 2-4 g daily, IM or IV in four equally divided doses. This may be increased up to 8 g/day for severe infections e.g. septicaemia and ednocarditis.

Children

Oral : The usual dose is 25 to 50 mg/kg/day, given in two or four equally divided doses.
the oral dosages should be taken before meals.

Parenteral : The usual dose is 50-100 mg/kg/day given in four equally divided doses. More serious infections may require 200-300 mg/kg/day.

Elderly :

There are no specific dosage recommendations or precautions for use in the elderly except, as with other drugs, to monitor those patients with impaired renal or hepatic functions.

Larger oral doses (upto 1g four times daily) may be given to all patients, irrespective of age and weight, for chronic infections, depending on the severity or site of infections. Therapy should be continued for a minimum of 48-72 hours after the patient becomes asymptomatic or evidence of bacterial eradication has been obtained, In infections caused by beta-haemolytic strains of streptococci, a minimum of 10 days treatment is recommended to guard against the risk of rheumatic fever or glomerulonephritis. In the treatment of chronic urinary tract infections, frequent bacteriological and clinical appraisal is necessary during therapy and may be necessary for several months afterwards. Persistent infections may require treatment for several weeks. Doses for children should not exceed doses recommended for adults.

DOSAGE IN RENAL IMPAIRMENT :

A modified dosage schedule in patients with decreased renal function is necessary. Each patient should be considered individually; the following reduced dosage schedule is recommended as a guideline, based on the creatinine clearance (mil/min/1.73 m2). In adults, the loading dose is 750 mg of **POLYCEF®** and the maintenance dose is 500 mg at the following time intervals :

Creatinine clearance	Time interval
More than 20 ml /min	6-12 hours
15-19 ml/min	12-24 hours
10-14 ml/min	24-40 hours
5-9 ml/min	40-50 hours
Less than 5 ml/min	50-70 hours

Further modification of the dosage schedule may be necessary in children.

Surgical prophylaxis : The recommended dose for surgical prophylaxis is a single pre-operative 1-2 g IM or IV dose. Subsequent parenteral or oral doses can be administered as appropriate.

ADMINISTRATION :

Oral : Using capsule or syrup

Intramuscular **:**

250 mg : Add 1.2 ml Water for Injection USP and shake vigorously.
500 mg : Add 2.0 ml Water for Injection USP and shake vigorously.
1gm : Add 4 ml Water for Injection USP and shake vigorously.

Intravenous :

250 mg : Dissolve in 5 ml of Water for Injection USP
500 mg : Dissolve in 5 ml of Water for Injection USP
1gm : Dissolve in 10 ml of Water for Injection USP

The solution may be slowly injected directly into a vein over a 3 to 5 minute period.

Solutions should be used within 2 hours when kept at room temperature. When stored at 5^0C, solutions retain potency for 12 hours. Reconstituted solutions may vary in colour from light to straw yellow; however this does not affect the potency.

CONTRA-INDICATIONS & WARNINGS:

Contra-indications : Cephradine is contra-indicated in patients with known hypersensitivity to the cephalosporin antibiotics.

Precautions : There is evidence of partial cross alergenicity between the penicillins and cephalosporins. Therefore cephradine should be used with caution in those patients with known hypersensitivity to penicillins.

As with all antibiotics, prolonged use may result in overgrowth of non-susceptible organisms. A false positive reaction for glucose on the urine may occur with reducting substances but not with enzyme-based tests.

Administration in renal failure : A modified dosage schedule in patients with decreased renal function is necessary (See dosage).

Pregnancy and breast feeding : Animal studies with cephradine have shown no teratogenecity. When antibiotic therapay is indicated during pregnancy cephradine may be considered appropriate.

Cephradine is excreted in breast milk and should be used with caution in lactating mothers.

SIDE-EFFECTS :

Side-effects are limited essentially to gastro-intestinal disturbances and on occasion to hypersensitivity phenomena. The latter are more likely to occur in individuals who have previously demonstrated hypersensitivity and those with a history of allergy, asthma, hay fever or urticarias. The majority of reported side effects have been mild. Skin rashes have occasionally been reported. Adverse reaction reports are rare, but include glossitis, heart burn, dizziness, tightness in the chest, nausea, vomiting, diarrhoea, abdominal pain etc. Skin and hypersensitivity reactions include urticaria, skin rashes, joint pains and oedema. As with other cephalosporins, mild transient eosinophilia, leucopoenia and neutropenia etc. have been reported.

Rarely have these side effects been severe enough to warrant cessation of therapy. As with other parenterally administered antibiotics, trasient pain may be experienced at the injection site, but is seldom the cause for discontinuing treatment. Thrombophlebitis has been reported following accidental subcutaneous injection, the preparation should be administered by deep intramuscular injection.

Clinical chemistry : Isolated instances of mild elevations of BUN, SGOT, SGPT. total bilirubin and alkaline phosphatase have been observed, but in most cases, the values tend to return to normal at the end of the therapy. No consistent pattern was observed that would suggest hepatocellular damage.

PHARMACEUTICAL PRECAUTIONS & STORAGE CONDITIONS :

Precaution : Keep out of the reach of children.

Storage : POLYCEF® capsules, suspension and Injection should be stored in a cool (below 30°C) dry place.

POLYCEF® syrup should be freshly prepared. Reconstituted syrup should be used within 7 days if kept at room temperature or within 14 days, if kept in a refrigerator. Solutions of cephradine should be protected from concentrated light or direct sunlight.

PACKAGE QUANTITIES

POLYCEF® 250mg Capsules : Cartons of 20 capsules in Alu-Alu blisterpack.

POLYCEF® 500 mg Capsules : Cartons of 28 capsules in Alu-Alu blisterpack.

POLYCEF® DS : Bottle containing powder to produce 100 ml of syrup when reconstituted and dropper, spoon and measuring cup.

POLYCEF® Syrup : Bottle containing powder to produce 100ml of syrup when reconstituted measuring cup.

POLYCEF® Pediatric Drops : Bottles containing powder to produce 15ml of syrup when reconstituted accompanied by measuring cup & dropper.

POLYCEF® 250mg IM/IV Injection : Each box containing 1 vial of 250mg cephradine and 1 ampoule of 5 ml water for injection USP.

POLYCEF® 500mg IM/IV Injection : Each box containing 1 vial of 500mg cephradine and 1 ampoule of 5 ml water for injection USP with Syringe.

POLYCEF® 1g IM/IV Injection : Each box containing 1 vial of 1g cephradine and 1 ampoule of 10 ml water for injection USP with Syringe.

Manufactured By
Renata Limited
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