CURISAFE

Cefadroxil monohydrate BROAD SPECTRUM ANTIBIOTIC

Pharmaceutical Forms:

CURISAFE Film coated Tablets: Each **CURISAFE** Tablet contains 1 g of **Cefadroxil** activity. Inactive Ingredients: Colloidal silicon dioxide, Magnesium stearate, Avicel PH 102, Low substituted hydroxypropyl cellulose, Eudragit E100, Talc powder, Titanium dioxide.

CURISAFE hard gelatin Capsules: Each **CURISAFE** Capsule contains 500 mg of **Cefadroxil** activity. Inactive Ingredients: Magnesium stearate, anhydrous colloidal silicon dioxide.

CURISAFE Powder for Oral Suspension:

Each 5 ml of reconstituted **CURISAFE** Suspension contain 125 mg or 250 mg of **Cefadroxil** activity.

Inactive Ingredients: Xanthan gum, Sodium benzoate, Polysorbate 80, Orange juice flavour, Orange flavour terpeneless, Pineapple flavor, FD&C Yellow No.6, Sucrose.

Each 5 ml of reconstituted **CURISAFE** Suspension contains 500 mg of **Cefadroxil** activity.

Inactive Ingredients: Microcrystalline cellulose, Sodium Carboxymethyl cellulose, Polysorbate 80, Sodium benzoate , Citric acid anhydrous, Orange flavor, Pineapple flavor, FD&C Yellow No.6 , Sucrose.

CURISAFE Pediatric Drops: Each 1 ml of reconstituted Pediatric Drops contains 100 mg of **Cefadroxil** activity. Inactive Ingredients: Xanthan gum, Sodium benzoate, Polysorbate 80, Natural & Artificial Orange juice, Orange flavour terpeneless, Artificial Pineapple flavour, FD&C Yellow No.6, Sucrose.

Properties:

CURISAFE (Cefadroxil monohydrate) is a bactericidal first generation cephalosporin. It exerts a bactericidal activity against both Gram-positive and Gram-negative micro-organisms by interfering with the terminal step in bacterial cell wall synthesis. **Cefadroxil** is markedly resistant to hydrolysis by β-lactamase therefore its spectrum covers both β-lactamase and non β-lactamase producing bacteria.

Pharmacokinetics:

Following oral administration of **CURISAFE** formulations, **Cefadroxil** is well absorbed from the gastrointestinal tract and its absorption is not affected by food. **Cefadroxil** is widely distributed in body tissues and fluids. 20% of the drug is bound to plasma proteins. Peak plasma concentrations are achieved within 1.5 to 2 hours and measurable levels are present 12 hours after oral administration. Most of Cefadroxil dose (more than 90%) is excreted unchanged in the urine within 24 hours. The plasma half-life of **Cefadroxil** is about 1.5 hours and is prolonged in patients with impaired renal function. **Cefadroxil** concentration is maintained well above the MICs of susceptible urinary pathogens throughout the dosing interval (12 hours). The drug crosses the placenta and small amounts appear in breast milk.

Bactericidal Spectrum:

CURISAFE exhibits an outstanding effectiveness against a wide range of Gram-positive pathogens including β-lactamase and non β-lactamase producing Staphylococci, hemolytic Streptococci, Streptococcus pneumoniae and Streptococcus pyogenes. It is also effective against several Gram-negative organisms including Escherichia coli, klebsiella pneumoniae and some strains of Proteus mirabilis, Haemophilus influenzae, Salmonella species and Shigella species.

Indications:

CURISAFE is indicated in the treatment of infections caused by Cefadroxil-susceptible strains of Gram-positive pathogens including β-lactamase and non β-lactamase producing Staphylococci, β-hemolytic streptococci, Streptococcus pneumoniae and Streptococcus pyogenes. It is also effective against several Gram-negative bacteria as follows:

- Infections of the Respiratory Tract: sinusitis, otitis media, tonsillitis, pharyngitis, laryngitis, bronchitis, bronchopneumonia, bronchiectasis, pulmonary abscess, empyema and pleurisy.
- Infections of the skin and soft tissues: cellulitis, erysipelas, pyoderma, lymphangitis, abscesses, decubitus ulcers, mastitis, furunculosis, impetigo and infected traumatic and postoperative wounds.
- Infections of the urinary Tract: pyelonephritis, cystitis, urethritis.
- Infections of the Genital Tract in Adults: prostatitis, orchitis, epididymo-orchitis, adnexitis, endometritis and other genital infections.
- Miscellaneous Infections: osteomyelitis, septic arthritis, intra-abdominal infections and dental infections.

Dosage and Administration:

CURISAFE is acid stable and may be administered orally without regard to meals. Administration with food may be helpful in diminishing potential gastrointestinal complaints occasionally associated with oral Cephalosporin therapy.

Adults: Urinary Tract Infection: for uncomplicated lower urinary tract infection(i.e. cystitis) the usual dosage is 1 or 2 g per day in single dose or two equally divided doses. For all other urinary tract infection the usual dosage is 2 g per day in two equally divided doses.

Skin and Skin structure infections: for skin and skin structure infections the usual dosage is 1 g per day in a single dose or two equally divided doses.

Pharyngitis and Tonsillitis: due to group A β-hemolytic streptococcal pharyngitis and tonsillitis 1g per day in a single dose or two equally divided doses for at least ten days.

Upper and Lower respiratory tract infections: for mild infections the usual dosage is 1 g per day in two equally divided doses. For moderate to severe infections the recommended dosage is 1 g to 2 g daily in two equally doses.

Children: The recommended dosage is 25 to 50 mg/kg/day in two equally divided doses (every 12 hours) as indicated. For pharyngitis, tonsillitis and impetigo the recommended daily dosage may be administrated as single dose or in two equally divided doses (every 12 hours).

CURISAFE ORAL SUSPENSION OR PEDIATRIC DROPS(dose q 12 h)				
Child Weight (Kg)	Drops 100 mg/1 ml (dropperful)	125 mg/5 ml (25 mg /ml)	250 mg/5 ml (50 mg/ml)	500 mg/5 ml (100 mg/ml)
4	0.5-1 dropperful	-	-	-
5	-	2.5- 5.0 ml	-	-
10	-	5.0- 10 ml	2.50- 5.0 ml	1.250- 2.50 ml
15	-	7.5- 15 ml	3.75- 7.5 ml	1.875- 3.75 ml
20	-	10.0- 20 ml	5.00- 10.0 ml	2.50- 5.00 ml
25	-	12.5- 25 ml	6.25- 12.5 ml	3.125- 6.25 ml

In the treatment of β-hemolytic streptococcal infections, a therapeutic dosage of **CURISAFE** should be administrated for at least 10 days. For the treatment of β-hemolytic streptococcal pharyngitis or tonsillitis in both adults and children. **CURISAFE** may be administrated in usual daily dose either in two divided doses or a single dose. In patients with renal impairment the dosage of **CURISAFE** should be adjusted according to creatinine clearance rates to prevent drug accumulation.

The following schedule is suggested in adults, the initial dose is 1 g of **CURISAFE** and the maintenance dose (based on the creatinine clearance rate) is 500 mg at the time intervals listed below:

Creatinine Clearance (ml/min/1.73m^2)	Dosage Interval
0 -10	36 Hours
10 - 25	24 Hours
25 - 50	12 Hours

Patients with creatinine clearance rates over 50ml/min/1.73m^2 may be treated as if they were patients having normal renal function.

In five adult anuric patients, it was demonstrated that an average of 63% of a 1 g oral dose is extracted from the body during a 6 to 8 hour hemodialysis session.

Reconstitution of **CURISAFE** Powder for Oral Suspension and Pediatric Drops:

The bottle is tapped lightly to loosen the powder. Water is added gradually to the powder and the bottle is shaken well after each addition till the reconstituted suspension reaches the level of the mark on the bottle. The Resultant suspension provides Cefadroxil activity of 500 mg or 250 mg or 125 mg per 5 ml oral suspension or of 100 mg per ml of reconstituted **CURISAFE** Pediatric Drops. It is stable for 14 days when kept refrigerated at (2 °C − 8°C)

Contraindications:

Hypersensitivity to Cefadroxil or other cephalosporins or to any of the excipients.

Previous history of immediate and/or severe hypersensitivity reactions (anaphylaxis) to penicillin or other beta-lactam antibiotics.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this product, since it contain sucrose.

Special warnings and precautions for use:

Special caution is required to determine any other type of previous hypersensitivity reactions to penicillin or to other beta-lactam medicinal products because patients hypersensitive to these medicines may be hypersensitive to **cefadroxil** as cross-allergy.

In patients with renal impairment the dose of **CURISAFE** must be reduced.

Side Effects:

CURISAFE is safe and well-tolerated. **CURISAFE** might cause GI disturbances including nausea, abdominal cramps and diarrhea. Less common side effects include urticaria, skin rash, angioneurotic edema and transient leucopenia.

Pregnancy and Lactation: Preparations containing Cephalosporins are used during pregnancy and lactation only if clearly indicated.

Drug Interactions:

Probenecid reduces renal excretion of **CEFADROXIL**. Aminoglycosides may increase the risk of nephrotoxicity. Anticoagulant effect of warfarin is increased by **CEFADROXIL**.

Interference with Laboratory Tests:

During Cephalosporin treatment, false positive results may be obtained for urinary glucose if determined by reduction methods. CEFADROXIL may cause false positive reaction for Ketones in the urine when tested using Nitroprusside. Direct Coomb's test may give false positive results.

Over dosage Treatment:

Accidental ingestion of high doses of **CEFADROXIL** containing preparations causes diarrhea, abdominal pain, nausea and vomiting. Treatment includes gastric lavage, activated charcoal intake, hemodialysis and treatment of symptoms.

Packing:

A carton box containing 2 Al/Al strips **CURISAFE** Tablets, each of 4 film coated tablets of 1 g Cefadroxil activity and an inner pamphlet.

A carton box containing 8 **CURISAFE** Capsules, each of 500 mg Cefadroxil activity and an inner pamphlet.

A carton box containing a plastic bottle containing **CURISAFE** powder to provide 60 ml suspension after reconstitution to give 125 mg or 250 mg or 500 mg of **CEFADROXIL** activity per 5 ml of the reconstituted suspension and an inner pamphlet.

A carton box containing a glass bottle containing CURISAFE Powder for Pediatric Drops to provide 100 mg **Cefadroxil** activity per 1 ml of the reconstituted pediatric drops and an inner pamphlet.

Storage:

Keep out of the reach of children.

For 1 gm Tablets & 500 mg Hard Gelatin Capsules: Store at temperature not exceeding 30ºC, in a dry place.

For 125mg/5ml or 250mg/5ml or 500mg/5ml Powder for Oral Suspension:

Dry Powder: Store at temperature not exceeding 30ºC, in a dry place.

Reconstituted suspension: 14 days when stored in a refrigerator (2°C-8°C)

For 100mg/ml Pediatric Drops:

Dry Powder: Store at temperature not exceeding 30ºC, in a dry place.

Reconstituted suspension: 14 days when stored in a refrigerator (2°C-8°C) & 7 days when kept at room temperature

Do not use the drug after the expiry date printed on the box.

Manufactured By:

Pharco B International

Borg El Arab –Alexandria

A.R.E

PHARCO B INTERNATIONAL