210 mm

140 mm

Capsule
Suspension
Solodrox
(Cefadroxil)

کیپسول
سسپینشن
سولوڈروکس
(سیفاڈروکسل)

COMPOSITION:

Solodrox capsule 500mg

Each capsule contains:

Cefadroxil (as monohydrate).....500mg

(USP Specifications)

Solodrox Dry Suspension 125mg / 5ml

Each 5ml after reconstitution contains:

Cefadroxil (as monohydrate).....125mg

(USP Specifications)

Solodrox DS Dry Suspension 250mg / 5ml

Each 5ml after reconstitution contains:

Cefadroxil (as monohydrate).....250mg

(USP Specifications)

DESCRIPTION:

Cefadroxil is a broad-spectrum antibiotic of the cephalosporin type, effective in Gram-positive and Gram-negative bacterial infections. It is a bactericidal antibiotic.

INDICATIONS:

Cefadroxil is a cephalosporin antibiotic bactericidal in vitro against a wide range of Gram-positive and Gram-negative microorganisms. Cefadroxil is indicated in the treatment of the following infections when due to susceptible microorganisms.

Respiratory tract infections: Pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes* (Group A beta-hemolytic streptococci), lobar and bronchopneumonia, acute and chronic bronchitis, pulmonary abscess, empyema, pleurisy, sinusitis, laryngitis, otitis media.

Skin and soft-tissue infections caused by staphylococci and/or streptococci:

Lymphadenitis, abscesses, cellulitis, decubitus ulcers, mastitis, furunculosis, erysipelas.

Urinary tract infections caused by *E. coli, P. mirabilis, and Klebsiella* species:

Pyelonephritis, cystitis, urethritis, gynecological infections.

Other infections: Osteomyelitis, septic arthritis.

MECHANISM OF ACTION:

Cefadroxil is a cephalosporin for oral administration, which inhibits bacterial wall synthesis of actively dividing cells by binding to one or more penicillin-binding proteins. The result is formation of a defective cell wall that is osmotically unstable and bacterial cell lysis.

DOSAGE & ADMINISTRATION:

For Capsule:

Adults and children weighing more than 40 kg (6 st. and 4 lbs): One to two capsules (500 mg to 1 g) twice a day, depending upon the severity of infection. Alternatively, in skin and soft tissue and uncomplicated urinary tract infections, 1 g once a day. In the treatment of beta-hemolytic streptococcal infections, Cefadroxil should be administered for at least 10 days.

Adults and children (7years & above) weighing less than 40 kg (6 st. and 4lbs):

One capsule (500 mg) twice a day.

Elderly: No specific dosage recommendations or precautions for use in the elderly except to monitor those patients with impaired renal function.

For Suspension:

For urinary tract infections, the recommended daily dosage for children is 30 mg/kg/day in divided doses every 12 hours. For pharyngitis, tonsillitis, and impetigo, the recommended daily dosage for children is 30 mg/kg/day in a single dose or in equally divided doses every 12 hours. For other skin and skin structure infections, the recommended daily dosage is 30 mg/kg/day in equally divided doses every 12 hours. In the treatment of beta-hemolytic streptococcal infections, a therapeutic dosage of Cefadroxil should be administered for at least 10 days. See chart for total daily dosage for children.

Daily Dosage of Cefadroxil Suspension				
Child's Weight		Strength		
Lbs.	Kg	125mg/ 5ml	250mg/ 5ml	500mg/ 5ml
10	4.5	1 tsp	—	
20	9.1	2 tsp	1 tsp	
30	13.6	3 tsp	1-1/2 tsp	
40	18.2	4 tsp	2 tsp	1 tsp
50	22.7	5 tsp	2-1/2 tsp	1-1/4 tsp
60	27.3	6 tsp	3 tsp	1-1/2 tsp
70	31.8+above	—	—	2 tsp

Renal Impairment Dosage:

In patients with renal impairment, the dosage should be adjusted according to creatinine clearance rates to prevent drug accumulation and serum levels should be monitored. A modified dosage schedule is unnecessary in patients with creatinine clearance rates of greater than 50 ml/min. In those patients with creatinine clearance rates of 50 ml/min or less, the following reduced dosage schedule is recommended as a guideline, based upon the creatinine clearance rate (ml/min/1.73m^2).

Patients with renal insufficiency may be treated with an initial dose of 500 mg to 1000 mg of cefadroxil. Subsequent doses may be administered according to the following table:

Creatinine clearance Dose	Dose	Interval
0-10 ml/min/1.73m^2	500-1000 mg	36 hours
11-25 ml/min/1.73m^2	500-1000 mg	24 hours
26-50 ml/min/1.73m^2	500-1000 mg	12 hours

PHARMACOKINETICS:

Cefadroxil is rapidly absorbed after oral administration.The bioavailability is unaffected by food. Following single doses of 500 mg and 1000 mg average peak serum levels were approximately 16 and 28μg/ml respectively. Measurable levels were present 12 hours after administration. Over 90% of the drug is excreted unchanged in the urine within 24 hours. Peak urine concentrations are approximately 1800μg/ml after a 500 mg dose. Increases in dose generally produce a proportionate increase in cefadroxil urinary concentration. Oral dosing produces effective tissues penetration in lungs, tonsil, liver, gall bladder, bile duct, prostate, bone, muscle and synovial fluid. The half-life is approximately 80 – 120 minutes, and protein binding is approximately 20%. Cefadroxil can be removed from the body by hemodialysis.

WARNINGS & PRECAUTIONS:

General : Cefadroxil should be used with caution in the presence of markedly impaired renal function (creatinine clearance rate of less than 50 ml/min/1.73m^2). In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy. Prolonged use of Cefadroxil may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. Cefadroxil should be prescribed with caution in individuals with history of gastrointestinal disease particularly colitis.

Drug/Laboratory Test Interactions

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when anti-globulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Pregnancy: Pregnancy Category B

Reproduction studies have been performed in mice and rats at doses up to 11 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefadroxil monohydrate. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

Cefadroxil has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

Nursing Mothers

Caution should be exercised when cefadroxil monohydrate is administered to a nursing mother.

210 mm

140 mm

History of gastro-intestinal disturbances
Cefadroxil should be used with caution in patients with a history of gastro-intestinal disturbances particularly colitis. Cefadroxil does not penetrate in the CSF and is not indicated for the treatment of Meningitis. Penicillin is the first drug of choice for the treatment of the Streptococcus pyogenes and for the prevention of rheumatic fever. Data for cefadroxil are not sufficiently substantial for prophylaxis therapy. As experience in premature infants and neonates is limited, the use of cefadroxil in these patients should only be undertaken with caution.

Patients with history of allergies
Special caution should be exercised in patients with history of severe allergies or asthma. In patients with a history of non severe hypersensitivity to penicillins, or other noncephalosporin beta–lactam drugs, cefadroxil should be used with special caution as cross allergies occur (incidence 5-10%). There is evidence of partial crossallergenicity between the penicillins and the cephalosporins. Should an allergic reaction to cefadroxil occur, the drug should be discontinued and the patient treated with the usual agents (pressor amines, corticosteroids and/or antihistamines), depending on the severity of the reaction. Patients who are allergic to aspirin have greater chances of developing an allergic reaction to one of the ingredients (colouring agent) in this medicine, namely Carmoisine (E122).

Allergic reactions
Treatment must be discontinued at once if allergic reactions occur (urticaria, exanthema, pruritus, fall of blood pressure and increased heart rate, respiratory disturbances, collapse, etc.) and suitable countermeasures should be taken (sympathomimetic, corticosteroids and/or antihistaminics).

Renal impairment
Caution is necessary in patients with renal impairment; the dosage must be adjusted according to the grade of renal impairment.

SIDE EFFECTS:
Gastrointestinal: Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Dyspepsia, nausea and vomiting have been reported rarely. Diarrhea has also occurred.
Hypersensitivity: Allergies (in the form of rash, urticaria, angioedema, and pruritus) have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.
Other: Other reactions have included hepatic dysfunction including cholestasis and elevations in serum transaminase, genital pruritus, genital moniliasis, vaginitis, moderate transient neutropenia, fever. Agranulocytosis, thrombocytopenia, idiosyncratic hepatic failure, erythema multiforme, Stevens-Johnson syndrome, serum sickness, and arthralgia have been rarely reported. In addition to the adverse reactions listed above which have been observed in patients treated with cefadroxil, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:
Toxic epidermal necrolysis, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, aplastic anemia, hemolytic anemia, hemorrhage, prolonged prothrombin time, positive Coombs' test, increased BUN, increased creatinine, elevated alkaline phosphatase, elevated aspartate aminotransferase (AST), elevated alanine aminotransferase (ALT), elevated bilirubin, elevated LDH, eosinophilia, pancytopenia, neutropenia. Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment, when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

DRUG INTERACTIONS:
Contraindication of concomitant use
Cefadroxil should not be combined with bacteriostatic antibiotics (e.g. tetracycline, erythromycin, sulfonamides, chloramphenicol) since an antagonistic effect is possible. Treatment with Cefadroxil in combination with aminoglycoside antibiotics, polymyxin B, colistin or high-dose loop diuretics should be avoided since such combinations can potentiate nephrotoxic effects.
Concomitant use not recommended
Frequent checks on coagulation parameters are necessary during concomitant long term use of anticoagulants or thrombocyte aggregation inhibitors to avoid haemorrhagic complications.
Precautions to be exercised
The concomitant administration of probenecid can produce higher and sustained concentrations of cefadroxil in the serum and in the bile. The occurrence of diarrhoea may impair the resorption of other medicaments and therefore lead to an impairment of their efficacy. Forced diuresis leads to a decrease of cefadroxil blood levels. Cefadroxil may attenuate the effect of oral contraceptives. Cefadroxil binds to cholestyramine which may lead to reduced bioavailability of cefadroxil.

CONTRAINDICATIONS:
Cefadroxil is contraindicated in patients with:
- History of hypersensitivity to cefadroxil, to any other cephalosporin or to any of the excipients of this product.
- History of severe reactions to penicillin or to any other beta-lactam drugs.

OVER DOSAGE:
No clinical reports are yet available on cefadroxil in this respect. However in view of experience gained with other cephalosporins the following symptoms are possible: Nausea, hallucinations, hyperreflexia, extrapyramidal symptoms, clouded consciousness, or even coma and renal functional impairment. First aid after intake of toxic doses: induce vomiting at once or gastric lavage, if necessary hemodialysis. Monitor and if necessary correct the water and electrolyte balance, monitor renal function. Ingestion of <250 mg/kg in children under six years of age was not associated with significant outcomes. The patient should be observed and treated symptomatically. For amounts >250 mg/kg, gastric lavage or stimulation of vomiting is appropriate.

STORAGE & INSTRUCTIONS:
Capsule:
Do not store above 30°C. Protect from heat, sunlight and moisture. Keep away from the reach of the children.
Suspension
Do not store above 30°C. Protect from heat, sunlight and moisture. Keep away from the reach of the children. After reconstitution, store in refrigerator and use within 7 days.
SHAKE WELL BEFORE USE.
Keep the container tightly closed. Discard unused portion after 7days.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:
Solodrox capsule 500mg
12 Capsules
Solodrox Dry Suspension 125mg / 5ml
60ml
Solodrox DS Dry Suspension 250mg / 5ml
60ml

کیپسول:

خوراک و ہدایات:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں۔ دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

سسپینشن:

خوراک و ہدایات:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں۔ دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔ بوتل کو ہلا کر اس میں موجود پاؤڈر کو بوتل کی دیواروں سے علیحدہ کرلیں۔ بوتل پر دیے گئے نشان سے تھوڑا نیچے تک تازہ ابلا ہوا ٹھنڈا پانی بوتل میں ڈالیں اور اچھی طرح ہلائیں۔ بوتل پر دیے گئے نشان تک مزید پانی ڈالیں اور اسطرح ہلائیں کہ یک جان سسپینشن تیار ہو جائے۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549,Sundar Industrial Estate,
Lahore, Pakistan.