DAPODOX
TABLET / POWDER FOR ORAL SUSPENSION.

Composition:
Dapodox tablets: Each dispersible tablet contains Cefpodoxime Proxetil equivalent to Cefpodoxime 100mg or 200mg.

Dapodox powder for oral suspension: Each 5ml of reconstituted suspension contains Cefpodoxime Proxetil equivalent to Cefpodoxime 100mg.

Pharmacological properties:
ATC Code: J01DD01.
Cefpodoxime proxetil is a beta-lactam antibiotic, a 3rd generation oral cephalosporin. It is the prodrug of cefpodoxime. Following oral administration, Cefpodoxime proxetil is taken up by the gastro-intestinal wall where it is rapidly hydrolysed to cefpodoxime, a bactericidal antibiotic, which is then absorbed systemically.The mechanism of action of cefpodoxime is based on inhibition of bacterial cell wall synthesis. It is stable to numerous beta-lactamases. Cefpodoxime has been shown to possess *in vitro* bactericidal activity against numerous Gram-positive and Gram-negative bacteria.

It is highly active against the Gram-positive organisms:
- *Streptococcus pneumonia*
- Streptococci of Groups A (*S. pyogenes*), B (*S. agalactiae*), C, F and G
- Other streptococci (*S. mitis, S. sanguis* and *S. salivarius*)
- *Corynebacterium diphtheria*

It is highly active against the Gram-negative organisms:
- *Haemophilus influenzae* (beta-lactamase and non beta-lactamase producing strains)
- *Haemophilus para-influenzae* (beta-lactamase and non beta-lactamase producing strains)
- *Branhamella catarrhalis* (beta-lactamase and non beta-lactamase producing strains)
- *Neisseria meningitides*
- *Neisseria gonorrhoeae*
- *Escherichia coli*
- *Klebsiella* Spp. (*K. pneumoniae*; *K. oxytoca*)
- *Proteus mirabilis*

It is moderately active against meticillin-sensitive staphylococci, penicillinase and non-penicillinase producing strains (*S. aureus* and *S. epidermidis*).

In addition, as with many cephalosporins, the following are resistant to cefpodoxime: enterococci, meticillin-resistant staphylococci *(S. aureus* and *S. epidermidis), Staphylococcus saprophyticus, Pseudomonas aeruginosa and Pseudomonas* Spp.*, Clostridium difficile, Bacteroides fragilis* and related species.

Pharmacokinetic properties:
Following oral administration, Cefpodoxime proxetil is taken up by the gastro-intestinal wall where it is rapidly hydrolysed to cefpodoxime, a bactericidal antibiotic, which is then absorbed systemically. When cefpodoxime proxetil is administered orally to fasting subjects as a tablet corresponding to 100mg of cefpodoxime, 51.5% is absorbed and absorption is increased by food intake. The volume of distribution is 32.3 L and peak levels of cefpodoxime occur 2 to 3 hrs after dosing. The maximum plasma concentration is 1.2mg/l and 2.5mg/l after doses of 100mg and 200mg respectively. Following administration of 100mg and 200mg twice daily over 14.5 days, the plasma pharmacokinetic parameters of cefpodoxime remain unchanged.
Serum protein binding of cefpodoxime, 40% principally to albumin. This binding is non saturable. Concentration of cefpodoxime in excess of the minimum inhibitory levels (MIC) for common pathogens can be achieved in lung parenchyma, bronchial mucosa, pleural fluid, tonsils, interstitial fluid and prostate tissue. As the majority of cefpodoxime is eliminated in the urine, the concentration is high. (Concentrations in 0-4, 4-8, 8-12 hr fractions after a single dose exceed MIC_{90} of common urinary pathogens). Good diffusion of cefpodoxime is also seen into renal tissue, with concentrations above MIC_{90} of the common urinary pathogens (0.6 - 3.1mg/g), 3-12hrs after an administration of a single 200mg dose. Concentrations of cefpodoxime in the medullary and cortical tissues is similar. The main route of excretion is renal, 80% is excreted unchanged in the urine, with an elimination half life of approx. 2.4 hours.

Indications:
- *Upper respiratory tract infections* caused by organisms sensitive to cefpodoxime, including sinusitis. In tonsillitis and pharyngitis, Cefpodoxime should be reserved for recurrent or chronic infections, where the causative organism is known or suspected to be resistant to commonly used antibiotics.
- *Lower respiratory tract infections* caused by organisms sensitive to cefpodoxime, including acute bronchitis and relapses or exacerbations of chronic bronchitis, and bacterial pneumonia, including patients at risk or compromised by other underlying illnesses.
- *Upper and lower urinary tract infections* caused by organisms sensitive to cefpodoxime including cystitis and acute pyelonephritis.
- *Skin and soft tissue infections* caused by organisms sensitive to cefpodoxime such as abscesses, cellulitis, infected wounds, furuncles, folliculitis, paronychia, carbuncles, burns and ulcers.
- Gonorrhoea, uncomplicated gonococcal urethritis.

Dosage and administration:
Cefuroxime Proxetil should be taken during meals with some liquid for optimum absorption.

Adults and children 12 years and above:

Type of Infection	Total Daily Dose	Dose Frequency	Duration
Pharyngitis and/or tonsillitis	200 mg	100 mg every 12 hours	5 to 10 days
Acute community-acquired pneumonia	400 mg	200 mg every 12 hours	14 days
Uncomplicated gonorrhea (men and women) and rectal gonococcal infections (women)	200 mg	single dose	
Skin and skin structure	800 mg	400 mg every 12 hours	7 to 14 days
Acute maxillary sinusitis	400 mg	200 mg Q 12 hours	10 days
Uncomplicated urinary tract infection	200 mg	100 mg Q 12 hours	7 days

Infants and Pediatrics 2 months to under 12 years:

Type of Infection	Total Daily Dose	Dose Frequency	Duration
Acute otitis media	10 mg/kg/day (Max 400 mg/day)	5 mg/kg every 12 hours (Max 200 mg/dose)	5 days
Pharyngitis and/or tonsillitis	10 mg/kg/day (Max 200 mg/day)	5 mg/kg/dose every 12 hours (Max 100 mg/dose)	5 to 10 days
Acute maxillary sinusitis	10 mg/kg/day (Max 400 mg/day)	5 mg/kg every 12 hours (Max 200 mg/dose)	10 days

Renal dysfunction:
For patients with severe renal impairment (<30 mL/min creatinine clearance), the dosing intervals should be increased to every 24 hours. In patients maintained on hemodialysis, the dose frequency should be 3 times/week after hemodialysis.When only the serum creatinine level is available, the following formula (based on sex, weight, and age of the patient) may be used to estimate creatinine clearance (mL/min). For this estimate to be valid, the serum creatinine level should represent a steady state of renal function.

Males: Weight (kg) x (140 - age)
(mL/min) 72 x serum creatinine (mg/100 mL)

Females: 0.85 x above value
(mL/min)

Patients with Cirrhosis:
Cefpodoxime pharmacokinetics in cirrhotic patients (with or without ascites) are similar to those in healthy subjects. Dose adjustment is not necessary in this population.

Contraindications:
Cefpodoxime proxetil is contraindicated in patients with a known allergy to cefpodoxime or to the cephalosporin group of antibiotics.

Warnings and precautions for use:
Before therapy with cefpodoxime proxetil is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefpodoxime, other cephalosporins, penicillins, or other drugs. If cefpodoxime is to be administered to penicillin sensitive patients, caution should be exercised because cross hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefpodoxime proxetil occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamine, and airway management, as clinically indicated.
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefpodoxime proxetil, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.*
Drug interactions:
Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H2 blockers reduces peak plasma levels by 24% to 42% and the extent of absorption by 27% to 32%, respectively. The rate of absorption is not altered by these concomitant medications. Oral anti-cholinergics (e.g., propantheline) delay peak plasma levels (47% increase in Tmax), but do not affect the extent of absorption (AUC).
Probenecid: As with other beta-lactam antibiotics, renal excretion of cefpodoxime is inhibited by probenecid and resulted in an approximately 31% increase in AUC and 20% increase in peak cefpodoxime plasma levels.
Nephrotoxic drugs: Although nephrotoxicity has not been noted when cefpodoxime proxetil was given alone, close monitoring of renal function is advised when cefpodoxime proxetil is administered concomitantly with compounds of known nephrotoxic potential..

Pregnancy and lactation:
Pregnancy: No adequate and well-controlled studies of cefpodoxime proxetil use in pregnant women, this drug should be used during pregnancy only if clearly needed.
Breast feeding mothers: Cefpodoxime is excreted in human milk, because of the potential for serious reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Side effects:
Common side effects: Diarrhea, Skin rashes, vomiting, headache, fungal infections.
Rare side effects: Abdominal pain, abdominal cramp, asthenia, fever, nausea, anorexia, dry mouth, stomatitis, pseudomembranous colitis, thrombocythemia, positive direct Coombs' test, eosinophilia, leukocytosis, leukopenia, prolonged partial thromboplastin time, thrombocytopenic purpura, myalgia, hallucination, hyperkinesia, nervousness, somnolence, epistaxis, rhinitis, skin moniliasis, urticaria, acne, exfoliative dermatitis, maculopapular rash, facial edema, congestive heart failure, palpitations, vasodilation, hematoma & hypertension,
Over dosage and Treatment:
The toxic symptoms following an overdose may include nausea, vomiting, epigastric distress, and diarrhea. In the event of serious toxic reaction from overdosage, hemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised.
Presentation:
Tablet: Alu / Alu blister pack of 1 x 10's in a unit carton.
Suspension: Powder for preparation of 60ml suspension in HDPE bottles.
Storage condition:
Store below 30°C. Protect from light and moisture.
Keep the medicine out of reach of children.

Manufactured for

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