SPINXO-200/100 DT TABLETS & SPINXO DRY SYRUP

COMPOSITION

SPINXO-200 DT
Each dispersible uncoated tablet contains:
Cefpodoxime proxetil, USP, equivalent to
Cefpodoxime ..... 200 mg
In a flavoured base

SPINXO-100 DT
Each dispersible uncoated tablet contains:
Cefpodoxime proxetil, USP, equivalent to
Cefpodoxime ..... 100 mg
In a flavoured base

SPINXO-50 Oral suspension
Each 5 ml of reconstituted suspension contains:
Cefpodoxime proxetil, USP, equivalent to
Cefpodoxime ..... 50 mg

SPINXO-100 Oral suspension
Each 5 ml of reconstituted suspension contains:
Cefpodoxime proxetil, USP, equivalent to
Cefpodoxime ..... 50 mg

INDICATIONS

• **Acute otitis media** caused by *Streptococcus pneumoniae*, (excluding penicillin-resistant strains),*Streptococcus pyogenes, Haemophilus influenzae* (including beta-lactamase-producing strains), or*Moraxella (Branhamella) catarrhalis* (including beta-lactamase-producing strains).
• **Pharyngitis and/or tonsillitis** caused by *Streptococcus pyogenes.*
NOTE: Only penicillin by the intramuscular route of administration has been shown to be effective in the prophylaxis of rheumatic fever. Cefpodoxime proxetil is generally effective in the eradication of streptococci from the oropharynx. However, data establishing the efficacy of cefpodoxime proxetil for the prophylaxis of subsequent rheumatic fever are not available.
• **Community-acquired pneumonia** caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (including beta-lactamase-producing strains).
• **Acute bacterial exacerbation of chronic bronchitis** caused by *Streptococcus pneumoniae, Haemophilus influenzae* (non-beta-lactamase-producing strains only), or *Moraxella catarrhalis*. Data are insufficient at this time to establish efficacy in patients with acute bacterial exacerbations of chronic bronchitis caused by beta-lactamase-producing strains of *Haemophilus influenzae*.
• **Acute, uncomplicated urethral and cervical gonorrhoea** caused by *Neisseria gonorrhoeae*(including penicillinase-producing strains).
• **Acute, uncomplicated ano-rectal infections in women** due to *Neisseria gonorrhoeae* (including penicillinase-producing strains).
NOTE: The efficacy of cefpodoxime in treating male patients with rectal infections caused by*Neisseria gonorrhoeae* has not been established. Data do not support the use of cefpodoxime proxetil in the treatment of pharyngeal infections due to *Neisseria gonorrhoeae* in men or women.

• **Uncomplicated skin and skin structure infections** *(such as abscesses, cellulitis, infected wounds, furuncles, folliculitis, paronychia, carbuncles and ulcers)* caused by *Staphylococcus aureus* (including penicillinase-producing strains) or *Streptococcus pyogenes.* Abscesses should be surgically drained as clinically indicated.
NOTE: In clinical trials, successful treatment of uncomplicated skin and skin structure infections was dose-related. The effective therapeutic dose for skin infections was higher than those used in other recommended indications.
• **Acute maxillary sinusitis** caused by *Haemophilus influenzae* (including beta-lactamase-producing strains), *Streptococcus pneumoniae,* and *Moraxella catarrhalis*.
• **Uncomplicated urinary tract infections (***cystitis and acute pyelonephritis)* caused by *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*, or *Staphylococcus saprophyticus*.
NOTE: In considering the use of cefpodoxime proxetil in the treatment of cystitis, the lower bacterial eradication rates of cefpodoxime proxetil should be weighed against the increased eradication rates and different safety profiles of some other classes of a pproved agents.

DOSAGE AND ADMINISTRATION

The recommended dosages, durations of treatment, and applicable patient population are as described in the following chart:

Patients with Normal Renal Function

Adults and adolescents (Aged 12 Years and Older)			
Type of Infection	**Total Daily Dose**	**Dose Frequency**	**Duration**
Pharyngitis and/or tonsillitis	200 mg	100 mg q12 hours	5–10 days
Acute community-acquired pneumonia	400 mg	200 mg q12 hours	14 days
Acute bacterial exacerbations of chronic bronchitis	400 mg	200 mg q12 hours	10 days
Uncomplicated gonorrhoea (men and women) and rectal gonococcal infections (women)	200 mg	single dose	-
Skin and skin structure	800 mg	400 mg q12 hours	7–14 days

Acute maxillary sinusitis	400 mg	200 mg q12 hours	10 days
Uncomplicated urinary tract infection	200 mg	100 mg q12 hours	7 days

Infants and paediatric patients (Aged 2 Months to 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 q12 hours (Max 200 mg/dose)	5 days
Pharyngitis and/or tonsillitis	10 mg/kg/day (Max 200 mg/day)	5 mg/kg q12 hours (Max 100 mg/dose)	5–10 days
Acute maxillary sinusitis	10 mg/kg/day (Max 400 mg/day)	5 mg/kg q12 hours (Max 200 mg/dose)	10 days

Infants Aged 15 Days to 2 Months
8 mg/kg/day in two divided doses.

Patients with Impaired Renal Function

The dosage of **SPINXO Oral Suspension/DT** does not require modification if the creatinine clearance exceeds 40 $ml.min^{-1}/1.73m^2$.
Below this value, pharmacokinetic studies indicate an increase in the plasma elimination half-life and the maximum plasma concentrations; hence, the dosage should be adjusted appropriately.

Creatinine Clearance (mL/min)	
39–10	Unit dose1 administered as a single dose every 24 hours (i.e., half of the usual adult dose).
<10	Unit dose1 administered as a single dose every 48 hours (i.e., quarter of the usual adult dose).
Haemodialysis patients	Unit dose1 administered after each dialysis session. The dose frequency should

	be three times/week after haemodialysis

NOTE: [1] The unit dose is either 100 mg or 200 mg, depending on the type of infection.

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 (mL/min)	Weight (kg) x (140 – age) 72 x serum creatinine (mg/100 mL)
Females (mL/min)	0.85 x above value

Patients with Cirrhosis

Cefpodoxime pharmacokinetics in cirrhotic patients (with or without ascites) is similar to those in healthy subjects. Dose adjustment is not necessary in this population.
Cefpodoxime proxetil for oral suspension may be given without regard to food.

SPINXO DT should be dispersed in a teaspoonful (5 ml) of boiled and cooled water before administration.

SPINXO Oral Suspension is provided in the form of a dry powder for reconstitution. Shake bottle to loosen the powder. Twist and open the vial of Sterile Water given with the pack. Add half quantity of the Sterile Water to the powder in the bottle. Re-cap bottle and shake the bottle vigorously. Adjust the volume up to the black arrow mark on the label by adding more Sterile Water and shake again. Store the reconstituted suspension in the refrigerator. It should be used within 14 days. Any extra portion left over should be thrown away. Shake well before each use.

CONTRAINDICATIONS

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

PACKAGING INFORMATION

SPINXO- 200/SPINXO-100 DT .....Strip pack of 10 tablets
SPINXO-50 Oral Suspension.with water for injection.....Bottle of 30ML
SPINXO-100 Oral Suspension.. with water for injection.....Bottle of 30ML