

Spinxo-Clav Tablets www.greencrossindia.com

COMPOSITION

SPINXO CLAV Tablets

Each film-coated tablet contains:

Cefpodoxime Proxetil IP

Equivalent to Cefpodoxime 200 mg

Clavulanate Potassium diluted IP

Equivalent to Clavulanic Acid 125 mg

INDICATIONS

SPINXO CLAV Tablets are indicated for the treatment of patients with mild-to-moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

- **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 (Branhamella) 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** 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 (Branhamella) catarrhalis*.

- **Uncomplicated urinary tract infections (cystitis)** 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 approved agents.

DOSAGE AND ADMINISTRATION

SPINXO CLAV Tablets should be swallowed whole without chewing.

Adults and Adolescents

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

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
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

*Dose of SPINXO CLAV Tablets is based on the cefpodoxime component.

Paediatric Use

General dosage recommendations for cefpodoxime in children are presented below:

Infants and pediatric patients (age 2 months through 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	5 mg/kg q12 hours	10 days

	(Max 400 mg/day)	(Max 200 mg/dose)
--	------------------	-------------------

*Dose of **SPINXO CLAV Tablets** is based on the cefpodoxime component.

Patients with Impaired Renal Function

Adults

The dosage of **SPINXO CLAV Tablets** does not require modification if creatinine clearance exceeds 40 mL/min-1/1.73 m².

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 dose ¹ administered as a single dose every 24 hours (ie, half of the usual adult dose).
<10	Unit dose ¹ administered as a single dose every 48 hours (ie, quarter of the usual adult dose).
Hemodialysis patients	Unit dose ¹ administered after each dialysis session. The dose frequency should be three times/week after hemodialysis

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)	$\frac{\text{Weight (kg)} \times (140 - \text{age})}{72 \times \text{serum creatinine (mg/100 mL)}}$
Females (mL/min)	0.85 x above value

Pediatric Use

There is no data available in the case of pediatric patients with impaired renal function.

CONTRAINDICATIONS

SPINXO CLAV Tablets are contraindicated in patients with a known allergy to penicillin, any other type of beta-lactam drug, the cephalosporin class of antibiotics, beta-lactamase inhibitors, or any other ingredients in this product formulation.

PACKAGING INFORMATION

SPINXO CLAV Tablets Strip pack of 6 tablets