

Proposed

L= 90 mm, H= 342 mm



Klarix[®]

Clarithromycin USP

Presentation

Klarix[®] 250 Tablet: Each film coated tablet contains Clarithromycin USP 250 mg.

Klarix[®] 500 Tablet: Each film coated tablet contains Clarithromycin USP 500 mg.

Klarix[®] 70 ml granules for Suspension: After reconstitution according to direction, each 5 ml suspension contains Clarithromycin USP 125 mg.

Description

Clarithromycin is a macrolide antibiotic. It acts by inhibiting microsomal protein synthesis by binding to the 50S subunit of the bacterial ribosome. Clarithromycin is active against most gram-positive bacteria, Chlamydia, some gram-negative bacteria and Mycoplasmas.

Indications and uses

- LRTIs for example, acute exacerbation of chronic bronchitis, community-acquired pneumonia
- URTIs for example, tonsillitis, pharyngitis, acute maxillary sinusitis and acute otitis media
- Uncomplicated skin and skin structure infections
- Adjunct therapy in peptic ulcer disease to eradicate *H. pylori*

Dosage and administration

Clarithromycin may be given with or without meals.

Adults (12 years or above)

Infection	Dose	Duration
Pharyngitis/Tonsillitis	250 mg twice daily	10 days
Acute maxillary sinusitis	500 mg twice daily	14 days
Acute exacerbation of chronic bronchitis	250-500 mg twice daily	7-14 days
Community-acquired pneumonia	250 mg twice daily	7-14 days
Uncomplicated skin and skin structure infections	250 mg twice daily	7-14 days
Adjunct therapy in peptic ulcer disease	500 mg twice/thrice daily	10-14 days

Children

Infection	Dosage			
<ul style="list-style-type: none">• Pharyngitis/Tonsillitis• Acute maxillary sinusitis• Acute otitis media• Acute exacerbation of chronic bronchitis• Community-acquired pneumonia• Uncomplicated skin and skin structure infections	7.5 mg/kg body weight twice daily; such as-			
	Body weight (kg)	Dose		Frequency & Duration Twice daily for usually 10 days
		mg	ml	
	9	62.5	2.5	
	17	125	5	
25	187.5	7.5		
33	250	10		

Dosage in renal impaired patients:

At creatinine clearance rate of less than 30 ml/min, the dosage should be halved to 250 mg daily or in the most severe infections to 250 mg twice daily. The duration of treatment should not exceed 14 days in these patients.

Side effects

The most frequently reported events in adults taking Clarithromycin were diarrhoea (3%), nausea (3%), abnormal taste (3%), dyspepsia (2%), abdominal pain/discomfort (2%) and headache (2%).

Precautions

Caution should be taken in administering this antibiotic to patients with impaired hepatic and renal function. Prolonged or repeated use of Clarithromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, Clarithromycin should be discontinued.

Contraindications

Hypersensitive to Clarithromycin, Erythromycin or any of the macrolide antibiotics. Patients receiving Terfenadine who have pre-existing cardiac abnormalities or electrolyte disturbances.

Drug interactions

Concomitant use of Clarithromycin who are receiving Theophylline may be associated with an increase in serum Theophylline concentrations. Clarithromycin may alter the metabolism of Terfenadine. The effects of Digoxin may be potentiated with concomitant administration of Clarithromycin. Clarithromycin results in decrease in serum levels of Rifabutin, followed by an increased risk of uveitis.

Use in pregnancy & lactation

Clarithromycin is not recommended for pregnant women. Breast milk from mothers receiving Clarithromycin should not be given to infants until treatment is completed. Clarithromycin may be used in neonates and children in appropriate doses.

Direction for reconstitution of suspension

Shake the bottle to loosen granules. Add 35 ml of boiled and cooled water with the help of the supplied cup, to the dry granules of the bottle. For ease of preparation, add water to the bottle in two proportions. Shake well after each addition until all the granules is in suspension.

Note: Shake the suspension well before each use. Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool and dry place, preferably in refrigerator.

Overdosage

Signs & Symptoms : Ingestion of large amounts of Clarithromycin can be expected to produce gastrointestinal symptoms. Symptoms of overdose may largely correspond to the profile of side effects.

Management: There is no specific antidote on overdose. Serum levels of Clarithromycin can not be reduced by haemodialysis or peritoneal dialysis.

Storage

Clarithromycin tablet and granules for suspension: Do not store above 30 °C. Keep away from light and out of the reach of children. The reconstituted suspension can be used for 7 days if kept at room temperature and for 14 days if kept in refrigerator.

Commercial Pack

Klarix[®] 250 Tablet: Each box contains 1 blister of 10 tablets.

Klarix[®] 500 Tablet: Each box contains 2 blisters of 7 tablets.

Klarix[®] 70 ml granules for Suspension: Each bottle contains dry granules for 70 ml suspension.

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