

# MACKTINICINE

## Ciprofloxacin & Tinidazole Tablets

### Composition:

Each film coated tablet contains:

Ciprofloxacin Hydrochloride USP

equivalent to Ciprofloxacin 500 mg

Tinidazole USP 600 mg

Excipients q.s.

Approved colour used

### Therapeutic Indications:

Ciprofloxacin 500 mg and Tinidazole 600 mg Film Coated Tablets are indicated for the treatment of a wide variety of infections caused by susceptible Gram-positive and Gram-negative organisms along with anaerobes and protozoa.

**Posology and Method of Administration:** Ciprofloxacin 500 mg and Tinidazole 600 mg Film Coated Tablets should be taken 1 hour before or 2 hours after meals with a glass of water.

**Adults:** One tablet twice daily for 5-10 days, depending on severity and response.

Children: Not recommended for children.

### Contraindications:

- Ciprofloxacin is contraindicated in persons with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antibacterial, or any of the product components
- Concomitant administration with tizanidine is contraindicated
- In patients with a previous history of hypersensitivity to tinidazole or other nitroimidazole derivatives. Reported reactions have ranged in severity from urticaria to Stevens-Johnson syndrome
- During first trimester of pregnancy
- In nursing mothers: Interruption of breast feeding is recommended during tinidazole therapy and for 3 days following the last dose

### Pregnancy and Lactation:

#### Ciprofloxacin- Pregnancy Category C-

There are no adequate and well-controlled studies in pregnant women. Ciprofloxacin should not be used during pregnancy unless the potential benefit justifies the potential risk to both foetus and mother. An expert review of published data on experiences with ciprofloxacin use during pregnancy by TERIS (the Teratogen Information System) concluded that therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk (quantity and quality of data = fair), but the data are insufficient to state that there is no risk.

#### Tinidazole -Teratogenic Effects: Pregnancy Category C

The use of tinidazole in pregnant patients has not been studied. Since tinidazole crosses the placental barrier and enters foetal circulation, it should not be administered to pregnant patients in the first trimester.

### Lactating Women

**Ciprofloxacin:** Ciprofloxacin is excreted in human milk. The amount of ciprofloxacin absorbed by the nursing infant is unknown. Because of the potential risk of serious adverse reactions (including articular damage) in infants nursing from mothers taking ciprofloxacin, 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.

**Tinidazole:** Tinidazole is excreted in breast milk. Tinidazole may continue to appear in breast milk for more than 72 hours after administration. Interruption of breastfeeding is recommended during tinidazole therapy and for 3 days following the last dose.

### Undesirable effects:

**Ciprofloxacin:** The following serious and otherwise important adverse drug reactions are discussed in greater detail in other sections of the labelling:

- Disabling and Potentially Irreversible Serious Adverse Reactions
- Tendinitis and Tendon Rupture
- Peripheral Neuropathy
- CNS Effects
- Exacerbation of Myasthenia Gravis
- Other Serious, and Sometimes Fatal, Adverse Reactions
- Hypersensitivity Reactions
- Hepatotoxicity
- Serious Adverse Reactions with Concomitant Theophylline
- Clostridium difficile-associated Diarrhoea
- Prolongation of the QT Interval
- Musculoskeletal Disorders in Paediatric Patients and Arthropathic Effects in Animals
- Photosensitivity/Phototoxicity
- Development of Drug-resistant Bacteria

**Dosage:** As directed by the physician.

**Storage:** Store in a cool, dry and dark place.

Keep the medicine away from children.

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