

# Amity Tablets\* Suspension\*

امیٹی ٹیبلٹس  
اسپینشن

**WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS.**

• Fluoroquinolones, including Ciprofloxacin, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:

- o Tendinitis and tendon rupture
- o Peripheral Neuropathy
- o Central nervous system effects

Discontinue Ciprofloxacin immediately and avoid the use of Fluoroquinolones, including Ciprofloxacin in patients who experience any of these serious adverse reactions.

• Fluoroquinolones, including Ciprofloxacin may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Ciprofloxacin in patients with known history of myasthenia gravis.

• As Fluoroquinolones, including Ciprofloxacin have been associated with serious adverse reactions, reserve Ciprofloxacin for use in patients who have no alternative treatment options for the following indications:

- o Acute exacerbation of chronic bronchitis
- o Acute sinusitis
- o Acute uncomplicated cystitis

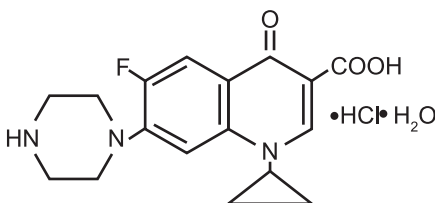
## COMPOSITION

**Each tablet contains:** Ciprofloxacin HCl eq. to Ciprofloxacin BP/USP 250 & 500 mg, respectively.

**Each 5 ml suspension contains:** Ciprofloxacin HCl eq. to Ciprofloxacin BP/USP 125 & 250 mg, respectively.

## DESCRIPTION

Ciprofloxacin hydrochloride tablets and oral suspension are synthetic broad spectrum antimicrobial agents for oral administration. Ciprofloxacin hydrochloride, a fluoroquinolone, is the monohydrochloride monohydrate salt of 1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolincarboxylic acid. It is a faintly yellowish to light yellow crystalline substance with a molecular weight of 385.8. Its empirical formula is  $C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_2O$  and its chemical structure is as follows:



## PHARMACOLOGY

**Mechanism of Action:** Ciprofloxacin is a member of the fluoroquinolone class of antibacterial agents. The bactericidal action of ciprofloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV (both Type II topoisomerases), which are required for bacterial DNA replication, transcription, repair, and recombination.

### Pharmacokinetics:

**Absorption:** The absolute bioavailability of ciprofloxacin when given as an oral tablet is approximately 70% with no substantial loss by first pass metabolism. Maximum serum concentrations are attained 1 to 2 hours after oral dosing. The serum elimination half-life in patients with normal renal function is approximately 4 hours. Serum concentrations increase proportionately with doses up to 1000 mg.

**Food:** The overall absorption of ciprofloxacin (AMITY) Tablet or ciprofloxacin (AMITY) Suspension, is not substantially affected. The pharmacokinetics of ciprofloxacin given as the suspension are also not affected by food. Avoid concomitant administration of ciprofloxacin (AMITY) with dairy products (like milk or yogurt) or calcium-fortified juices alone since decreased absorption is possible; however, ciprofloxacin (AMITY) may be taken with a meal that contains these products.

**Distribution:** The binding of ciprofloxacin to serum proteins is 20% to 40% which is not likely to be high enough to cause significant protein binding interactions with other drugs. After oral administration, ciprofloxacin is widely distributed throughout the body. Tissue concentrations often exceed serum concentrations in both men and women, particularly in genital tissue including the prostate. Ciprofloxacin is present in active form in the saliva, nasal and bronchial secretions, mucosa of the sinuses, sputum, skin blister fluid, lymph, peritoneal fluid, bile, and prostatic secretions. Ciprofloxacin has also been detected in lung, skin, fat, muscle, cartilage, and bone. The drug diffuses into the cerebrospinal fluid (CSF); however, CSF concentrations are generally less than 10% of peak serum concentrations. Low levels of the drug have been detected in the aqueous and vitreous humors of the eye.

**Metabolism:** Four metabolites have been identified in human urine which together account for approximately 15% of an oral dose. The metabolites have antimicrobial activity, but are less active than unchanged ciprofloxacin. Ciprofloxacin is an inhibitor of human cytochrome P450 1A2 (CYP1A2) mediated metabolism. Co-administration of ciprofloxacin with other drugs primarily metabolized by CYP1A2 results in increased plasma concentrations of these drugs and could lead to clinically significant adverse events of the co-administered drug.

**Excretion:** The serum elimination half-life in patients with normal renal function is approximately 4 hours. Approximately 40 to 50% of an orally administered dose is excreted in the urine as unchanged drug. The urinary excretion of ciprofloxacin is virtually complete within 24 hours after dosing. The renal clearance of ciprofloxacin, which is approximately 300 mL/minute, exceeds the normal glomerular filtration rate of 120 mL/minute. Thus, active tubular secretion would seem to play a significant role in its elimination. Co-administration of probenecid with ciprofloxacin results in about a 50% reduction in the ciprofloxacin renal clearance and a 50% increase in its concentration in the systemic circulation. Although bile concentrations of ciprofloxacin are several fold higher than serum concentrations after oral dosing, only a small amount of the dose administered is recovered from the bile as unchanged drug. An additional 1% to 2% of the dose is recovered from the bile in the form of metabolites. Approximately 20% to 35% of an oral dose is recovered from the feces within 5 days after dosing. This may arise from either biliary clearance or transintestinal elimination.

**Microbiology:** Ciprofloxacin has been shown to be active against most isolates of the following bacteria, both in vitro and in clinical infections.

**Gram-positive bacteria:** *Bacillus anthracis*, *Enterococcus faecalis*, *Staphylococcus aureus* (methicillin-susceptible isolates only), *Staphylococcus epidermidis* (methicillin-susceptible isolates only), *Staphylococcus saprophyticus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*.

**Gram-negative bacteria:** *Campylobacter jejuni*, *Citrobacter koseri*, *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Morganella morganii*, *Neisseria gonorrhoeae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia rettgeri*, *Providencia stuartii*, *Pseudomonas aeruginosa*, *Salmonella typhi*, *Serratia marcescens*, *Shigella boydii*, *Shigella dysenteriae*, *Shigella flexneri*, *Shigella sonnei*, *Yersinia pestis*.

## INDICATIONS & USAGE

**Skin and Skin Structure Infections:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of skin and skin structure infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, methicillin-susceptible *Staphylococcus aureus*, methicillin-susceptible *Staphylococcus epidermidis*, or *Streptococcus pyogenes*.

**Bone and Joint Infections:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of bone and joint infections caused by *Enterobacter cloacae*, *Serratia marcescens*, or *Pseudomonas aeruginosa*.

**Complicated Intra-Abdominal Infections:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of complicated intra-abdominal infections (used in combination with metronidazole) caused by *Escherichia coli*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, *Klebsiella pneumoniae*, or *Bacteroides fragilis*.

**Infectious Diarrhea:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of infectious diarrhea caused by *Escherichia coli* (enterotoxigenic isolates), *Campylobacter jejuni*, *Shigella boydii*, *Shigella dysenteriae*, *Shigella flexneri* or *Shigella sonnei* when antibacterial therapy is indicated.

**Typhoid Fever:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of

typhoid fever caused by *Salmonella typhi*. The efficacy of ciprofloxacin in the eradication of the chronic typhoid carrier state has not been demonstrated.

**Uncomplicated Cervical and Urethral Gonorrhoea:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of uncomplicated cervical and urethral gonorrhoea due to *Neisseria gonorrhoeae*.

**Inhalational Anthrax (Post-Exposure):** Ciprofloxacin (AMITY) is indicated in adults and pediatric patients from birth to 17 years of age for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*.

**Plague:** Ciprofloxacin (AMITY) is indicated for treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (Y. pestis) and prophylaxis for plague in adults and pediatric patients from birth to 17 years of age.

**Chronic Bacterial Prostatitis:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of chronic bacterial prostatitis caused by *Escherichia coli* or *Proteus mirabilis*.

**Lower Respiratory Tract Infections:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of lower respiratory tract infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, or *Streptococcus pneumoniae*. Ciprofloxacin (AMITY) is not a drug of first choice in the treatment of presumed or confirmed pneumonia secondary to *Streptococcus pneumoniae*. Ciprofloxacin (AMITY) is indicated for the treatment of acute exacerbations of chronic bronchitis (AECB) caused by *Moraxella catarrhalis*.

Because fluoroquinolones, including ciprofloxacin (AMITY), have been associated with serious adverse reactions and for some patients AECB is self-limiting, reserve ciprofloxacin (AMITY) for treatment of AECB in patients who have no alternative treatment options.

**Urinary Tract Infections: Urinary Tract Infections in Adults:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of urinary tract infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter koseri*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, methicillin-susceptible *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, or *Enterococcus faecalis*.

**Acute Uncomplicated Cystitis:** Ciprofloxacin (AMITY) is indicated in adult female patients for treatment of acute uncomplicated cystitis caused by *Escherichia coli* or *Staphylococcus saprophyticus*.

Because fluoroquinolones, including ciprofloxacin (AMITY), have been associated with serious adverse reactions and for some patients acute uncomplicated cystitis is self-limiting, reserve ciprofloxacin (AMITY) for treatment of acute uncomplicated cystitis in patients who have no alternative treatment options.

**Complicated Urinary Tract Infection and Pyelonephritis in Pediatric Patients:** Ciprofloxacin (AMITY) is indicated in pediatric patients aged one to 17 years of age for treatment of complicated urinary tract infections (cUTI) and pyelonephritis due to *Escherichia coli*. Ciprofloxacin (AMITY) is not a drug of first choice in the pediatric population due to an increased incidence of adverse reactions compared to controls, including reactions related to joints and/or surrounding tissues.

**Acute Sinusitis:** Ciprofloxacin (AMITY) is indicated in adult patients for treatment of acute sinusitis caused by *Haemophilus influenzae*, *Streptococcus pneumoniae*, or *Moraxella catarrhalis*. Because fluoroquinolones, including ciprofloxacin (AMITY), have been associated with serious adverse reactions and for some patients acute sinusitis is self-limiting, reserve ciprofloxacin (AMITY) for treatment of acute sinusitis in patients who have no alternative treatment options.

## CONTRAINDICATIONS

**Hypersensitivity:** Ciprofloxacin (AMITY) is contraindicated in persons with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antibacterials, or any of the product components.

**Tizanidine:** Concomitant administration with tizanidine is contraindicated.

## ADVERSE EFFECTS

The following adverse drug reactions are serious and otherwise important:

- Disabling and Potentially Irreversible Serious Adverse Reactions
- Tendinitis and Tendon Rupture
- Peripheral Neuropathy
- Central Nervous System Effects
- Other Serious and Sometimes Fatal Adverse Reactions
- Hypersensitivity Reactions
- Hepatotoxicity
- Serious Adverse Reactions with Concomitant Theophylline
- *Clostridium difficile*-Associated Diarrhea
- Prolongation of the QT Interval
- Musculoskeletal Disorders in Pediatric Patients
- Photosensitivity/Phototoxicity
- Development of Drug Resistant Bacteria

The most frequently reported drug related effects were nausea (2.5%), diarrhea (1.6%), abnormal liver function tests (1.3%), vomiting (1.0%), and rash (1.0%). Medically important adverse reactions that occurred in less than 1% of ciprofloxacin patients are listed in Table 1.

**Table 1: Medically Important Adverse Reactions that occurred in less than 1% of Ciprofloxacin Patients**

System Organ Class :	Adverse Reactions
<b>Body as a Whole</b>	Headache, Abdominal pain/discomfort.
<b>Cardiovascular</b>	Syncope, Angina Pectoris, Myocardial Infarction, Cardiopulmonary Arrest, Tachycardia, Hypotension.
<b>Central Nervous System</b>	Restlessness, Dizziness, Insomnia, Nightmares, Hallucinations, Paranoia, Psychosis (toxic), Manic Reaction, Irritability, Tremor, Ataxia, Seizures, Malaise, Anorexia, Phobia, Depersonalization, Depression, Paresthesia, Abnormal gait, Migraine.
<b>Gastrointestinal</b>	Intestinal perforation, Gastrointestinal bleeding, Cholestatic jaundice, Hepatitis, Pancreatitis.
<b>Hemic/Lymphatic</b>	Petechia.
<b>Metabolic/Nutritional</b>	Hyperglycemia, Hypoglycemia.
<b>Musculoskeletal</b>	Arthralgia, Joint stiffness, Muscle weakness.
<b>Renal/Urogenital</b>	Interstitial nephritis, Renal failure.
<b>Respiratory</b>	Dyspnea, Laryngeal edema, Hemoptysis, Bronchospasm.

**Adverse Laboratory Changes:** Changes in laboratory parameters while on ciprofloxacin (AMITY) are listed in Table 2.

**Table 2: Laboratory Parameters that are Affected by Ciprofloxacin**

	Adverse Laboratory Change
<b>Hepatic</b>	Elevations of ALT (SGPT), AST (SGOT), Alkaline phosphatase, LDH, Serum bilirubin.
<b>Hematologic</b>	Eosinophilia, Leukopenia, Decreased blood platelets, Elevated blood platelets, Pancytopenia.
<b>Renal</b>	Elevations of serum creatinine, BUN, Crystalluria, Cylindruria, Hematuria.
<b>Other</b>	Elevation of serum gamma-glutamyl transferase, Elevation of serum amylase, Reduction in blood glucose, Elevated uric acid, Decrease in hemoglobin, Anemia, Bleeding diathesis, Increase in blood monocytes, Leukocytosis.

## DRUG INTERACTIONS

Ciprofloxacin is an inhibitor of human cytochrome P450 1A2 (CYP1A2) mediated metabolism. Co-administration of ciprofloxacin (AMITY) with other drugs primarily metabolized by CYP1A2 results in increased plasma concentrations of these drugs

and could lead to clinically significant adverse events of the co-administered drug.

**Table 3: Drugs that are Affected by and Affecting Ciprofloxacin**

Drugs that are Affected by Ciprofloxacin		
Drug(s)	Recommendation	Comments
Tizanidine	Contraindicated.	Potential of hypotensive and sedative effects of tizanidine.
Theophylline	Avoid Use. (Plasma exposure likely to be increased and prolonged).	If unavoidable, monitor for theophylline toxicity.
Drugs Known to Prolong QT Interval	Avoid Use.	Further QT interval prolongation.
Oral antidiabetic drugs	Use with caution, hypoglycemia potentiated.	Monitor blood glucose.
Phenytoin	Use with caution. Altered serum levels of phenytoin (increased and decreased).	Monitor phenytoin therapy.
Cyclosporine	Use with caution (transient elevations in serum creatinine).	Monitor renal function (in particular serum creatinine).
Anti-coagulant drugs	Use with caution (Increase in anticoagulant effect).	Monitor prothrombin time and INR frequently.
Methotrexate	Use with caution. Inhibition of methotrexate renal tubular transport potentially leading to increased methotrexate plasma levels.	Monitor for methotrexate toxicity.
Ropinirole	Use with caution.	Monitor for ropinirole-related adverse reactions and adjust the dose.
Clozapine	Use with caution.	Monitor for clozapine-related adverse reactions and adjust the dose.
NSAIDs	Use with caution.	NSAIDs (but not acetyl salicylic acid) in combination of very high doses of quinolones have been shown to provoke convulsions.
Sildenafil	Use with caution. Two-fold increase in exposure.	Monitor for sildenafil toxicity.
Duloxetine	Avoid Use. Five-fold increase in duloxetine exposure.	If unavoidable, monitor for duloxetine toxicity.
Caffeine/ Xanthine Derivatives	Use with caution. Reduced clearance resulting in elevated levels and prolongation of serum half-life.	Ciprofloxacin inhibits the formation of paraxanthine after caffeine administration (or pentoxifylline containing products). Monitor for xanthine toxicity and adjust the dose.
Drug(s) Affecting Pharmacokinetics of Ciprofloxacin		
Antacids, Sucralfate, Multivitamins and Other Products	Ciprofloxacin should be taken at least two hours before or six hours after multivalent cation-containing products.	Decrease ciprofloxacin absorption, resulting in lower serum and urine levels.
Probenecid	Use with caution (interferes with renal tubular secretion of Ciprofloxacin and increases its serum levels).	Potential of ciprofloxacin toxicity may occur.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** Ciprofloxacin should not be used during pregnancy unless the potential benefit justifies the potential risk to both fetus and mother. **Nursing Mothers:** 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 (AMITY), 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. **Pediatric Use:** Ciprofloxacin (AMITY) is not a drug of first choice in the pediatric population due to an increased incidence of adverse reactions. **Geriatric Use:** Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as ciprofloxacin (AMITY). Caution should be used when prescribing ciprofloxacin (AMITY) to elderly patients especially those on corticosteroids. **Renal Impairment:** Some modification of dosage is recommended, particularly for patients with severe renal dysfunction. **Hepatic Impairment:** In patients with stable chronic liver cirrhosis, no significant changes in ciprofloxacin pharmacokinetics have been observed. The pharmacokinetics of ciprofloxacin in patients with acute hepatic insufficiency have not been studied.

**WARNINGS AND PRECAUTIONS**

**Disabling and Potentially Irreversible Serious Adverse Reactions Including Tendinitis and Tendon Rupture, Peripheral Neuropathy, and Central Nervous System Effects:** Fluoroquinolones, including ciprofloxacin, have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). These reactions can occur within hours to weeks after starting ciprofloxacin. Patients of any age or without pre-existing risk factors have experienced these adverse reactions. Discontinue ciprofloxacin (AMITY) immediately at the first signs or symptoms of any serious adverse reaction. **Exacerbation of Myasthenia Gravis:** Fluoroquinolones, including ciprofloxacin, have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis. Avoid ciprofloxacin (AMITY) in patients with known history of myasthenia gravis. **Hepatotoxicity:** Cases of severe hepatotoxicity, including hepatic necrosis, life-threatening hepatic failure, and fatal events, have been reported with ciprofloxacin. In the event of any signs and symptoms of hepatitis, discontinue treatment immediately. **Clostridium difficile-Associated Diarrhea:** *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including ciprofloxacin.

**DOSAGE & ADMINISTRATION**

Ciprofloxacin (AMITY) Tablets and Oral Suspension should be administered orally as described in the appropriate Dosage Guidelines Tables.

**Dosage in Adults:** The determination of dosage and duration for any particular patient must take into consideration the severity and nature of the infection, the

susceptibility of the causative microorganism, the integrity of the patient's host-defense mechanisms, and the status of renal and hepatic function.

**Table 4: Adult Dosage Guidelines**

Infection	Dose	Frequency	Usual Durations <sup>1</sup>
Skin and Skin Structure	500-750 mg	every 12 hours	7 to 14 days
Bone and Joint	500-750 mg	every 12 hours	4 to 8 days
Complicated Intra-Abdominal <sup>2</sup>	500 mg	every 12 hours	7 to 14 days
Infectious Diarrhea	500 mg	every 12 hours	5 to 7 days
Typhoid Fever	500 mg	every 12 hours	10 days
Uncomplicated Urethral and Cervical Gonococcal Infections	250 mg	single dose	single dose
Inhalational anthrax (post-exposure) <sup>3</sup>	500 mg	every 12 hours	60 days
Plague <sup>3</sup>	500 - 750 mg	every 12 hours	14 days
Chronic Bacterial Prostatitis	500 mg	every 12 hours	28 days
Lower Respiratory Tract Infections	500 - 750 mg	every 12 hours	7 - 14 days
Urinary Tract Infections	250 - 500 mg	every 12 hours	7 - 14 days
Acute Uncomplicated Cystitis	250 mg	every 12 hours	3 days
Acute Sinusitis	500 mg	every 12 hours	10 days

1. Generally ciprofloxacin should be continued for at least 2 days after the signs and symptoms of infection have disappeared, except for inhalational anthrax (post-exposure).

2. Used in conjunction with metronidazole.

3. Begin drug administration as soon as possible after suspected or confirmed exposure.

**Dosage in Pediatric Patients:** Dosing and initial route of therapy for cUTI or pyelonephritis should be determined by the severity of the infection. Ciprofloxacin (AMITY) should be administered as described in Table 5.

**Table 5: Pediatric Dosage Guidelines**

Infection	Dose	Frequency	Total Duration
Complicated Urinary Tract or Pyelonephritis (patients from 1 to 17 years of age)	10 mg/kg to 20 mg/kg (maximum 750 mg per dose; not to be exceeded even in patients weighing more than 51 kg)	every 12 hours	10-21 days
Inhalational Anthrax (Post- Exposure)	15 mg/kg (maximum 500 mg per dose)	every 12 hours	60 days
Plague	15 mg/kg (maximum 500 mg per dose)	Every 8 to 12 hours	10-21 days

**Dosage Modifications in Patients with Renal Impairment:** Dosage guidelines for use in patients with renal impairment are shown in Table 6.

**Table 6: Recommended Starting and Maintenance Doses for Adult Patients with Impaired Renal Function**

Creatinine Clearance	Dose
> 50	See Usual Dosage
30-50	250-500 mg every 12 hours
5-29	250-500 mg every 18 hours
Patients on hemodialysis or Peritoneal dialysis	250-500 mg every 24 hours (after dialysis)

**METHOD OF PREPARATION**

1. Tap the bottle to loosen the powder. Put some boiled and cooled water into the bottle and shake well.

2. Add more boiled and cooled water into the bottle upto the mark on the label and shake vigorously.

3. Suspension is ready for use. Reconstituted suspension should be stored in refrigerator (between 2-8 °C). Once prepared it should be used within 14 days.

**OVERDOSAGE**

In the event of acute overdosage, reversible renal toxicity has been reported in some cases. Empty the stomach by inducing vomiting or by gastric lavage. Observe the patient carefully and give supportive treatment, including monitoring of renal function, urinary pH and acidity, if required, to prevent crystalluria and administration of magnesium, aluminum, or calcium containing antacids which can reduce the absorption of ciprofloxacin. Adequate hydration must be maintained. Only a small amount of ciprofloxacin (less than 10%) is removed from the body after hemodialysis or peritoneal dialysis.

**STORAGE / PRECAUTIONS**

**AMITY 250 & 500 mg Tablets:** Store in a cool, dry and dark place between 15-30 °C. **AMITY Suspension 125 & 250 mg /5 ml:** Store in a cool, dry and dark place between 15-30 °C before reconstitution of the suspension. Reconstituted suspension should be stored in refrigerator (between 2-8 °C). Keep all medicines out of the reach of children. To be used on the prescription of Registered Medical Practitioners only.

**PRESENTATION**

AMITY 250 & 500 mg Tablets are available in packing containing 10 tablets, respectively, whereas AMITY Suspension 125 & 250 mg /5 ml are available in a bottle (approx. 60 ml when prepared as directed).

**\*Scotmann Specs.**

خبراک: ڈاکٹر کی ہدایت کے مطابق۔  
احتیاط: اینٹی بیوٹکس 250 اور 500 ملی گرام ٹیبلٹس، روٹی، مٹی اور گرمی سے بچائیں۔ 15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔ اینٹی بیوٹکس 125 اور 250 ملی گرام فی 5 ملی لیٹر، روٹی، مٹی اور گرمی سے بچائیں۔ سسپنشن تیار کرنے سے پہلے 15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔ تازہ سسپنشن ریفریجریٹر میں (2 سے 8 ڈگری سینٹی گریڈ کے درمیان) محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔ مستند ڈاکٹر کے نسخہ پر استعمال کریں۔

Complete Medical Information available only for doctors on request.



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