W: 100 mm x H: 345 mm

Ciprocin® 200 IV

Ciprofloxacin 0.2% w/v

COMPOSITION
Ciprocin® 200 IV: Each 100 ml solution contains Ciprofloxacin 200 mg as Ciprofloxacin Lactate INN.

PHARMACOLOGY
Ciprofloxacin is a synthetic broad-spectrum antimicrobial agent for intravenous administration. The bactericidal action of Ciprofloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair, and recombination.

INDICATION
Ciprocin® 200 IV is indicated for the treatment of following infections caused by sensitive bacteria-

- Urinary Tract Infection
- Lower Respiratory Tract Infection
- Nosocomial Pneumonia
- Skin and Skin Structure Infection
- Bone and Joint Infection
- Complicated Intra-Abdominal Infection
- Acute Sinusitis
- Chronic Bacterial Prostatitis
- Infectious Diarrhea
- Inhalational Anthrax

DOSAGE AND ADMINISTRATION
Adult

Indication	Severity	Dose	Frequency	Days
Urinary Tract	Mild to Moderate	200 mg	q12h	7-14 days
	Severe or Complicated	400 mg	q12h	7-14 days
Lower Respiratory Infection	Mild to Moderate	400 mg	q12h	7-14 days
	Severe or Complicated	400 mg	q8h	7-14 days
Nosocomial Pneumonia	Mild or Moderate or Severe	400 mg	q8h	10-14 days
Skin and Skin Structure Infection	Mild to Moderate	400 mg	q12h	7-14 days
	Severe or Complicated	400 mg	q8h	7-14 days
Bone and Joint Infection	Mild to Moderate	400 mg	q12h	≥ 4-6 weeks
	Severe or Complicated	400 mg	q8h	≥ 4-6 weeks
Intra-Abdominal Infection	Complicated	400 mg	q12h	7-14 days
Acute Sinusitis	Mild to Moderate	400 mg	q12h	10 days
Chronic Bacterial Prostatitis	Mild to Moderate	400 mg	q12h	28 days

Ciprocin® 200 IV should be administered by intravenous infusion over a period of 60 minutes.

Conversion of I.V. to Oral Dosing in Adults
Parenteral therapy may be switched to oral therapy when the condition warrants, at the discretion of the physician.

Equivalent AUC Dosing Regimens

Ciprofloxacin Oral Dosage	Equivalent Ciprofloxacin IV dose
250 mg Tablet q 12 h	200 mg IV q 12 h
500 mg Tablet q 12 h	400 mg IV q 12 h
750 mg Tablet q 12 h	400 mg IV q 8 h

Children
Ciprofloxacin is usually not recommended for use in children. However, if the benefit of ciprofloxacin therapy are considered to overweigh the potential risk, the dosage should be 5-10 mg/kg/day in two divided doses, depending on the severity of the infections.

USE IN PREGNANCY AND LACTATION
The safety and effectiveness of Ciprofloxacin in pregnant and lactating women have not been established. Ciprofloxacin should not be used during pregnancy unless the potential benefit justifies the potential risk to both fetus and mother.
Ciprofloxacin is excreted in human milk. The amount of Ciprofloxacin absorbed by the nursing infant is unknown. Because of the potential for serious adverse reactions 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.

SIDE EFFECT
In clinical trials the following events were reported, regardless of drug relationship, in greater than 1% of patients treated with intravenous Ciprofloxacin: nausea, diarrhea, central nervous system disturbance, local I.V. site reactions, liver function tests abnormal, eosinophilia, headache, restlessness, and rash. Many of these events were described as only mild or moderate in severity, abated soon after the drug was discontinued, and required no treatment.

CONTRAINDICATION
Ciprofloxacin is contraindicated in persons with a history of hypersensitivity to Ciprofloxacin, any member of the quinolone class of antimicrobial agents. Concomitant administration with tizanidine is contraindicated.

DRUG INTERACTION
Concurrent administration of Ciprofloxacin with theophylline may lead to elevated serum concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline-related adverse reactions. If concomitant use cannot be avoided, serum levels of theophylline should be monitored and dosage adjustments made as appropriate. Probenecid interferes with renal tubular secretion of Ciprofloxacin and produces an increase in the level of Ciprofloxacin in the serum. This should be considered if patients are receiving both drugs concomitantly. Altered serum levels of phenytoin (increased and decreased) have been reported in patients receiving concomitant Ciprofloxacin.

OVERDOSE
In the event of acute overdosage, the patient should be carefully observed and given supportive treatment, including monitoring of renal function. Adequate hydration must be maintained.

PRECAUTION
Ciprocin® 200 IV should be administered by slow infusion over a period of 60 minutes. Local IV site reactions have been reported with the intravenous administration of Ciprofloxacin. These reactions are more frequent if infusion time is 30 minutes or less or if small veins of the hand are used.

INSTRUCTION FOR THE USE OF Ciprocin® 200 IV
1. Check the bag for minute leaks by squeezing the inner bag firmly. If leaks are found, or if seal is not intact, discard the solution.
2. Do not use if the solution is cloudy or a precipitate is present.
3. Do not use flexible bags in series connections.
4. Close flow control clamp of administration set.
5. Remove cover from port at bottom of bag.
6. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.
7. Suspend bag from hanger.
8. Squeeze and release drip chamber to establish proper fluid level in chamber during infusion of **Ciprocin®** 200 IV.
9. Open flow control clamp to expel air from set. Close clamp.
10. Regulate rate of administration with flow control clamp.

STORAGE
Store below 25°C and protect from light. Avoid extreme heat and freezing. Keep out of reach of children.

HOW SUPPLIED
Ciprocin® 200 IV: Each box contains 1 bag of 100 ml solution of Ciprofloxacin for intravenous infusion.

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

LFT0160