Floxabid® IV

Ciprofloxacin

Description

Floxabid® IV is a preparation of Ciprofloxacin which is a fluoroquinolone antibiotic. It has broad-spectrum of activity against most gram-negative aerobic bacteria including *Enterobacteriaceae*, *Pseudomonas aeruginosa, Klebsiella pneumoniae, Salmonella* spp., *Moraxella catarrhalis;* gram-positive aerobic bacteria including *Streptococcus* spp., *Staphylococcus aureus* (methicillin-susceptible) and other microorganisms e.g. *Chlamydia* and *Mycoplasma*. It functions by inhibiting DNA gyrase, a type II topoisomerase and topoisomerase IV enzymes necessary to separate bacterial DNA, thereby inhibiting cell division.

Indications

Floxabid® IV is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions and patient populations listed below when the intravenous administration offers a route of administration advantageous to the patient.

- Urinary Tract Infections
- Lower Respiratory Tract Infections
- Nosocomial Pneumonia
- Skin and Skin Structure Infections
- Bone and Joint Infection
- Complicated Intra-Abdominal Infections
- Acute Sinusitis
- Chronic Bacterial Prostatitis
- Empirical Therapy for Febrile Neutropenic Patients
- Inhalational Anthrax (post-exposure)
- Infectious Diarrhea

Dosage & administration

Floxabid® IV should be administered by intravenous infusion over a period of 60 minutes. Slow infusion of a dilute solution into a larger vein will minimize patient discomfort and reduce the risk of venous irritation.

Adult

The usual intravenous doses are given below:

Indication	Severity	Dose	Frequency	Usual duration
Urinary Tract Infections	Mild/Moderate Severe/Complicated	200 mg 400 mg	12 hourly 12 hourly	7-14 days 7-14 days
Lower Respiratory Tract Infections	Mild/Moderate Severe/Complicated	400 mg 400 mg	12 hourly 8 hourly	7-14 days 7-14 days
Nosocomial Pneumonia	Mild/Moderate/Severe	400 mg	8 hourly	10-14 days
Skin and Skin Structure Infections	Mild/Moderate Severe/Complicated	400 mg 400 mg	12 hourly 8 hourly	7-14 days 7-14 days
Bone and Joint Infection	Mild/Moderate Severe/Complicated	400 mg 400 mg	12 hourly 8 hourly	≥ 4-6 weeks ≥ 4-6 weeks
Complicated Intra-Abdominal Infections	Complicated	400 mg	12 hourly	7-14 days
Acute Sinusitis	Mild/Moderate	400 mg	12 hourly	10 days
Chronic Bacterial Prostatitis	Mild/Moderate	400 mg	12 hourly	28 days
Empirical Therapy for Febrile Neutropenic Patients	Severe	400 mg	8 hourly	7-14 days
Infectious Diarrhea	Mild/Moderate/Severe	400 mg	12 hourly	5-7 days
Inhalational Anthrax (post-exposure)		400 mg	12 hourly	60 days

Dosage guideline for pediatric patient

In pediatric patients (1 to 17 years of age) with moderate to severe infection, the dosage should be 6 to 10 mg/kg IV every 8 hourly.

Use in pregnancy & lactation

Pregnancy: Ciprofloxacin is pregnancy category C. The safety and effectiveness of Ciprofloxacin in pregnant woman is not established. It should not be used during pregnancy unless the potential benefit justifies the potential risk to both fetus and mother.

Lactation: Ciprofloxacin is excreted in breast milk. Therefore, it is not recommended during breastfeeding.

Side effects

The most common side effects include nausea, vomiting, abdominal pain, diarrhoea, headache, dizziness, sleep disorders, rash, pruritus, anaphylaxis, photosensitivity, increase in blood urea and creatinine, transient disturbances in liver enzymes and bilirubin, arthralgia and myalgia, blood disorders (including eosinophilia, leucopenia, thrombocytopenia and altered prothrombin concentration). The less frequent side effects include anorexia, restlessness, hallucinations, confusion and disturbances in vision, taste and smell.

Contraindications

Ciprofloxacin is contraindicated in patients with known hypersensitivity to Ciprofloxacin or to other quinolones or any of the excipients.

Precautions

Ciprofloxacin should be used with caution in patients with suspected or known CNS disorders such as epilepsy or other factors which predispose to seizures and convulsion.

Drug interactions

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.

Overdose

In case of acute overdose of Ciprofloxacin, the patient should be carefully observed and given supportive treatment including monitoring of renal function. Adequate hydration must be maintained. Only a small amount of Ciprofloxacin (<10%) is removed from the body after hemodialysis or peritoneal dialysis.

Pharmaceutical precaution

Keep away from the reach of children. Store in a cool (below 25°C) & dry place protected from light.

Special precautions for disposal and other handling

- Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.
- Do not remove 'Flip off seal' until ready for use. The product should be used immediately after opening.
- Do not use containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.
- The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
- Discard after single use.
- Discard any unused portion.
- Do not reconnect partially used bottles.

Presentation

Each 100 ml Floxabid® IV contains Ciprofloxacin 200 mg as Lactate INN (2 mg/ml) for intravenous infusion.

Package quantity

Floxabid® IV is available in 100 ml glass vial.

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Manufactured by
Popular Pharmaceuticals Ltd.
For
ACI Limited
Narayanganj, Bangladesh

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