Information For the Use Levofloxacin 500mg Infusion

Lexoziff IV Infusion

Levofloxacin 500mg Infusion

Description

Levofloxacin 500mg Infusion is an intravenous antibiotic used for the treatment of moderate to severe infections caused by susceptible bacteria. Levofloxacin is a broad-spectrum fluoroquinolone antibiotic that inhibits bacterial DNA synthesis by interfering with the activity of DNA gyrase and topoisomerase IV, two enzymes critical for bacterial replication. This results in bacterial cell death and helps control bacterial infections.

The intravenous infusion formulation allows for direct and rapid administration in patients who are unable to take oral medications or require faster drug action.

Composition

Each 100 ml of the infusion contains:

• Levofloxacin: 500 mg

Excipients:

The infusion may also contain sodium chloride, water for injection, hydrochloric acid, or sodium hydroxide, as necessary to adjust the pH of the solution.

Indications

Levofloxacin 500mg Infusion is indicated for the treatment of infections caused by susceptible organisms, including:

- Respiratory Tract Infections:
 - Community-acquired pneumonia (CAP)
 - Hospital-acquired pneumonia (HAP)
 - Acute exacerbation of chronic bronchitis

- Acute sinusitis
- Urinary Tract Infections (UTIs):
 - Complicated and uncomplicated UTIs
 - Pyelonephritis
- Skin and Soft Tissue Infections:
 - Infections of the skin, soft tissues, and wounds caused by susceptible organisms.
- Intra-abdominal Infections:
 - Including complicated intra-abdominal infections.
- Bone and Joint Infections:
 - Complicated infections in bone and joints caused by susceptible bacteria.
- Pelvic Infections:
 - Including infections in the pelvic region (e.g., pelvic inflammatory disease).

This infusion formulation is typically used in hospitalized patients or when oral administration is not possible or inadequate.

Dosage and Administration

- Recommended Dosage:
 - Adults:
 - The usual dose is 500 mg administered once daily by intravenous infusion over 60 minutes. The duration of treatment depends on the type and severity of the infection, generally ranging from 5 to 14 days.
 - Renal Impairment:
 - Dosage adjustment may be necessary for patients with impaired renal function. For moderate to severe renal impairment, the dose may need to be reduced, or the infusion interval extended.
- Administration:
 - The infusion should be given intravenously over a period of 60 minutes.

- It is recommended to not administer the infusion as an intravenous bolus (rapid injection), as this can cause adverse reactions.
- The solution should be visually inspected for particulate matter or discoloration before administration, and if found, the infusion should not be used.
- Reconstitution and dilution instructions must be followed as provided in the specific product leaflet.
- Switching to Oral Formulation:
 - When patients stabilize, the treatment may be switched to the oral form of Levofloxacin (500 mg) once daily.

serious arrhythmias. It should be used cautiously in patients with known heart conditions, especially those with electrolyte imbalances or on other medications that prolong the QT interval.

- Clostridium difficile-associated Diarrhea: As with all antibiotics, Levofloxacin can cause an overgrowth of Clostridium difficile, leading to pseudomembranous colitis. If diarrhea occurs during or after treatment, the patient should seek immediate medical attention.
- Hypoglycemia: Use caution in patients with diabetes, as Levofloxacin may cause hypoglycemia.
- Renal Impairment: The dose should be adjusted in patients with renal impairment to avoid toxicity.

Contraindications

- Hypersensitivity to Levofloxacin, other quinolone antibiotics, or any of the excipients in the infusion.
- History of tendon disorders related to quinolone use, such as tendonitis or tendon rupture.
- Severe renal impairment with a creatinine clearance less than 20 mL/min (without dose adjustment).
- Pregnancy and Lactation: Levofloxacin is contraindicated in pregnancy and breastfeeding unless the benefits outweigh the risks.

Warnings and Precautions

- Tendon Disorders: Levofloxacin has been associated with an increased risk of tendonitis and tendon rupture, particularly in elderly patients and those on corticosteroids. Patients should be advised to report any tendon pain, swelling, or inflammation immediately.
- CNS Effects: Levofloxacin can cause side effects such as confusion, dizziness, seizures, or hallucinations. It should be used with caution in patients with a history of CNS disorders, including epilepsy.
- QT Prolongation: Levofloxacin may cause QT interval prolongation, which can lead to

Side Effects

Common side effects may include:

- Nausea and vomiting
- Diarrhea
- Headache
- Insomnia
- Dizziness or lightheadedness
- Rash or itching

Serious side effects (although rare) may include:

- Tendon rupture or tendonitis
- Severe allergic reactions, including anaphylaxis
- Seizures or other CNS effects (e.g., confusion, hallucinations)
- Prolonged QT interval or arrhythmias
- Liver enzyme elevation or liver failure
- Clostridium difficile-associated diarrhea
- Hypoglycemia (especially in diabetic patients)
- Peripheral neuropathy (nerve damage)

If any serious side effects are observed, the treatment should be stopped, and medical attention sought immediately.

Drug Interactions

- Antacids and Iron: Antacids containing magnesium or aluminum, as well as iron supplements, can interfere with the absorption of Levofloxacin. It is recommended to take these medications at least 2 hours before or after Levofloxacin.
- Warfarin: Levofloxacin may enhance the anticoagulant effects of warfarin, leading to an increased risk of bleeding.
- Corticosteroids: Concurrent use with corticosteroids may increase the risk of tendon rupture.
- QT-prolonging Drugs: Combining Levofloxacin with other medications that prolong the QT interval (e.g., antiarrhythmics, certain antidepressants) may increase the risk of serious arrhythmias.

renal function, potential side effects, and drug interactions is essential to ensure safe and effective use. Always follow the prescribed dosage and administration guidelines for optimal therapeutic outcomes.

Manufactured in India for:

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Storage Instructions

- Storage before Reconstitution:
 - Store at room temperature (15°C to 25°C) in a dry place, away from direct light.
- Storage after Reconstitution:
 - The infusion should be used immediately after preparation. If not used, it may be stored for a limited time under specific conditions (refer to the product's packaging for exact storage instructions).

Presentation

- Form: Intravenous infusion
- Strength: 500 mg per 100 ml
- Pack Size: Available in 100 ml vials

Conclusion

Levofloxacin 500mg Infusion provides an effective treatment for a range of serious bacterial infections, particularly in hospitalized or severely ill patients. As a broad-spectrum fluoroquinolone antibiotic, it is suitable for respiratory, urinary, skin, soft tissue, and intra-abdominal infections. Close monitoring of