Delameg™

Delafloxacin

2039

Presentation

Delameg™ IV Infusion: Each vial contains Delafloxacin Meglumine INN equivalent to Delafloxacin 300 mg as lyophilized cake or powder.

Pharmacology

Delafloxacin is a fourth generation Fluoroquinolone with expanded activity against Gram positive bacteria including multidrug resistant strains of *Streptococcus pneumoniae & Staphylococcus aureus (MRSA), as well as atypical pathogens*. Like other Fluoroquinolones, Delafloxacin is active against a wide range of aerobic Gram positive and Gram negative organisms. The antibacterial activity of Delafloxacin is due to the inhibition of both bacterial topoisomerase IV and DNA gyrase (topoisomerase II) enzymes which are required for bacterial DNA replication, transcription, repair, and recombination.

Indications and uses

Delafloxacin is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and Community-Acquired Bactetial Pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, mycoplasma pneumoniae, Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group, Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa.*

Dosage and administration

Infection	Dosage and Route of Administration	Duration
Acute bacterial skin and skin structure infections (ABSSSI)	300 mg of Delafloxacin every 12 hours over 60 minutes by IV infusion	5 to 14 Days
Community-Acquired Bactetial Pneumonia (CABP)		5 to 10 Days

Use in patients under 18 years of age is not recommended.

Dosage adjustment for the patients with renal impairment

Estimated Glomerular Filtration Rate (eGFR) (ml/min/1.73 m²)	Recommended Dosage Regimen
	Injection
30-89	No dosage adjustment
15-29	200 mg every 12 hours
End Stage Renal Disease (ESRD) (<15 including hemodialysis)	Not Recommended

Reconstitution and Dilution

1. Lyophilized powder must be reconstituted and then further diluted under aseptic conditions. Reconstitute the powder in the vial using 10.5 ml of 0.9% Sodium Chloride Solution or 5% Dextrose for each 300 mg vial. Shake the vial vigorously until contents are completely dissolved. The reconstituted vial contains 300 mg per 12 ml (25 mg/ml) of Delafloxacin as a clear yellow to amber colored solution.
2. Then the reconstituted solution must be diluted to a total volume of 250 ml using either 0.9% Sodium Chloride or 5% Dextrose to achieve a concentration of 1.2 mg/ml, prior to administration. Prepare the required dose for intravenous infusion by withdrawing the appropriate volume from the reconstituted vial per below:

Preparation of dose for infusion

Injection Dose	Volume of Reconstituted Solution to Withdraw
300 mg	12 mL
200 mg	8 mL

3. Transfer the required volume of reconstituted solution from the vial to an intravenous bottle to achieve a 250 ml volume of infusion solution. Discard any unused portion of the reconstituted solution.

Contraindications

This drug is contraindicated in patients with known hypersensitivity to Delafloxacin or any of the Fluoroquinolone class of antibacterial drugs, or any of the components of Delameg.

Side effects

Most common side effects are nausea, diarrhea, headache, transaminase elevations, and vomiting. Other serious or adverse reactions may be occurred such as tendinitis and tendon rupture, peripheral neuropathy, Central Nervous system effects, blood glucose disturbances, Psychitric disorders, renal and urinary disorder, skin and subcutaneous disorders, vascular disorders etc.

Precautions

Drug must be discontinued immediately at the first signs or symptoms of any serious adverse reaction such as tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion).

Use in pregnancy and lactation

The limited available data with Delafloxacin use in pregnant women are insufficient to inform a drug-associated risk of major birth defects and miscarriages.
There are no data available on the presence of delafloxacin in human milk, the effects on the breastfeeding infant, or the effects on milk production.

Drug interactions

Delafloxacin IV should not be co-administered with any solution containing multivalent cations, e.g., Magnesium, Calcium through the same intravenous line. Delafloxacin IV should not be co-infused with other medications.

Overdosage

Treatment of overdose with Delafloxacin should consist of observation and general supportive measures. Hemodialysis removed about 19% of Delafloxacin and 56% Sulfobutylether beta cyclodextrin after intravenous administration of Delafloxacin.

Storage condition

Do not store vial of Delafloxacin lyophilized cake or powder above 30 °C. Reconstituted or diluted solution may be stored up to 24 hours at room temperature (20 °C to 25 °C) or refrigerated temperature (2 °C to 8 °C); Do not freeze.

Commercial pack

Delameg™ IV Infusion: Each box contains 1 vial of Delafloxacin 300 mg Infusion, 1 bottle of 250 ml normal saline, one 20 ml disposable syringe, 1 infusion set, 1 hanger, 1 first aid bandage and 1 alocohol pad.

Manufactured by
Incepta Pharmaceuticals Ltd
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