

LINCOSA
Injection

LF-0197

LF-0197

Composition : Each mL contains :
Lincomycin HCl Eq to Lincomycin 300 mg
Benzyl alcohol 20 mg

Pharmacology/Pharmacokinetics : Lincomycin is an antibiotic with a range of antibacterial activity similar to that of erythromycin. It is active against *Streptococcus pyrogenes*, *Str. pneumoniae*, *Staphylococcus aureus*, *Bacteroides* spp. and *Haemophilus influenzae*. It is bacteriostatic in low concentrations and bactericidal in high concentrations and acts by interfering with the synthesis of deoxyribonucleic acid.

Absorption : Lincomycin is incompletely absorbed after oral administration and its rate of absorption is reduced after meals.

Blood concentration : After an oral dose of 500 mg to fasting subjects, peak serum concentrations of 3 to 10 µg/mL are attained in about 2 hours. After an intramuscular dose of 500 to 600 mg peak serum concentrations of 1 to 12 µg/mL are attained in 1 to 2 hours. During therapy with intravenous infusions of 5 to 8 g daily peak concentrations of 25 to 35 µg/mL and minimum concentrations of 10 to 12 µg/mL are attained.

Distribution : Widely and rapidly distributed throughout the body tissues and fluids it appears in peritoneal and pleural fluids crosses the placenta and is secreted in milk. It is taken up by bone and enters the cerebrospinal fluid when the meninges are inflamed. Protein binding about 70 to 90% bound to plasma proteins.

Excretion : Excreted in both urine and bile. In an oral dose, 2 to 9% may be excreted in the urine in 24 hours with 30 to 40% appearing in the feces. Up to about 60% of an injected dose is excreted in the urine.

Indications : For infections caused by Staphylococci and other gram positive pathogens.

Dosage and Administration : Adults : Intramuscular injection 600 mg 1-2 times a day. Intravenous infusion 600 mg 2-3 times a day.

For Intravenous administration, each gram of lincomycin should be diluted in 100 mL of compatible infusion solution and infused over at least one hour.

Please see IV compatible solutions in **Stability after dilution** section.

Contraindications : This drug is contraindicated in patients previously found to be hypersensitive to Lincomycin or Clindamycin. It is not indicated in the treatment of minor bacterial infection or viral infection. Should not be used in patients with diarrhea.

Precautions :

As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

- Lincomycin therapy has been associated with severe colitis which may end fatally.
- It should be reserved for serious infections where less toxic antimicrobial agents are inappropriate.
- It should not be used in patients with nonbacterial infections, such as most upper respiratory tract infections.
- Its use in newborns is contraindicated.

Pregnancy and lactation : Safe use of Lincomycin in pregnant women has not been established. Lincomycin is distributed into milk. Because of the potential for serious adverse reactions from Lincomycin in nursing infants, a decision should be made whether to discontinue nursing or the drug taking into account the importance of the drug to the woman.

Side effects : Diarrhea, allergic reactions, supra-infection with yeast may occur, and rarely, liver damage. Pseudomembranous colitis may be a very serious complication of treatment with Lincomycin.

Overdosage (Symptoms and Treatments)

Symptoms : Skin dryness, abdominal pain, gastrointestinal disturbances, bloody diarrhea and severe colitis.

Treatment : Take the patient to the hospital for symptomatic treatment.

Interactions With Other Medicaments

Kaolin-Pectin : GI absorption is decreased for Lincomycin by as much as 90% when it is administered with Kaolin-Pectin antidiarrheals, resulting in decreased plasma concentrations of the antibiotic.

Neuromuscular Blocking Agents

Nondepolarizing : The actions of neuromuscular blockers may be enhanced, possibly contributing to profound and severe respiratory depression.

Food Interaction : Food impairs the absorption of Lincomycin; do not take anything by mouth (except water) for 1 to 2 hours before and after Lincomycin.

Storage Conditions : Store in cool dry place at controlled room temperature below 30°C. Protect from light.

Stability after dilution : LINCOSA injection after diluted with 5% Dextrose in water, 5% Dextrose in normal saline, 10% Dextrose in water, 10% Dextrose in normal saline and Lactated Ringer's, the colour of solutions are clear colorless solution.

Intravenous Infusion solutions for dilution

IV infusion solution	Concentration	Diluting preparation
5% Dextrose in water/ D5W	6 mg/mL	600 mg/2mL of LINCOSA injection dilute to 100 mL with D5W
5% Dextrose in normal saline/ D5S	6 mg/mL	600 mg/2mL of LINCOSA injection dilute to 100 mL with D5S
10% Dextrose in water/ D10W	6 mg/mL	600 mg/2mL of LINCOSA injection dilute to 100 mL with D10W
10% Dextrose in normal saline/ D10S	6 mg/mL	600 mg/2mL of LINCOSA injection dilute to 100 mL with D10S
Lactated Ringer's solution	6 mg/mL	600 mg/2mL of LINCOSA injection dilute to 100 mL with Lactated Ringer's solution

* Diluted Lincomycin in Partial-Fill Flexible plastic container.

LINCOSA Injection after diluted with IV infusion solutions at concentration 6 mg/mL and then stored at 25°C±2°C in Partial-Fill Flexible plastic containers remain stable for 24 hours.

Reg. No. MAL19950513AZ

Shelf-life : 3 years

Pack sizes : 10 boxes x [1 vial/box x 10 mL/vial]

Description : It is a clear colorless sterile solution for injection.

Date of Revision : 29 September 2021

Manufactured by :
 **L.B.S. LABORATORY LTD., PART.**
602 Soi Panichanant, Sukhumvit 71 Rd.,
Bangkok 10110 Thailand.

Product Registration Holder :
HEALOL PHARMACEUTICALS SDN. BHD.
74-3, Jalan Wangsa Delima 6, KLSC Wangsa Maju,
53300 Kuala Lumpur, Malaysia.