

LINMYCIN INJECTION 300MG/ML

Ingredient(s):

Each ml contains:

Lincomycin (as Lincomycin Hydrochloride) 300mg
Benzyl Alcohol (as preservative)..... 9.45mg

Pharmacodynamic:

1. Lincomycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the bacterial ribosome. Lincomycin is predominantly bacteriostatic *in vitro*.
2. Cross-resistance has been demonstrated between clindamycin and lincomycin. Resistance in staphylococci and streptococci is most often due to methylation of specific nucleotides in the 23S RNA of the 50S ribosomal subunit, which can determine cross resistance to macrolides and streptogramins B (MLS_B phenotype). Macrolide-resistant isolates of these organisms should be tested for inducible resistance to lincomycin/clindamycin using the D-zone test.

Pharmacokinetic:

1. Intramuscular administration of a single dose of 600mg of lincomycin produces average peak serum concentrations of 11.6mcg/ml at 60 minutes and maintains therapeutic concentrations for 17 to 20 hours for most susceptible gram-positive organisms. Urinary excretion after this dose ranges from 1.8 to 24.8% (mean: 17.3%).
2. A two-hour intravenous infusion of 600mg of lincomycin achieves average peak serum concentrations of 15.9mcg/ml and maintains therapeutic concentrations for 14 hours for most susceptible gram-positive organisms. Urinary excretion ranges from 4.9 to 30.3% (mean: 13.8%).
3. The biological half-life after intramuscular or intravenous administration is 5.4 ± 1.0 hours. The serum half-life of lincomycin may be prolonged in patients with severe renal impairment compared to patients with normal renal function. In patients with hepatic impairment, serum half-life may be two-fold longer than in patients with normal hepatic function. Hemodialysis and peritoneal dialysis are not effective in removing lincomycin from the serum.
4. Tissue distribution studies indicate that bile is an important route of excretion. Significant concentrations have been demonstrated in most body tissues. Although lincomycin appears to diffuse into cerebrospinal fluid (CSF), concentrations of lincomycin in the CSF appear inadequate for the treatment of meningitis.

Indication:

For the treatment of serious infections due to streptococci, pneumococci, staphylococci and other susceptible organisms, it may be administered concomitantly with other antimicrobial agents when indicated.

Dosage and Administration:

Intramuscular:

Adults:

Serious infections – 600mg (2ml) intramuscularly every 24 hours.

More severe infections – 600mg (2ml) intramuscularly every 12 hours or more often, as determined by the severity of the infection.

Children over 2 years of age:

Serious infections – one intramuscular injection of 10mg/kg (5mg/lb) every 24 hours.

More severe infections – one intramuscular injection of 10mg/kg (5mg/lb) every 12 hours or more often.

Intravenous:

Intravenous doses are given on the basis of 1g of Lincomycin diluted in not less than 100ml of appropriate solution and infused over a period of not less than 1 hour.

Adults: For serious infections, doses of 600mg (2ml) to 1g (3.3ml) are given every 8-12 hours. For more severe infections, these doses may have to be increased. In life-threatening situations, daily intravenous doses of as much as 8g (26.7ml) have been given. Intravenous doses are given on the basis of 1g of Lincomycin diluted in not less than 100ml of appropriate solution and infused over a period of not less than 1 hour. These doses may be repeated as often as required to the limit of the maximum recommended daily dose of 8g of Lincomycin.

Patients with diminished renal function: When therapy with lincomycin is required in individuals with severe renal impairment, an appropriate dose is 25 to 30% of that recommended for patients with normally functioning kidneys.

Children over 2 years of age: 10-20mg/kg/day (5-10 mg/lb/day) depending on the severity of the infection may be infused in divided doses as described above for adults.

To be used only by physician.

Route of Administration:

Parenteral (Intramuscular and Intravenous injection).

Instructions for Use:

Dilution and Infusion Rates

Dose	Vol. of Diluent	Infusion Time
600mg	100ml	1 hour
1g	100ml	1 hour
2g	200ml	2 hours
3g	300ml	3 hours
4g	400ml	4 hours

(Source: Lincocin® lincomycin injection, USP)

Infusion Solutions:

- a) 10% Dextrose solution
- b) 10% Dextrose & 0.9% Sodium Chloride Solution
- c) Compound Sodium Lactate solution

Physical Compatibilities

Physically compatible for 48 hours at room temperature.

Contraindication(s):

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 infections or viral infections.

Precaution(s) / Warning(s):

1. Lincomycin therapy has been associated with severe colitis which may end fatally.
 2. It should be reserved for serious infections where less toxic antimicrobial agents are inappropriate.
 3. It should not be used in patients with nonbacterial infections, such as most upper respiratory tract infections.
 4. Its use in newborns is contraindicated.
5. Hypersensitivity reactions (such as anaphylactic reaction, angioedema and serum sickness) have been reported, some of these in patients known to be sensitive to penicillin. If an allergic reaction should occur, the drug should be discontinued and the usual agents (adrenaline, corticosteroids, antihistamines) should be available for emergency treatment.

6. In patients with impaired hepatic or renal function, the serum half-life of Lincomycin is increased. Consideration should be given to decreasing the frequency and dose of Lincomycin administered in patients with impaired hepatic or liver function. Since adequate data are not yet available in patients with pre-existing liver disease, its use in such patients is not recommended at this time unless special clinical circumstances so indicate.

Warning

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

Interaction with Other Medicaments:

It has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, it should be used with caution in patients receiving such agents.

Antagonism has been demonstrated between Lincomycin and Erythromycin *in vitro*. Because of possible clinical significance, these two drugs should not be administered concurrently.

Pregnancy and Lactation:

Pregnancy

Lincomycin should be used during pregnancy only if clearly needed and it is not indicated in the newborn.

Lactation

Lincomycin has been reported to appear in breast milk in ranges of 0.5 to 2.4mcg/ml. It should not be used during lactation unless alternative arrangements can be made for feeding the baby.

Side Effect(s):

Infections and Infestations

Uncommon: Vaginal infection

Not known: Pseudomembranous colitis, *Clostridium difficile colitis*

Gastrointestinal Disorders

Common: Diarrhoea, vomiting, nausea

Rare: Stomatitis

Not known: Enterocolitis, glossitis, abdominal discomfort

Blood and Lymphatic System Disorders

Not known: Pancytopenia, agranulocytosis, aplastic anaemia, leukopenia, neutropenia, thrombocytopenic purpura

Immune System Disorders

Not known: Anaphylactic reaction, angioedema, serum sickness

Skin and Subcutaneous Tissue Disorders

Uncommon: Rash and urticaria

Rare: Pruritus

Not known: Steven-Johnson syndrome, erythema multiforme, dermatitis bullous, dermatitis exfoliative, anal pruritus

Hepatobiliary Disorders

Not known: Jaundice, liver function test abnormal, transaminases increased

Renal and Urinary Disorders

Not known: Renal impairment, oliguria, proteinuria, azotaemia

Cardiac Disorders

Not known: Cardio-respiratory arrest

Vascular Disorders

Not known: Hypotension, thrombophlebitis

Ear and Labyrinth Disorders

Not known: Vertigo, tinnitus

General Disorders and Administration Site Conditions

Not known: Injection site abscess sterile, injection site induration, injection site pain, injection site irritation.

Symptoms and Treatment for Overdosage:

At therapeutic doses, the primary toxic effects may involve the gastrointestinal tract and may include severe diarrhoea and pseudomembranous colitis may result in death. Rapid administration of large doses has resulted in ventricular dysrhythmias, hypotension and cardiac arrest. Dermatitis, nephrotoxicity, hepatotoxicity, and various haematological abnormalities are toxic effects that occur less frequently.

No specific antidote is known. Support respiratory and cardiac function and monitoring serum concentration in patients with markedly reduced renal and hepatic function may be indicated during high-dose therapy. Monitor full blood count in patients with significant exposure as lincomycin may produce abnormalities of the haematopoietic system. Because lincomycin may cause hepatotoxicity, monitor liver function tests in patients with significant exposure.

Haemodialysis and peritoneal dialysis are not effective in removing lincomycin from the serum.

Incompatibilities:

Lincomycin is incompatible with novobiocin, kanamycin and phenytoin.

Shelf-Life:

3 years from the date of manufacture. After dilution for infusion administration, the shelf life is 48 hours below 30°C.

Storage Condition(s):

Store at temperature below 30°C. Protect from light and moisture. After dilution for infusion administration, the storage condition is below 30°C.

Product Description:

A clear & colourless to slightly yellowish solution.

Dosage Form and Packaging Available:

Solution for injection or infusion in vial of 2ml x 10 vials per box and 10ml x 10 vials per box.



Manufacturer and Product Registration Holder:
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