

Pfizer

لنكوسين

Lincocin® (Lincomycin)

THERAPEUTIC INDICATIONS

Lincocin® has been shown to be effective in the treatment of the following infections when caused by susceptible strains of gram positive aerobes such as streptococci, pneumococci, and staphylococci, or by susceptible anaerobic bacteria.

- Upper respiratory infections including tonsillitis, pharyngitis, otitis media, sinusitis, scarlet fever and as adjuvant therapy for diphtheria. Effectiveness in the treatment of mastoiditis would be anticipated.
- Lower respiratory infections including acute and chronic bronchitis and pneumonia.

- Skin and soft tissue infections including cellulitis, furuncles, abscesses, impetigo, acne and wound infections. Conditions like erysipelas, lymphadenitis, paronychia (panaritium), mastitis and cutaneous gangrene, should, if caused by susceptible organisms, respond to lincomycin therapy.

- Bone and joint infections including osteomyelitis and septic arthritis.

- Septicemia and endocarditis. Selected cases of septicemia and/or endocarditis due to susceptible organisms have responded well to lincomycin. However, bactericidal drugs are often preferred for these infections.

- Bacillary dysentery. Although Shigella is resistant to lincomycin in vitro (MIC approximately 200-400 mcg/mL), lincomycin has been effective in its treatment due to the very high levels of lincomycin attained in the bowel (approximately 3000-7000 mcg/gram of stool).

POSOLGY AND METHOD OF ADMINISTRATION

1. Dosage in Adults

- Oral Administration
- Infections due to susceptible organisms, 500 mg t.i.d. (q8h).
- More severe infections: 500 mg q.i.d. (q6h).
- For optimal absorption, it is

recommended that nothing be given by mouth for a period of 1 to 2 hours before or after oral administration of lincomycin.

Intramuscular Injection

- 600 mg IM every 24 hours.
- More severe infections: 600 mg IM every 12 hours (or more often) as determined by the severity of the infection.

Intravenous Infusion

Intravenous doses are given on the basis of 1 gram of lincomycin diluted in not less than 100 mL of appropriate solution and infused over a period of not less than 1 hour. Note: Severe cardiopulmonary reactions have occurred when this drug has been given at greater than the recommended concentration and rate.

- 600 mg to 1 gram every 8 to 12 hours.
- For more severe infections these doses may have to be increased.
- In life threatening situations, daily intravenous doses of as much as 8 grams have been given.

- 10 mg/kg/day as 1 intramuscular injection.
- More severe infections: 10 mg/kg given every 12 hours or more often.

Intravenous Infusion

- 10 to 20 mg/kg/day, depending on the severity of the infection, may be infused in divided doses as described in the section on Dilution and Infusion rates.

3. Dosage in Patients with Diminished Hepatic or Renal Function: In patients with impaired hepatic function or impaired renal function, lincomycin's serum half-life is increased. Consideration should be given to decreasing the frequency of administration of lincomycin in patients with impaired hepatic or renal function.

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

4. Beta-hemolytic streptococcal infections: Treatment should be continued for at least 10 days.

5. Incompatibilities: (This list may not be all-inclusive due to the multiple factors influencing drug compatibility data.)

When combined with lincomycin in an infusion solution, novobiocin, kanamycin, and phenytoin are each physically incompatible with lincomycin.

CONTRAINDICATIONS

Lincomycin is contraindicated in patients previously found sensitive to lincomycin or clindamycin or to any other component of the product.

WARNINGS & PRECAUTIONS

The injection formulation contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including lincomycin, and may range in severity from mild to life-threatening. Therefore, it is important to consider the diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary

Dilution and Infusion Rates

Dose	Volume of Diluent	Time
600 mg	100 mL	1 hr
1 gram	100 mL	1 hr
2 grams	200 mL	2 hr
3 grams	300 mL	3 hr
4 grams	400 mL	4 hr

These doses may be repeated as often as required to the limit of the maximum recommended daily dose of 8 grams of lincomycin.

2. Dosage in Children (over 1 month of age)

- Oral Administration
- 30 mg/kg/day divided into 3 or 4 equal doses.
- More severe infections: 60 mg/kg/day divided into 3 or 4 equal doses.
- For optimal absorption, it is recommended that nothing be given by mouth for a period of 1 to 2 hours before or after oral administration of lincomycin.
- Intramuscular Injection

cause of "antibiotic-associated colitis". After the primary diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate-to-severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis.

Although lincocin appears to diffuse into cerebrospinal fluid, levels of lincocin in the CSF may be inadequate for the treatment of meningitis. Thus, the drug should not be used in the treatment of meningitis.

If lincocin antibiotic therapy is prolonged, liver and kidney function tests should be performed. The use of antibiotics may result in overgrowth of non-susceptible organisms, particularly yeasts.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including lincocin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Lincocin should not be injected IV as a bolus but should be infused as described in the DOSAGE AND ADMINISTRATION section.

INTERACTION

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

Lincocin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents.

Therefore, lincocin should be used

with caution in patients receiving such agents.

PREGNANCY AND LACTATION

No adverse effects on survival of offspring from birth to weaning were seen in studies performed in rats using oral doses of lincocin up to 1000 mg/kg (7.5 times the maximum human dose of 8 g/day). No teratogenic effects were seen in a study conducted in rats treated with more than 55 times the highest recommended adult human dose of 8 g/day.

In humans, lincocin crosses the placenta and results in cord serum levels about 25% of the maternal serum levels. No significant accumulation occurs in the amniotic fluid. There are no controlled studies in pregnant women; however, the progeny of 302 patients treated with lincocin at various stages of pregnancy showed no increases in congenital anomalies or delayed development compared to a control group for up to 7 years after birth. Lincocin should be used during pregnancy only if clearly needed.

Lincocin has been reported to appear in human breast milk in concentrations of 0.5 to 2.4 mcg/mL.

UNDESIRABLE EFFECTS

● Gastrointestinal—Nausea, vomiting, abdominal distress and persistent diarrhea and, with oral preparations, esophagitis.

● Hematopoietic—Neutropenia, leukopenia, agranulocytosis, and thrombocytopenic purpura. Rare reports of aplastic anemia and pancytopenia.

● Hypersensitivity Reactions—Hypersensitivity reactions, serum sickness and anaphylaxis. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, have been associated with lincocin administration.

● Skin and Mucous Membranes—Pruritus, skin rashes, urticaria, vaginitis, and rarely exfoliative and vesiculobullous dermatitis have been reported.

● Liver—Jaundice and abnormal liver function tests.

● Cardiovascular—Hypotension following parenteral administration has been reported, particularly after too rapid administration. Rare instances of cardiopulmonary arrest have been reported after too rapid intravenous administration.

● Local Reactions—Local irritation, pain, induration, and sterile abscess formation have been seen with IM injection. Thrombophlebitis has been reported with IV injection.

OVERDOSAGE

Hemodialysis or peritoneal dialysis does not effectively remove lincocin from the blood.

SHELF LIFE

Lincocin® Injection : 36 months
Lincocin® Syrup : 24 months
Lincocin® Capsules : 36 months

HOW SUPPLIED

Lincocin® is available as:

- Lincocin® Injection 300 mg/ mL (ampoule)
- Lincocin® Injection 600 mg/ 2 mL (ampoule)
- Lincocin® Syrup 250 mg/ 5 mL in 60mL bottle
- Lincocin® Capsules 500 mg

DOSAGE

Use as directed by the physician.

INSTRUCTIONS

Avoid exposure to heat, sunlight & freezing.
Store below 30°C.
Keep out of the reach of children.

CAUTION

To be sold on the prescription of a registered medical practitioner only.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: دوا کو گرمی، سورج کی روشنی اور نم ہونے سے بچائیں۔
دوا کو 30°C سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔
تاکید: صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخہ پر فروخت کریں۔

Lincocin Capsules & Syrup

Manufactured by:
Pfizer Pakistan Ltd.
B-2, S.I.T.E., Karachi, Pakistan.

Lincocin Sterile Solution

Manufactured by:
sanofi-aventis Pakistan Ltd.
Plot. 23, Sector. 22,
Korangi Industrial Area, Karachi. 



Packed by:
Pfizer Pakistan Ltd.
B-2, S.I.T.E., Karachi, Pakistan.