



# Olinc<sup>®</sup> IM/IV Injection Capsules

(Lincomycin)

اولینک / انجکشن / کپسولز  
(لنکومایسین)

## DESCRIPTION:

OLINC contains lincomycin hydrochloride which is the monohydrated salt of lincomycin. The chemical name for lincomycin hydrochloride is Methyl 6,8-dideoxy-6-(1-methyl-trans-4-propyl-L2-pyrrolidinecarboxamido)-1-thio-D-erythro- $\alpha$ -D-galacto-octopyranoside monohydrochloride monohydrate. The molecular formula of lincomycin hydrochloride is  $C_{18}H_{34}N_2O_6S.HCl.H_2O$  and the molecular weight is 461.01. Lincomycin hydrochloride is a white or partially white, crystalline powder.

## COMPOSITION:

### Olinc 150mg/ml Injection

#### Each Ampoule contains:

Lincomycin.....150mg as Lincomycin HCl U.S.P.  
(Product Specs.: U.S.P.)

### Olinc 300mg/ml Injection

#### Each Ampoule contains:

Lincomycin.....300mg as Lincomycin HCl U.S.P.  
(Product Specs.: U.S.P.)

### Olinc 600mg/2ml Injection

#### Each Ampoule contains:

Lincomycin.....600mg as Lincomycin HCl U.S.P.  
(Product Specs.: U.S.P.)

### Olinc 500mg Capsule

#### Each Capsule contains:

Lincomycin.....500mg as Lincomycin HCl U.S.P.  
(Product Specs.: U.S.P.)

## CLINICAL PHARMACOLOGY:

### Pharmacodynamic Properties:

Pharmacotherapeutic group: Antibiotics, Lincosamide. ATC code: J01FF02

### Mechanism Of Action:

Lincomycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S

subunit of the bacterial ribosome. Lincomycin is predominantly bacteriostatic.

### Microbiology:

#### Gram-Positive Bacteria:

- Corynebacterium diphtheriae
- Streptococcus pyogenes
- Viridans group streptococci
- Staphylococcus aureus
- Streptococcus pneumoniae

#### Anaerobic Bacteria:

- Clostridium tetani
- Clostridium perfringens

### Pharmacokinetic Properties

Oral administration of a single 500 mg dose of lincomycin in the fasting state produces an average peak serum level of 5.3  $\mu$ g/mL at 2 hours post-dose. Administration immediately after a meal reduces oral absorption.

Intramuscular administration of a single dose of 600 mg of lincomycin produces average peak serum concentrations of 11.6 mcg/mL at 60 minutes and maintains therapeutic concentrations for 17 to 20 hours. Urinary excretion after this dose ranges from 1.8 to 24.8 percent. A two hour intravenous infusion of 600 mg of lincomycin achieves average peak serum concentrations of 15.9 mcg/mL and maintains therapeutic concentrations for 14 hours. Urinary excretion ranges from 4.9 to 30.3 percent.

The biological half-life after intramuscular or intravenous administration is  $5.4 \pm 1.0$  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 twofold longer than in patients with normal hepatic function. Hemodialysis and peritoneal dialysis are not effective in removing lincomycin from the serum.

Tissue level studies indicate that bile is an important route of excretion. Significant levels have been demonstrated in the majority of body tissues. Although lincomycin

appears to diffuse into cerebrospinal fluid (CSF), levels of lincomycin in the CSF appear inadequate for the treatment of meningitis.

#### **THERAPEUTIC INDICATIONS:**

OLINC is indicated in the treatment of serious infections due to susceptible strains of streptococci, pneumococci, and staphylococci. Its use should be reserved for penicillin-allergic patients. It is used in Upper respiratory infections, Lower respiratory infections, Skin and soft tissue infections, Bone and joint infections, Septicemia, endocarditis and Bacillary dysentery.

#### **DOSAGE AND ADMINISTRATION:**

##### **Oral:**

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

##### *Adults:*

Infections due to susceptible organisms, 500 mg t.i.d. (q8h). More severe infections: 500 mg q.i.d. (q6h).

##### *Pediatric patients over 1 month of age:*

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.

#### **Intramuscular**

##### *Adults:*

For serious infections 600 mg (2 mL) intramuscularly every 24 hours. For more severe infections 600 mg (2 mL) intramuscularly every 12 hours or more often.

##### *Pediatric patients over 1 month of age:*

For serious infections one intramuscular injection of 10 mg/kg every 24 hours. For more severe infections one intramuscular injection of 10 mg/kg every 12 hours or more often.

#### **Intravenous:**

##### *Adults:*

The intravenous dose will be determined by the severity of the infection. For serious infections doses of 600 mg of lincomycin (2 mL of OLINC) to 1 gram are given 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. Intravenous doses are given on the basis of 1 gram of lincomycin diluted in not less than 100 mL.

##### *Pediatric patients over 1 month of age:*

10 to 20 mg/kg/day depending on the severity of the infection may be infused in divided doses as described above for adults.

Safety and effectiveness in pediatric patients below the age of one month have not been established.

#### *Subconjunctival Injection:*

0.25 mL (75 mg) injected subconjunctivally will result in ocular fluid concentrations of antibacterial (lasting for at least 5 hours) sufficient for most susceptible pathogens.

#### *Patients with Renal Impairment:*

An appropriate dose is 25 to 30% of that recommended for patients with normally functioning kidneys.

#### **METHOD OF ADMINISTRATION:**

Lincomycin should not be injected intravenously undiluted as a bolus, but should be infused over at least 60 minutes. Skipping doses or not completing the full course of therapy may decrease the effectiveness of the immediate treatment and increase the likelihood that bacteria will develop resistance and will not be treatable by OLINC or other antibacterial drugs in the future.

#### **CONTRAINDICATIONS:**

This drug is contraindicated in patients previously found to be hypersensitive to lincomycin or clindamycin.

#### **WARNINGS AND PRECAUTIONS:**

OLINC should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. OLINC should be used with caution in patients with a history of asthma or significant allergies. Severe cardiopulmonary reactions have occurred when this drug has been given at greater than the recommended concentration and rate.

#### **Clostridium difficile associated diarrhea**

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Lincomycin, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

#### **Hypersensitivity**

Severe hypersensitivity reactions, including anaphylactic reactions and severe cutaneous adverse reactions (SCAR) such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), and erythema multiforme (EM) have been reported in patients receiving OLINC therapy. If an anaphylactic reaction or severe skin reaction occurs, OLINC should be discontinued and appropriate therapy should be initiated.

#### **Benzyl Alcohol Toxicity in Pediatric Patients (Gasping Syndrome)**

The preservative benzyl alcohol has been associated with serious adverse events, including the "gasping syndrome", and death in pediatric patients. The minimum

amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birth weight infants may be more likely to develop toxicity.

#### DRUG INTERACTIONS:

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

#### ADVERSE EFFECTS:

**Gastrointestinal disorders:** Diarrhea, nausea, vomiting, glossitis, stomatitis, abdominal pain, abdominal discomfort, anal pruritus.

**Skin and subcutaneous tissue disorders:** Toxic epidermal necrolysis, Stevens-Johnson syndrome, acute generalized exanthematous pustulosis, dermatitis bullous, dermatitis exfoliative, erythema multiforme, rash, urticaria, pruritus.

**Infections and infestations:** Vaginal infection, pseudomembranous colitis, Clostridium difficile colitis.

**Blood and lymphatic system disorders:** Pancytopenia, agranulocytosis, aplastic anemia, leukopenia, neutropenia, thrombocytopenic purpura.

**Immune system disorders:** Anaphylactic reaction, angioedema, serum sickness.

**Hepatobiliary disorders:** Jaundice, liver function test abnormal, transaminases increased.

**Renal and urinary disorders:** Renal impairment, oliguria, proteinuria, azotemia.

**Cardiac disorders:** Cardio-respiratory arrest.

**Vascular disorders:** Hypotension, thrombophlebitis.

**Ear and labyrinth disorders:** Vertigo, tinnitus.

**Neurologic disorders:** Headache, dizziness, somnolence.

**General disorders and administration site conditions:** Injection site abscess sterile, injection site induration, injection site pain, injection site irritation.

#### USE IN PREGNANCY AND LACTATION:

**Pregnancy:** There are no adequate and well-controlled studies in pregnant women. OLINC should be used during pregnancy only if clearly needed.

**Lactation:** Lincomycin has been reported to appear in human milk. Decision should be made whether to discontinue nursing, or to discontinue the drug, taking into account the importance of the drug to the mother.

#### INCOMPATIBILITIES

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

#### OVERDOSE:

Serum concentrations of lincomycin are not appreciably affected by hemodialysis and peritoneal dialysis.

#### SHELF LIFE:

OLINC Injection and Capsules : 3 Years

#### STORAGE AND INSTRUCTIONS:

Protect from heat & sunlight, store below 30°C.

The expiration date refer to the product correctly stored at the required condition.

Keep out of the reach of children.

#### PRECAUTIONS:

Do not use if injection is leaking, solution is cloudy or contains un-dissolved particles. Patients and healthcare professionals can also report suspected adverse drug reaction at [ade@bosch-pharma.com](mailto:ade@bosch-pharma.com).

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

#### PRESENTATION:

**Olinc 150mg / ml Injection:** Pack of 5's ampoules.

**Olinc 300mg / ml Injection:** Pack of 5's & 50's ampoules.

**Olinc 600mg / 2ml Injection:** Pack of 5's & 50's ampoules.

**Olinc 500mg Capsule:** Alu Alu blister pack of 10 capsules.

ہدایات:

دھوپ اور گرمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

احتیاط: انجکشن لیک ہونے، دھندلا ہونے یا اس میں کوئی غیر حل

پزیرشے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

پتلیوں کی پیچھے سے دُور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔



Manufactured by:

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