

### 1.3 Product Information

#### 1.3.1 Summary of Product Characteristics(SmPC)

##### 1 Name of the medicinal product

Lincomycin Capsules 500mg

##### 2 Anatomic Therapeutic and Chemical (ATC) Classification and Distribution Category:

Category:

Antibacterial (systemic)

##### 3 Qualitative and quantitative composition

ACTIVE SUBSTANCES:

Approved Name (INN)	Formula dosage	Reason to include	Specification
Lincomycin Hydrochloride	500mg	Active	USP

EXCIPIENTS:

Approved Name (INN)	Formula dosage	Specification
Magnesium stearate	10.0mg	BP

##### 4 Clinical particulars

Lincomycin is used for:

Treating serious infections caused by certain bacteria.

Lincomycin is a lincomycin antibiotic. It works by stopping the production of essential proteins needed by certain bacteria to survive.

Do NOT use lincomycin if:

you are allergic to any ingredient in lincomycin

you are taking erythromycin

Contact your doctor or health care provider right away if any of these apply to you.

Before using lincomycin:

Some medical conditions may interact with lincomycin. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

if you are pregnant, planning to become pregnant, or are breast-feeding

if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement

if you have allergies to medicines, foods, or other substances

if you have diarrhea, intestinal problems, liver problems, kidney problems, or asthma

Some MEDICINES MAY INTERACT with lincomycin. Tell your health care provider if you are taking any other medicines, especially any of the following:

Erythromycin because it may decrease lincomycin's effectiveness

This may not be a complete list of all interactions that may occur. Ask your health care provider if lincomycin may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How to use lincomycin:

Use lincomycin as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Lincomycin is given as an injection at your doctor's office, hospital, or clinic.

Contact your health care provider if you have any questions.

- If you miss a dose of lincomycin, call your doctor to find out what to do.

Ask your health care provider any questions you may have about how to use lincomycin.

**Important safety information:**

- Tell your doctor or dentist that you take lincomycin before you receive any medical or dental care, emergency care, or surgery.

- Lincomycin only works against bacteria; it does not treat viral infections (eg, the common cold).
- Be sure to use lincomycin for the full course of treatment. If you do not, the medicine may not clear up your infection completely. The bacteria could also become less sensitive to this or other medicines. This could make the infection harder to treat in the future.
- Long-term or repeated use of lincomycin may cause a second infection. Tell your doctor if signs of a second infection occur. Your medicine may need to be changed to treat this.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- Lincomycin has benzyl alcohol in it. Do not use it in NEWBORNS or INFANTS. It may cause serious and sometimes fatal side effects. If you have questions, check with your doctor or pharmacist.
- Lab tests may be performed while you use lincomycin. These tests may be used to monitor your condition or check for side effects. Be sure to keep all doctor and lab appointments.
- Use lincomycin with caution in the ELDERLY; they may be more sensitive to its effects, especially diarrhea. Monitor carefully for changes in bowel frequency.
- PREGNANCY and BREAST-FEEDING: If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using lincomycin while you are pregnant. Lincomycin is found in breast milk. Do not breast-feed while taking lincomycin.

**Possible side effects of lincomycin:**

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

*Diarrhea; dizziness; nausea; pain or irritation at the injection site; vomiting.*

**Seek medical attention right away if any of these SEVERE side effects occur:**

*Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); bloody or watery stools; change in how much urine is passed; difficulty swallowing; dizziness; mouth irritation or mouth sores; ringing in the ears; severe or persistent diarrhea; stomach pain or cramps; swelling of hands, eyes, or throat; yellowing of skin or eyes.*

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects. To report side effects to the appropriate agency, please read the

**If OVERDOSE is suspected:**

Contact 1-800-222-1222 (the American Association of Poison Control Centers), your local , or emergency room immediately.

**Proper storage of lincomycin:**

Lincomycin is handled and stored by a health care provider. You will not store it at home. Keep all medicines out of the reach of children and away from pets.

**General information:**

- If you have any questions about lincomycin, please talk with your doctor, pharmacist, or other health care provider.
- Lincomycin is to be used only by the patient for whom it is prescribed. Do not share it with other people.
- If your symptoms do not improve or if they become worse, check with your doctor.
- Check with your pharmacist about how to dispose of unused medicine.

This information should not be used to decide whether or not to take lincomycin or any other medicine. Only your health care provider has the knowledge and training to decide which medicines are right for you. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about lincomycin. It does NOT include all

information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to lincomycin. This information is not specific medical advice and does not replace information you receive from your health care provider. You must talk with your healthcare provider for complete information about the risks and benefits of using lincomycin.

Lincomycin is best taken with a full glass (8 ounces) of water on an empty stomach (either 1 hour before or 2 hours after meals), unless otherwise directed by your doctor.

To help clear up your infection completely, keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days. If you have a ``strep" infection, you should keep taking this medicine for at least 10 days. This is especially important in ``strep" infections. Serious heart problems could develop later if your infection is not cleared up completely. Also, if you stop taking this medicine too soon, your symptoms may return.

This medicine works best when there is a constant amount in the blood. To help keep the amount constant, do not miss any doses. Also, it is best to take each dose at evenly spaced times day and night. For example, if you are to take 4 doses a day, doses should be spaced about 6 hours apart. If this interferes with your sleep or other daily activities, or if you need help in planning the best times to take your medicine, check with your health care professional.

#### Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For infections caused by bacteria:
  - For oral dosage form (capsules):
    - Adults and teenagers—500 milligrams (mg) every six to eight hours.
    - Infants up to 1 month of age—Use and dose must be determined by your doctor.
    - Children 1 month of age and older—Dose is based on body weight. The usual dose is 7.5 to 15 mg per kilogram (kg) (3.4 to 6.8 mg per pound) of body weight every six hours; or 10 to 20 mg per kg (4.5 to 9.1 mg per pound) of body weight every eight hours.
  - For injection dosage form:
    - Adults and teenagers—600 mg to 1 gram injected into a vein over at least one hour, every eight to twelve hours; or 600 mg injected into a muscle every twelve to twenty-four hours.
    - Infants up to 1 month of age—Use and dose must be determined by your doctor.
    - Children 1 month of age and older—Dose is based on body weight. The usual dose is 10 mg per kg (4.5 mg per pound) of body weight injected into a muscle every twelve to twenty-four hours; or 3.3 to 6.7 mg per kg (1.5 to 3 mg per pound) of body weight injected into a vein every eight hours; or 5 to 10 mg per kg (2.3 to 4.5 mg per pound) of body weight injected into a vein every twelve hours.

## **5 Pharmacological properties**

### **5.1 Pharmacodynamic properties**

Lincomycin is a lincosamide antibiotic that comes from the yeast *Streptomyces lincolnensis*. Lincomycin has been shown to be active in vitro against the following microorganisms: Aerobic gram-positive cocci: *Streptococcus pyogenes* and Viridans group streptococci; Aerobic gram-positive bacilli: *Corynebacterium diphtheriae*; Anaerobic gram-positive non-sporeforming bacilli: *Propionibacterium acnes*; Anaerobic

gram-positive sporeforming bacilli: Clostridium tetani and Clostridium perfringens.

## **5.2 Pharmacokinetic properties**

### Absorption:

Rapidly absorbed from the gastrointestinal tract following oral administration. Approximately 20 to 30% absorbed orally in fasting state; absorption decreased when taken with food.

### Distribution:

Widely and rapidly distributed to most fluids and tissues, except cerebrospinal fluid (CSF); high concentrations in bone, bile, and urine; lincomycin may reach significant concentrations in the eye following parenteral administration.

Readily crosses the placenta. Up to 25% of maternal serum concentrations. Also distributed into breast milk.

### Protein binding:

Protein binding decreases with increased plasma concentrations. Range, 28 to 86% (average, 70 to 75%). Albumin is not thought to be the primary binding component.

### Biotransformation:

Presumed to be hepatic; metabolites have not been fully characterized.

### Half-life:

Normal renal function—5.4 hours (range, 4 to 6 hours).

End-stage renal disease—10 to 20 hours.

Impaired hepatic function—Half-life almost doubled.

Time to peak serum concentration

Oral: 2 to 4 hours.

Intramuscular: 0.5 hour.

Intravenous: End of infusion.

Elimination:

Renal, biliary. Mean urinary recovery of unchanged drug over a 24-hour period ranges from 10–47% after an intramuscular dose, 13–72% after an intravenous dose, and 3–13% after a fasting oral dose. Approximately 30–40% of an oral dose is excreted unchanged in the feces within 72 hours.

In dialysis—Not removed from the blood by hemodialysis or peritoneal dialysis.

### **5.3 Preclinical safety data**

Not available