1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed.

VADIS PHARMACEUTICALS LIMITED	
BRAND NAME:	**VADIS LINCOMYCIN CAPSULES**
GENERIC NAME	**LINCOMYCIN CAPSULES BP 500 MG**

MODULE 1 – ADMINISTRATIVE INFORMATION AND PRESCRIBING INFORMATION

1. Name of the medicinal product

Vadis Lincomycin Capsules

2. Qualitative and quantitative composition

Each capsule contains

Lincomycin Hydrochloride BP

equivalent to Lincomycin 500 mg

3. Pharmaceutical form

Navy blue and light blue colored capsules

4. Clinical particulars

4.1 Therapeutic indications

Lincomycin is an antibiotic used in the treatment of staphylococcal, streptococcal, and *Bacteroides fragilis* infections.

- Septicemia
- Severe osteoarticular infection
- Severe otorhinolaryngeal infection
- Severe postoperative digestive infection
- Severe respiratory infection
- Severe skin and soft tissue infection
- Severe stomatological infection
- Severe urogenital infection

4.2 Posology and method of administration

Oral use:

To be adapted according to physiopathologic status.

Do not ingest anything except water for 1 to 2 hours before and after taking lincomycin.

Adults: 1.5 g to 2 g/24 hours.

Children: 30 to 60 mg/kg/24 hours.

4.3 Contraindications

Hypersensitivity to lincosamides, Hypersensitivity to one of the components, Lactation

4.4 Special warnings and precautions for use

The lincomycin injection formulation contains benzyl alcohol. The preservative benzyl alcohol has been associated with serious adverse events, including the gasping syndrome, and death in pediatric patients. Although normal therapeutic doses of this product ordinarily deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the gasping syndrome, the minimum amount of benzyl alcohol at which toxicity may occur is not known. The risk of benzyl alcohol toxicity depends on the quantity administered and the hepatic capacity to detoxify the chemical. Premature and low-birth weight infants may be more likely to develop toxicity.

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

If lincomycin 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 lincomycin, 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.

Effects on the Ability to Drive or Use Machinery: The effect of lincomycin on the ability to drive or operate machinery has not been systematically evaluated.

Lincomycin therapy has been associated with severe colitis which may end fatally. Therefore, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as previously described in the Indications section. It should not be used in patients with nonbacterial infections such as most upper respiratory tract infections. Studies indicate a toxin(s) produced by *Clostridia* is one primary cause of antibiotic associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Endoscopic examination may reveal pseudomembranous colitis.

4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of Lincocin Capsule may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Lincocin Capsule may interact with the following drugs and products:

- Alcuronium
- Atracurium
- Bamifylline
- Clindamycin
- Distigmine
- Erythromycin
- Kaolin

- Rocuronium

4.6 Pregnancy and lactation

Benzyl alcohol can cross the placenta (see Precautions).

No adverse effects on survival of offspring from birth to weaning were seen in studies performed in rats using oral doses of lincomycin up to 1,000 mg/kg (7.5 times the maximum human dose of 8 g/day). No teratogenic effects were seen in study conducted in rats treated with more than 55 times the highest recommended adult human dose of 8 g/day.

In humans, lincomycin 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 lincomycin 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. Lincomycin should be used during pregnancy only if clearly needed.

Until further clinical experience is obtained, Lincocin preparations (lincomycin) are not indicated in the newborn.

Lincomycin has been reported to appear in breast milk in ranges of 0.5 to 2.4 mcg/ml.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects

Gastrointestinal: nausea, vomiting, abdominal distress and persistent diarrhea (see Warnings) and, with oral preparations, esophagitis.

Hematopoietic: neutropenia, leukopenia, agranulocytosis, and thrombocytopenic purpura have been reported. There have been rare reports of aplastic anemia and pancytopenia in which lincomycin could not be ruled out as the causative agent.

Hypersensitivity Reactions: Hypersensitivity reactions such as angioneurotic edema, serum sickness and anaphylaxis have been reported, some of these in patients sensitive to penicillin.

Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, have been associated with lincomycin administration.

Skin and Mucous Membranes: Pruritus, skin rashes, urticaria, vaginitis, and rare instances of exfoliative and vesiculobullous dermatitis have been reported.

Liver: Jaundice and abnormal liver function tests (particularly elevation of serum transaminase) have been observed during lincomycin therapy.

Cardiovascular: Instances of hypotension following parenteral administration have been reported, particularly after too rapid administration. Rare instances of cardiopulmonary arrest have been reported after too rapid i.v. administration (see Dosage).

4.9 Overdose

- Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Lincocin Capsule, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.
- Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.
- Please consult your physician or pharmacist or product package for more information.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action:-

Lincomycin inhibits protein synthesis in susceptible bacteria by binding to the 50 S subunits of bacterial ribosomes and preventing peptide bond formation upon transcription. It is usually considered bacteriostatic, but may be bactericidal in high concentrations or when used against highly susceptible organisms.

Lincomycin is a lincosamide antibiotic that produced by *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

Urinary excretion after this dose ranges from 1.8 to 24.8 percent (mean: 3 percent). Biliary excretion is also an important route of excretion. The biological half-life after intramuscular or intravenous administration is 5.4 ± 1.0 hours.

5.3 Preclinical safety data

No further information of relevance to add.

6. Pharmaceutical particulars

6.1 List of excipients

Magnesium stearate, Starch, Sodium Starch Glycolate, Aerosil

6.2 Incompatibilities

None.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Blisters: Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

3x4 capsules

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

Vadis Pharmaceuticals Limited,

Plot RD 14, Phase 2, Ext. Trans-Ekulu,

Enugu-Nigeria

8. Marketing authorisation number(s)

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9. Date of first authorisation/renewal of the authorisation

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10. Date of revision of the text
