SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lincomycin hydrochloride capsules

Strength: 500mg

Dosage form: hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient name	Quantity per unit	Function
Lincomycin hydrochloride	Lincomycin hydrochloride equivalent to lincomyicin 500mg	Active substance
Magnesium stearate	1.83mg	Lubricant

3 PHARMACEUTICAL FORM

0# hard capsules, filled with white or almost white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is a mainly bacteriostatic drug used in the treatment of serious anaerobic infections, notably due to Bacteroides fragilis. It is also used for some Gram-positive infections due to pneumococci, staphylococci (including meticillin-resistant forms), and streptococci.

4.2 Posology and method of administration

Lincomycin HCL capsules should be administered orally to adults as described in the following Dosage table.

The adult oral dose is 500 mg 3~4 times daily.

The usual oral dose of lincomycin for infants and children aged 1 month and over is 30 to 60 mg/kg daily in divided doses.

4.3 Contraindications

Lincomycin hydrochloride capsules should not be given to patients hypersensitive to it or to the closely related drug Clindamycin.

4.4 Special warnings and precautions for use

Lincomycin should not be given to patients hypersensitive to it or to the closely related drug lincomycin. It should be used with caution in patients with a history of gastrointestinal disease, particularly colitis, and stopped immediately if significant diarrhoea or colitis occurs. Middle-aged and elderly female patients may be at greater

risk of severe diarrhoea or pseudomembranous colitis, especially after abdominal surgery. Caution has also been advised in atopic patients. Periodic tests of liver and kidney function and blood counts have been recommended in patients on prolonged therapy, and in infants. Caution is required during parenteral use in neonates, since some parenteral formulations contain benzyl alcohol which may cause fatal 'gasping syndrome'

4.5 Interaction with other medicinal products and other forms of interaction

Lincomycin hydrochloride capsules has neuromuscular blocking activity and may enhance the effect of other drugs with this action.

leading to a potential danger of respiratory depression. Lincomycin may antagonise the effects of parasympathomimetics.

Lincomycin may competitively inhibit the effects of macrolides, ketolides, streptogramins, linezolid, and chloramphenicol because they all bind to the same subunit of the ribosome. Antagonism between lincomycin and erythromycin has been shown *in vitro*.

4.6 Fertility, pregnancy and lactation

Taking of this product by pregnant is forbidden.

It is report that the concentrations of lincomycin in breast milk were 0.7 to 3.8 micrograms/mL after doses of 150 mg orally to 600 mg intravenously. The last available guidance from the American Academy of Pediatrics[1] considered that use of lincomycin was usually compatible with breast feeding. Nevertheless, UK product information states that although it is unlikely that a breast-fed infant could absorb significant amounts, caution should be exercised when lincomycin is given during breast feeding.

4.7 Effects on ability to drive and use machines

Not applicable for lincomycin hydrochloride capsules.

4.8 Undesirable effects

Use of lincomycin has been associated with the development of diarrhoea in up to 20% of patients; symptoms have occurred with topical as well as oral or parenteral formulations. In about 2 to 10% of patients severe or even fatal antibiotic-associated or pseudomembranous colitis may develop during therapy or up to several weeks afterwards. Early reports showed that it occurred more frequently in middle-aged and

elderly women, particularly after abdominal surgery; it may also occur rarely after vaginal use. Lincomycin should be stopped immediately if significant diarrhoea or colitis occurs; recovery usually occurs within 3 weeks of stopping the drug. Protein supplementation and use of an antibacterial active against *Clostridium* spp. should be considered for severe antibiotic-associated colitis. For further information on the treatment of antibiotic-associated colitis.

Other gastrointestinal effects include nausea, vomiting, abdominal pain or cramps; an unpleasant or metallic taste has occasionally been reported after high intravenous doses. Oesophagitis and oesophageal ulceration has been reported particularly after ingestion of capsules with insufficient water. Taste disturbances may also be associated with oral and topical use of lincomycin.

Rashes and urticaria, the most common hypersensitivity reactions, occur in up to 10% of patients usually after 1 to 2 weeks of therapy. Erythema multiforme, Stevens-Johnson syndrome, and exfoliative and vesiculobullous dermatitis have been reported rarely, and a few cases of anaphylaxis have occurred.

Other adverse effects include transient leucopenia or occasionally agranulocytosis, eosinophilia, thrombocytopenia, polyarthritis, and abnormalities of liver function tests; in some cases overt jaundice and hepatic damage have been reported. Renal dysfunction, shown by azotaemia, oliguria, and/or proteinuria, has been reported rarely.

Although local irritation is rare, intramuscular injection has led to induration and sterile abscess, and thrombophlebitis may occur after intravenous use. Too rapid intravenous infusion can result in rare instances of cardiopulmonary arrest and hypotension. Some parenteral formulations contain benzyl alcohol which may cause fatal 'gasping syndrome' in neonates,

Topical application may be associated with local irritation, skin dryness, and contact dermatitis; sufficient lincomycin may be absorbed to produce systemic effects. Cervicitis, vaginitis, vaginal candidiasis, and vulvovaginal irritation have been reported with intravaginal use; a small amount of systemic absorption also occurs.

4.9 Overdose

Once patient take overdose medicine, send to hospital immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chemical name: Methyl 6-amino-6,8-dideoxy-*N*-[(2*S*,4*R*)-1-methyl-4-propylprolyl]-1-thio-α-D-*erythro*-D-*galacto*-octopyranoside

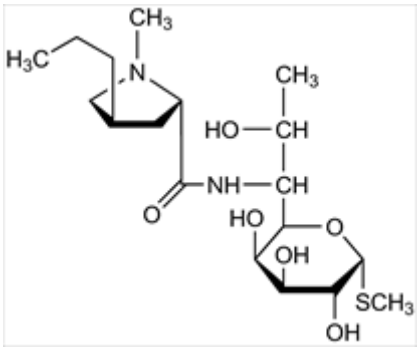
Molecular formula: $C_{18}H_{34}N_2O_6S$ =406.5

CAS: 154-21-2

ATC code: J01FF02

ATC code (veterinary): QJ01FF02

UNII code: BOD072YW0F



Chemical Structure of Lincomycin

5.2 Pharmacokinetic properties

About 20 to 35% of an oral dose of lincomycin is rapidly absorbed from the gastrointestinal tract; after a 500-mg dose, peak plasma concentrations of about 2 to 3 micrograms/mL are reached within 2 to 4 hours. Food markedly reduces the rate and extent of absorption. An intramuscular injection of 600 mg produces average peak plasma concentrations of between 11 and 12 micrograms/mL at 60 minutes and a 2-hour intravenous infusion of 600 mg produces an average of about 16 micrograms/mL.

The biological half-life of lincomycin is about 5 hours and may be prolonged in hepatic or renal impairment. Serum half-life may be doubled in patients with hepatic impairment and up to 3 times longer in those with severe renal impairment.

Lincomycin is widely distributed in the tissues including bone and body fluids but diffusion into the CSF is poor, although it may be slightly better when the meninges are inflamed. It diffuses across the placenta and is distributed into breast milk.

Lincomycin is partially inactivated in the liver; unchanged drug and metabolites are excreted in the urine, bile, and faeces. Lincomycin is not effectively removed from the blood by haemodialysis or peritoneal dialysis.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate 1.83mg/capsules

6.2 Incompatibilities

Solutions of lincomycin hydrochloride have an acid pH and incompatibility may be expected with alkaline preparations, or with drugs unstable at low pH. Licensed product information for the injectable solution states that physical incompatibility has been reported with novobiocin, kanamycin, and phenytoin.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Lincomycin hydrochloride capsules should stored in airtight container at a temperature not exceed 30℃.

6.5 Nature and contents of container

The container closure system we adopt PVC blister and Al foil, 4 capsules per blister, 3 blister per box.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Chris nelb Pharmaceutical Ltd.

8 MARKETING AUTHORISATION NUMBER(S)

A4-05823

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Jun. 20, 2023

10MANUFACTURER

Yangzhou No. 3 pharmaceutical Co., Ltd.
No.51 Guotai Road,Yiling Town,Jiangdu District,Yangzhou City,Jiangsu, P.R.China