AUSTRALIAN PRODUCT INFORMATION - LINCOCIN lincomycin 600mg/2mL (as hydrochloride monohydrate) injection vial

1. NAME OF THE MEDICINE

Lincomycin hydrochloride monohydrate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains lincomycin hydrochloride monohydrate equivalent to lincomycin base 300 mg;

Excipients with known effect

- benzyl alcohol, 9.45 mg

For the full list of excipients, see section 6.1, List of Excipients.

3. PHARMACEUTICAL FORM

LINCOCIN Injection is a clear, colourless or almost colourless solution, practically free from particles.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

LINCOCIN is indicated in the treatment of serious infections due to susceptible strains of gram-positive aerobes such as streptococci, pneumococci and staphylococci.

Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgement of the physician, a penicillin is inappropriate. Because of the risk of colitis (see section 4.4, Special Warnings and Precautions for Use), before selecting lincomycin the physician should consider the nature of infection and the suitability of less toxic alternatives (e.g. erythromycin).

LINCOCIN has been demonstrated to be effective in the treatment of staphylococcal infections resistant to other antibiotics and susceptible to lincomycin. Staphylococcal strains resistant to LINCOCIN have been recovered; culture and susceptibility studies should be done in conjunction with LINCOCIN therapy. In the case of macrolides, partial but not complete cross resistance may occur. The drug may be administered concomitantly with other antimicrobial agents with which it is compatible when indicated (see section 4.4, Special Warnings and Precautions for Use).

The specific infections for which LINCOCIN is indicated are as follows:

* 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 skin structure infections including cellulitis, furuncles, abscesses, impetigo, acne and wound infections. Conditions such as 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.

* Septicaemia and endocarditis. Selected cases of septicaemia 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 micrograms/mL), lincomycin has been effective in its treatment due to the very high levels of lincomycin attained in the bowel (approximately 3000-7000 micrograms/gram of stool).

4.2 DOSE AND METHOD OF ADMINISTRATION

Note: If significant diarrhoea occurs during therapy, this antibiotic should be discontinued (see section 4.4, Special Warnings and Precautions for Use).

LINCOCIN is incompatible with novobiocin, kanamycin and phenytoin.

With beta-haemolytic streptococcal infections, treatment should continue for at least 10 days to diminish the likelihood of subsequent rheumatic fever or glomerulonephritis.

Intramuscular

Adults:

Serious infections	- 600 mg (2 mL) intramuscularly every 24 hours.
More serious infections	- 600 mg (2 mL) intramuscularly every 12 hours or more often, as determined by the severity of the infection.

Children over 1 month of age:

Serious infections	- one intramuscular injection of 10 mg/kg/day.
More serious infections	- one intramuscular injection of 10 mg/kg every 12 hours or more often.

Intravenous

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

Adults:

Serious infections - 600 mg to 1 g given every 8-12 hours.

More severe infections - the above doses may be increased. In life-threatening situations, daily intravenous doses of as much as 8 g have been given.

Children over 1 month of age:

Depending on the severity of the infection, 10-20 mg/kg/day may be infused in divided doses as described below.

Dilution and Infusion Rates

Dose	Vol. Diluent	Time
600 mg	100 mL	1 hr
1 g	100 mL	1 hr
2 g	200 mL	2 hr
3 g	300 mL	3 hr
4 g	400 mL	4 hr

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

The following infusion solutions have been found to be physically compatible with LINCOCIN: Glucose Intravenous Infusion 5%, Glucose Intravenous Infusion 10%, Sodium Chloride 0.9% and Glucose 5% Intravenous Infusion, Sodium Chloride 0.9% and Glucose 10% Intravenous Infusion, Compound Sodium Lactate Intravenous Infusion, Sodium Lactate 1/6 Molar and Dextran 70 Intravenous Infusion.

Please note that these compatibility determinations are physical observations only, not chemical determinations. Adequate clinical evaluation of the safety and efficacy of these combinations has not been performed.

Patients with diminished renal function: When LINCOCIN therapy is required in individuals with severe impairment of renal function, an appropriate dose is 25 to 30% of that recommended for patients with normal renal function.

Monitoring

During prolonged LINCOCIN therapy, periodic liver function and renal studies and blood counts should be performed

4.3 CONTRAINDICATIONS

This drug is contraindicated in patients previously found to be hypersensitive to lincomycin or clindamycin. It is not indicated in the treatment of minor bacterial infections or viral infections.

Lincomycin is not indicated in the newborn.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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

Risk of Colitis

The use of lincomycin can lead to the development of severe colitis. Fatalities have been reported. Therefore LINCOCIN should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in the INDICATIONS section. It should not be used in patients with non-bacterial infections such as most upper respiratory tract infections.

A toxin produced by *Clostridium difficile* appears to be the primary cause. The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with the use of antibiotics, including parenteral lincomycin. Symptoms may occur up to several weeks after cessation of antibiotic therapy.

Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone, however, in moderate to severe cases appropriate therapy with a suitable oral antibacterial agent effective against *C. difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated.

Drugs which delay peristalsis (e.g. opiates and diphenoxylate with atropine [LOMOTIL®]) may prolong and/or worsen the condition and should not be used.

Review of experience to date suggests that a subgroup of older patients with associated severe illness may tolerate diarrhoea less well. When LINCOCIN is indicated in these patients, they should be carefully monitored for change in bowel frequency.

Clostridium difficile associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including lincomycin, and may range in severity from mild diarrhoea 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 diarrhoea 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 be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Allergies

LINCOCIN, like any drug, should be used with caution in patients with a history of asthma or significant allergies.

Hypersensitivity Reactions

Hypersensitivity reactions (such anaphylactic reaction, angioedema and serum sickness) have been reported, some of these in patients known to be sensitive to penicillin. If an allergic reaction should occur, the drug should be discontinued and the usual agents (adrenalin, corticosteroids, antihistamines) should be available for emergency treatment.

Severe hypersensitivity reactions, including anaphylactic reactions and severe cutaneous adverse reactions (SCAR) such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP), and erythema multiforme (EM) have been reported in patients receiving lincomycin therapy. If an anaphylactic reaction or severe skin reaction occurs, lincomycin should be discontinued and appropriate therapy should be initiated (see section 4.8 Adverse Effects (Undesirable Effects)).

Superinfections

The use of antibiotics occasionally results in overgrowth of non-susceptible organisms - particularly yeasts. Should superinfections occur, appropriate measures should be taken. When patients with pre-existing monilial infections require LINCOCIN therapy, concomitant antimonilial treatment should be given.

Meningitis

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

Use in hepatic impairment

In patients with impaired hepatic or renal function, the serum half-life of lincomycin is increased. Consideration should be given to decreasing the frequency and dose of lincomycin administered in patients with impaired hepatic or liver function.

Since adequate data are not yet available in patients with pre-existing liver disease, its use in such patients is not recommended at this time unless special clinical circumstances so indicate

Use in renal impairment

See section 4.4, Special Warnings and Precautions for Use, Use in hepatic impairment)

Use in the Elderly

No data available.

Paediatric Use

LINCOCIN Injection contains benzyl alcohol which is associated with severe adverse effects, including fatal "Gasping Syndrome", in paediatric patients. The minimum amount of benzyl alcohol at which toxicity may occur is unknown. The risk of benzyl alcohol toxicity depends

on the quantity administered and the liver and kidneys' capacity to detoxify the chemical. Premature and low birth weight infants may be more likely to develop toxicity.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy:

Category A

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 limited data on the use of lincomycin in pregnant women.. tThe 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. Lincomycin is not indicated in the newborn (see section 4.3, Contraindications). Benzyl alcohol can cross the placenta (see section 4.4, Special Warnings and Precautions for Use, Paediatric Use).

No embryo fetal toxicity was observed in rats dosed with 10% lincomycin in the diet (equivalent to 5000 mg/kg/day) during organogenesis.

Use in lactation

LINCOCIN has been reported to appear in breast milk in ranges of 0.5 to 2.4 micrograms/mL. It should not, therefore, be used during lactation unless alternative arrangements can be made for feeding the baby.

4.7 EFFECT ON ABILITY TO DRIVE AND USE MACHINES

No studies were conducted to determine the effect of LINCOCIN on ability to drive and use machines.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Adverse reactions are listed according to the following categories:

Very common: ≥1/10

Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: cannot be estimated from available data

Infections and Infestations

Uncommon: Vaginal infection.

Not known: Pseudomembranous colitis, *Clostridium difficile* colitis.

Gastrointestinal Disorders

Common: Diarrhoea, vomiting, nausea.

Rare: Stomatitis.

Not known: Enterocolitis (see section 4.4, Special Warnings and Precautions for Use), oesophagitis[a], glossitis, abdominal discomfort.

Blood and Lymphatic System Disorders

Not known: Pancytopenia, agranulocytosis, aplastic anaemia, leukopenia, neutropenia, thrombocytopenic purpura.

Immune System Disorders

Not known: Anaphylactic reaction, angioedema, serum sickness (see section 4.4, Special Warnings and Precautions for Use).

Skin and Subcutaneous Tissue Disorders

Uncommon: Rash, urticaria.

Rare: Pruritus.

Not known: Toxic epidermal necrolysis, Stevens-Johnson syndrome, acute-generalised exanthematous pustulosis, erythema multiforme, dermatitis bullous, dermatitis exfoliative, anal pruritus.

Hepatobiliary Disorders

Not known: Jaundice, liver function test abnormal, transaminases increased.

Renal and Urinary Disorders[b]

Not known: Renal impairment, oliguria, proteinuria, azotaemia.

Cardiac Disorders

Not known: Cardio-respiratory arrest[c].

Vascular Disorders

Not known: Hypotension[d], thrombophlebitis[e].

Ear and Labyrinth Disorders

Not known: Vertigo, tinnitus.

General Disorders and Administration Site Conditions

Not known: Injection site abscess sterile[f], injection site induration[f], injection site pain[f], injection site irritation[f].

a. Reported with oral preparations.
b. No direct relationship of lincomycin to renal damage has been established.
c. Rare instances have been reported after too rapid intravenous administration.
d. Following parenteral administration, particularly after too rapid administration.
e. Reported with intravenous injection. This reaction can be minimised by avoidance of indwelling intravenous catheters.
f. Reported with intramuscular injection. These reactions can be minimised by deep intramuscular injection.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at https://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

The minimal toxic or lethal dose is not well established. At therapeutic doses, the primary toxic effects may involve the gastrointestinal tract and may include severe diarrhoea and pseudomembranous colitis that may result in death. Rapid administration of large doses has resulted in ventricular dysrhythmias, hypotension and cardiac arrest. Dermatitis, nephrotoxicity, hepatotoxicity, and various haematological abnormalities are toxic effects that occur less frequently.

No specific antidote is known. Support respiratory and cardiac function. In cases of overdose, drug levels of lincomycin are not clinically useful. However, monitoring serum concentrations in patients with markedly reduced renal and hepatic function may be indicated during high-dose therapy. Monitor full blood count in patients with significant exposure as lincomycin may produce abnormalities of the haematopoietic system. Because lincomycin may cause hepatotoxicity, monitor liver function tests in patients with significant exposure.

Haemodialysis and peritoneal dialysis are not effective in removing lincomycin from the serum.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

LINCOCIN is an antibiotic produced by fermentation of *Streptomyces lincolnensis*. LINCOCIN inhibits bacterial protein synthesis by binding to the 50S subunit of the bacterial ribosome. LINCOCIN is predominantly bacteriostatic *in vitro*. The antibacterial activity of LINCOCIN appears to best correlate with the length of time the concentration of active ingredient remains above the minimum inhibitory concentration (MIC) of the infecting organism.

Mechanism of Resistance

Cross resistance between LINCOCIN and clindamycin is complete. Resistance in staphylococci and streptococci is most often due to methylation of specific nucleotides in the 23S RNA of the 50S ribosomal subunit, which can determine cross resistance to macrolides and streptogramins B (MLS_B phenotype). Macrolide-resistant isolates of these organisms should be tested for inducible resistance to lincomycin/clindamycin using the D zone test

Antibacterial Spectrum

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

LINCOCIN is cross-resistant with clindamycin. A decrease in clindamycin/lincomycin susceptibility over time has been noted in particular among methicillin-resistant *Staphylococcus aureus* and in some species of *Clostridium*.

In vitro studies indicate that the following organisms are usually sensitive to concentrations achieved normally in the serum following recommended doses:

Aerobic and facultative gram-positive bacteria:

- *Staphylococcus aureus* (methicillin-susceptible strains only)
- *Streptococcus pyogenes*
- Viridans group streptococci
- *Streptococcus pneumoniae*
- *Corynebacterium diphtheriae.*

Anaerobic and microaerophilic bacteria:

- *Clostridium tetani,*
- *Clostridium perfringens*
- Propionibacterium acnes.

Note:

The drug is not active against most strains of *Enterococcus faecalis*, nor against *Neisseria gonorrhoeae, Neisseria meningitidis, Haemophilus influenzae* or other gram-negative organisms or yeasts. Some strains of *Clostridium perfringens* and strains of some less common human pathogens of Clostridia may be lincomycin-resistant. Depending on the sensitivity of the organism and concentration of the antibiotic, it may be either bactericidal or bacteriostatic. Cross resistance has not been demonstrated with penicillin, chloramphenicol, ampicillin, cephalosporins or the tetracyclines. Despite chemical differences, LINCOCIN exhibits antibacterial activity similar but not identical to the macrolide antibiotics (e.g. erythromycin). Some cross-resistance (with erythromycin) including a phenomenon

known as dissociated cross-resistance or macrolide effect has been reported. Microorganisms have not developed resistance to LINCOCIN rapidly when tested by *in vitro* or *in vivo* methods. Staphylococci develop resistance to LINCOCIN in a slow step-wise manner based on *in vitro* serial subculture experiments. Studies indicated that LINCOCIN does not share antigenicity with penicillin compounds.

Methodology for determining in vitro susceptibility to lincomycin

Susceptibility testing should be conducted using standardized laboratory methods, such as those described by the Clinical and Laboratory Standards Institute (CLSI) or the European Committee on Antimicrobial Susceptibility Testing (EUCAST). Because CLSI and EUCAST have not established susceptibility breakpoints for LINCOCIN, clindamycin should be tested instead. Resistance to lincosamides may be inducible by macrolides in macrolide-resistant staphylococci, *Streptococcus pneumoniae*, and beta-hemolytic streptococci. Macrolide-resistant isolates of these organisms should be screened for inducible clindamycin resistance using the D-zone test or other standard methodology.

Table 1: CLSI dilution and disk diffusion susceptibility interpretive criteria for clindamycin

Organism	**Susceptibility Interpretive Criteria**					
	Minimal Inhibitory Concentrations (MIC in µg/mL)			**Disk Diffusion (Zone Diameters in mm)**		
	S	**I**	**R**	**S**	**I**	**R**
Staphylococcus spp.	≤0.5	1–2	≥4	≥21	15–20	≤14
Streptococcus pneumoniae, β-hemolytic streptococci and viridans group streptococci	≤0.25	0.5	≥1	≥19	16–18	≤15
Anaerobic Bacteria	≤2	4	≥8	NA	NA	NA

Disk content 2 µg.
MIC interpretive criteria for anaerobes are based on agar dilution.
NA=not applicable.

The validity of both the dilution and disk diffusion test methods should be verified using quality control (QC) strains, as indicated by CLSI. Acceptable limits when testing clindamycin against these organisms are listed in the table below.

Table 2: Quality control ranges for clindamycin susceptibility tests (CLSI)

Organism	**Minimum Inhibitory Concentration Range (MIC in µg/mL)**	**Disk Diffusion Range (Zone Diameters in mm)**
Staphylococcus aureus ATCC 29213	0.06–0.25	NA
Staphylococcus aureus ATCC 25923	NA	24–30
Streptococcus pneumoniae ATCC 49619	0.03–0.12	19–25
Bacteroides fragilis ATCC 25285	0.5–2	NA

Bacteroides thetaiotaomicron ATCC 29741	2–8	NA
Eggerthella lenta ATCC 43055	0.06–0.25	NA

MIC ranges for anaerobic bacteria are based on agar dilution.
NA=Not applicable
ATCC® is a registered trademark of the American Type Culture Collection

Table 3: EUCAST dilution and disk diffusion susceptibility interpretive criteria for clindamycin

Organism	**Minimal Inhibitory Concentrations (MIC in µg/mL)**		**Disk Diffusion (Zone Diameters in mm)**	
	S	**R**	**S**	**R**
Staphylococcus spp.	≤ 0.25	>0.5	≥22	<19
Streptococcus groups A, B, C, G	≤0.5	>0.5	≥17	<17
Streptococcus pneumoniae	≤0.5	>0.5	≥19	<19
Viridans group streptococci	≤0.5	>0.5	≥19	<19
Gram-positive anaerobes (except *Clostridium difficile*)	≤4	--	NA	NA
Gram-negative anaerobes	≤4	--	NA	NA

Disk content 2 µg.
MIC interpretive criteria for anaerobes are based on agar dilution.
NA=not applicable.

Table 4: Quality control ranges for clindamycin susceptibility tests (EUCAST)

Organism	**Minimum Inhibitory Concentration Range (MIC in µg/mL)**	**Disk Diffusion Range (Zone Diameters in mm)**
Staphylococcus aureus ATCC 29213	0.06–0.25	23-29
Streptococcus pneumoniae ATCC 49619	0.03–0.12	22-28

NA=Not applicable
ATCC® is a registered trademark of the American Type Culture Collection

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

LINCOCIN is absorbed rapidly after a 500 mg oral dose in the fasting state, producing an average peak serum level of 5.3 micrograms/mL at 2 hours post dose, . Doubling the dose

increases but does not double the peak serum levels. Food in the stomach reduces total absorption as well as peak serum levels.

Distribution

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.

Metabolism

Tissue level studies indicate that bile is an important route of excretion. The excretion of lincomycin in urine and bile does not account for all of the administered dose and a substantial proportion of the drug appears to be inactivated in the body, presumably in the liver.

The biological half-life, after, intramuscular administration is approximately 5hours.

Excretion

Urinary recovery of drug in a 24-hour period ranges from 1.0% to 31% (mean: 4.0%) after a single oral dose of 500 mg. Bile is an important route of excretion.

Intramuscular administration of a single dose of 600 mg of lincomycin produces an average peak serum level of 11.6 micrograms/mL at 60 minutes and maintains therapeutic levels for 17 to 20 hours for most susceptible gram-positive organisms. Urinary excretion after this dose ranges from 1.8% to 24.8% (mean: 10.3%).

The intravenous infusion over a 2-hour interval of 600 mg of lincomycin achieves average peak serum levels of 15.9 μg/mL and yields therapeutic levels for 14 hours for most susceptible gram-positive organisms. Urinary excretion ranges from 4.9% to 23.3% (mean: 15.1%).

Haemodialysis and peritoneal dialysis do not effectively remove lincomycin from the blood.

Special Populations

Patients with Renal Impairment

The serum half-life of LINCOCIN may be prolonged in patients with severe impairment of renal function compared to patients with normal renal function.

Patients with Hepatic Impairment

In patients with abnormal hepatic function, serum half-life may be two-fold longer than in patients with normal hepatic function.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Lincomycin was not genotoxic in various in vitro and in vivo genotoxicity studies including bacterial reverse mutation assays, gene mutation assays in mammalian cells and Drosophila melanogaster germ cells, chromosomal aberration assays in human lymphocytes, and in vivo micronucleus assays. It induced DNA damage in one unscheduled DNA synthesis (UDS) assay

in primary rat hepatocytes, but it was negative in another UDS assay in rat hepatocytes and in a UDS assay in Chinese hamster lung fibroblasts.

Carcinogenicity

Lincomycin was not carcinogenic in rats at up to 100 mg/kg/day administered in the diet for 26 months.

Effects on Fertility

No effects on fertility were observed in rats administered lincomycin at oral doses up to 1000 mg/kg/day.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Benzyl alcohol
Water for injections, q.s.

6.2 INCOMPATIBILITIES

LINCOCIN is incompatible with novobiocin, kanamycin and phenytoin.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25ºC. Protect from light. Do not freeze.

6.5 NATURE AND CONTENTS OF CONTAINER

LINCOCIN Injection is available as 5 x 2 mL vials.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

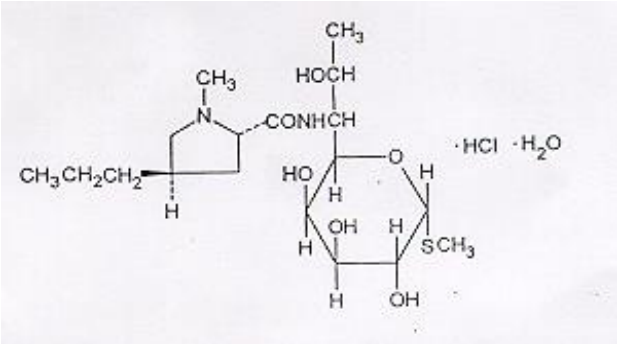
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Chemical Name: Lincomycin hydrochloride consists mainly of the monohydrate of methyl 6,8-dideoxy-6-[(*2S,4R*)-1-methyl-4-propylpyrrolidine-2-carboxamido]-1-thio-D-erythro-α-D-galacto-octopyranoside hydrochloride.

The structure of lincomycin hydrochloride monohydrate is:



LINCOCIN (lincomycin hydrochloride) is the monohydrated salt of lincomycin, a substance produced by the growth of a member of the lincolnensis group of *Streptomyces lincolnensis (fam. Streptomycetaceae)*. It is a white, or practically white, crystalline powder and is odourless or has a faint odour. Its solutions are acid and are dextrorotatory. LINCOCIN is freely soluble in water, soluble in dimethylformamide and very slightly soluble in acetone.

CAS number

CAS Number: 7179-49-9

7. MEDICINE SCHEDULE (POISONS STANDARD)

S4, Prescription Only Medicine

8. SPONSOR

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
Toll Free Number: 1800 675 229
www.pfizer.com.au

9. DATE OF FIRST APPROVAL

2 August 1991

10. DATE OF REVISION

27 March 2020

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Summary table of changes

Section changed	Summary of new information
8	Update to sponsor address
Throughout	Active ingredient AAN updated