AUSTRALIAN PRODUCT INFORMATION

CLINDAMYK®

(Clindamycin hydrochloride) capsules

1 NAME OF THE MEDICINE

Clindamycin hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	:	Clindamycin hydrochloride, equivalent to 150 mg of clindamycin. Clindamycin hydrochloride is white or almost white, crystalline powder, very soluble in water, slightly soluble in ethanol (96 per cent).

Clindamycin is methyl 7-chloro-6,7,8-trideoxy-6-[(2*S,*4*R*)-1-methyl-4-propylpyrrolidine-2- carboxamido]-1-thio-α-L-*threo*-D-*galacto*-octapyranoside (CAS 18323-44-9). It is a semi- synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent compound lincomycin.
Each [dosage form] contains xx mg of [active ingredient] as the active ingredient.

Excipients with known effect: Lactose monohydrate.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

CLINDAMYK Capsules 150mg	:	The capsules consist of a white cap and white body imprinted with 'Clin 150' in black printing ink.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Clindamycin hydrochloride capsules are indicated in the treatment of serious infections caused by susceptible anaerobic bacteria.

Clindamycin capsules are also 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 or other patients for whom, in the judgement of the physician, a penicillin is inappropriate.

Anaerobes

Serious respiratory tract infections such as empyema, anaerobic pneumonitis and lung abscess; serious skin and skin structure infections; septicaemia; intra-abdominal infections such as peritonitis and intra-abdominal abscess (typically resulting from anaerobic organisms resident in the normal gastrointestinal tract); infections of the female pelvis and genital tract such as endometritis, non-gonococcal tubo-ovarian abscess, pelvic cellulitis and post-surgical vaginal cuff infection.

Streptococci

Serious respiratory tract infections; serious skin and skin structure infections, septicaemia.

Staphylococci

Serious respiratory tract infections; serious skin and skin structure infections; septicaemia;

acute haematogenous osteomyelitis.

Pneumococci

Serious respiratory tract infections.

Adjunctive Therapy

In the surgical treatment of chronic bone and joint infections due to susceptible organisms. Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

Bacteriological studies should be performed to determine the causative organisms and their susceptibility to clindamycin.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults

150 mg every six hours

300 mg every six hours - more serious infections

450 mg every six hours - severe infections

Absorption of clindamycin is not appreciably modified by ingestion of food, and clindamycin may be taken with meals with no significant reduction of the serum level. To avoid the possibility of oesophageal irritation, clindamycin capsules should be taken with a full glass of water and at least 30 minutes before lying down.

In the treatment of anaerobic infections (see Section 4.1 THERAPEUTIC INDICATIONS), clindamycin phosphate injection should be used initially. This may be followed by oral therapy with clindamycin hydrochloride capsules at the discretion of the physician.

In cases of beta-haemolytic streptococcal infections, treatment should continue for at least 10 days.

Children

For formulation reasons, clindamycin capsules are not recommended in newborns, infants and children.

4.3 CONTRAINDICATIONS

Clindamycin capsules are contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin, lincomycin or any of the ingredients as listed in Section 6.1 LIST OF EXCIPIENTS.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Severe hypersensitivity reactions, including severe skin reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), and Kounis syndrome have been reported in patients receiving clindamycin therapy. If a hypersensitivity or severe skin reaction occurs, the drug should be discontinued and appropriate therapy should be initiated (see Section 4.3 CONTRAINDICATIONS and Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)). The usual agents (adrenaline (epinephrine), corticosteroids, antihistamines, colloid infusion) should be available for emergency treatment of serious reactions.

The use of clindamycin capsules can lead to the development of severe colitis. Fatalities have been reported. Most of these patients have been found to be colonised with *C difficile*. Therefore, the drug should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in the Section 4.1 THERAPEUTIC INDICATIONS. It should not be used in patients with non-bacterial infections such as most upper respiratory tract infections.

It is important to consider the diagnosis of antibiotic associated colitis in patients who develop diarrhoea or colitis associated with antibiotic use. Antibiotic-associated colitis appears to result from a toxin produced by *Clostridium difficile* in the alimentary tract. The severity of the colitis may range from mild watery diarrhoea

to severe, persistent, life- threatening bloody diarrhoea. The diagnosis is usually made by recognition of the clinical symptoms. The symptoms may occur during therapy or up to several weeks after cessation of therapy. Additional confirmatory signs of antibiotic-associated colitis include pseudomembrane formation seen with colonoscopy, *C difficile* culture from the stool, or assay of the stool for *C difficile* toxin.

Mild cases 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 hydrochloride with atropine sulfate monohydrate (LOMOTIL®), may prolong and/or worsen the condition and should not be used.

Antibiotic-associated colitis and diarrhoea (due to *C difficile*) occur more frequently and may be more severe in debilitated and/or elderly patients (>60 years). When clindamycin is indicated in these patients, they should be carefully monitored for change in bowel frequency.

C. difficile associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, 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.

Clindamycin should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Since clindamycin does not diffuse adequately into the cerebrospinal fluid, the drug should not be used in the treatment of meningitis.

Clindamycin should not be used in patients with non-bacterial infections.

Clindamycin should be prescribed with caution in atopic individuals.

During prolonged therapy, periodic liver and kidney function tests and blood counts should be performed.

Clindamycin is potentially nephrotoxic. Acute kidney injury including acute renal failure has been reported. Therefore, monitoring of renal function should be considered during therapy of patients with pre-existing renal dysfunction or taking concomitant nephrotoxic drugs and monitoring of renal function should be performed if therapy is prolonged.

Patients with very severe renal disease and/or very severe hepatic accompanied by severe metabolic aberrations should be dosed with caution, and serum clindamycin levels monitored during high-dose therapy.

Certain infections may require incision and drainage or other indicated surgical procedures in addition to antibiotic therapy. The use of clindamycin occasionally results in overgrowth of non-susceptible organisms - particularly yeasts. Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Due to the risk of oesophagitis and oesophageal ulcer, it is important to ensure compliance with administration guidance (see Sections 4.2 Dose and method of administration and 4.8 Adverse effects (undesirable effects)).

Use in the elderly

No data available

Paediatric Use

When clindamycin is administered to newborns and infants, appropriate monitoring of organ system functions is desirable. For formulation reasons, clindamycin capsules are not recommended in newborns, infants and children.

Effects on Laboratory Tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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

Antagonism has been demonstrated between clindamycin and erythromycin *in vitro*. Because of possible clinical significance, these two drugs should not be administered concurrently.

In vitro studies of human liver and intestinal microsomes showed that clindamycin is metabolized predominantly by CYP3A4 and to a lesser extent by CYP3A5, to the major metabolite clindamycin sulfoxide and minor metabolite N-desmethylclindamycin. Therefore, inhibitors of CYP3A4 and CYP3A5 may reduce clindamycin clearance and inducers of these isoenzymes may increase clindamycin clearance. In the presence of strong CYP3A4 inducers such as rifampicin, monitor for loss of effectiveness.

In vitro studies indicate that clindamycin does not inhibit CYP1A2, CYP2C9, CYP2C19, CYP2E1 or CYP2D6 and only moderately inhibits CYP3A4.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

Fertility was not impaired in rats given 300 mg/kg/day in the diet.

Use in Pregnancy: Category A

Clindamycin crosses the placenta in humans. After multiple doses, amniotic fluid concentrations were approximately 30% of maternal concentrations. Clindamycin should be used in pregnancy only if clearly needed.

Use in Lactation

Clindamycin has been reported to appear in breast milk in ranges of <0.5 to 3.8 micrograms/mL. Clindamycin has the potential to cause adverse effects on the breastfed infant's gastrointestinal flora such as diarrhea or blood in the stool, or rash. Therefore, clindamycin is not recommended for nursing mothers.

If oral or intravenous clindamycin is required by a nursing mother, it is not a reason to discontinue breastfeeding, but an alternate drug may be preferred. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical needs for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The adverse effects listed in the table below are presented by system organ class. Within each frequency category, the adverse effects are presented in the order of frequency and then of clinical importance.

System Organ Class	Common (≥ 1/100 to < 1/10)	Uncommon (≥1/1000 to < 1/100)	Rare (≥1/10000 to < 1/1000)	Frequency not known (cannot be estimated from available data)
Infections and infestations	Pseudomembranous colitis			*C. difficile* colitis* Vaginal infection*
Blood and lymphatic system disorders	Eosinophilia			Agranulocytosis*, leucopenia*, neutropenia*, thrombocytopenia*
Immune system disorders				Anaphylactic shock* Anaphylactoid reaction* Anaphylactic reaction* Kounis syndrome* Hypersensitivity*
Nervous system disorders		Dysgeusia		
Gastrointestinal disorders	Diarrhoea, abdominal pain	Nausea, vomiting		Oesophagitis‡≠*, oesphageal ulcer‡≠*
Hepatobiliary disorders				Jaundice*
Skin and subcutaneous tissue disorders	Rash maculo-papular	Urticaria	Erythema multiforme, pruritus	Toxic epidermal necrolysis (TEN)*, Steven Johnson syndrome (SJS)*, drug reaction with eosinophilia and systemic symptoms (DRESS)*, dermatitis exfoliative*, dermatitis bullous, rash morbilliform, acute generalised exanthematous pustulosis (AGEP)*, Angioedema*, Cutaneous vasculitis* Symmetrical drug-related intertriginous and flexural exanthema*
Musculoskeletal and connective tissue disorders				Polyarthritis
Renal and urinary disorders				Renal dysfunction (as evidenced by azotemiz, oliguria and /or proteinuria) Acute kidney injury*
Investigations	Liver function test abnormal			

CIOMS III categories: Very Common ≥1/10 (≥10%); Common ≥ 1/100 to <1/10 (≥1% and < 10%); Uncommon ≥1/1000 to <1/100 (≥0.1% and < 1%); Rare ≥ 1/10,000 to <1/1000 (≥0.01% and <0.1%); Very Rare <1/10,000 (<0.01%)

‡ Adverse reactions apply to oral formulation.

≠ Possible occurrence of oesophagitis and oesophageal ulcer, particularly if taken in a lying position and/or with a small amount of water.

* Have been reported during post-marketing experience.

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 www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Overdosage with orally administered clindamycin has been rare. Adverse reactions similar to those seen with normal doses can be expected, however, unexpected reactions could occur (see Section 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)).

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. Dermatitis, nephrotoxicity, hepatotoxicity, and various haematological abnormalities are toxic effects that occur less frequently. Rapid administration of large doses intravenously has resulted in ventricular dysrhythmias, hypotension and cardiac arrest.

Recommended treatment

No specific antidote is known. Support respiratory and cardiac function. In cases of overdose, drug levels of clindamycin 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 clindamycin may produce abnormalities of the haematopoietic system. Because clindamycin may cause hepatotoxicity, monitor liver function tests in patients with significant exposure.

Neither haemodialysis nor peritoneal dialysis appear to be effective in reducing clindamycin levels significantly.

Serious anaphylactoid reactions require immediate emergency treatment with adrenaline (epinephrine). Oxygen and intravenous corticosteroids should also be administered as indicated.

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

Clindamycin is a lincosamide antibiotic that inhibits bacterial protein synthesis. It binds to the 50S ribosomal subunit and affects both ribosome assembly and the translation process. Although clindamycin phosphate is inactive in vitro, rapid in vivo hydrolysis converts this compound to the antibacterially active clindamycin. At usual doses, clindamycin exhibits bacteriostatic activity in vitro.

Pharmacodynamic effects

Efficacy is related to the time period over which the agent level is above the minimum inhibitory concentration (MIC) of the pathogen (%T/MIC).

Resistance

Resistance to clindamycin is most often due to mutations at the rRNA antibiotic binding site or methylation of specific nucleotides in the 23S RNA of the 50S ribosomal subunit. These alterations can determine in vitro cross resistance to macrolides and streptogrammins B (MLS_B phenotype). Resistance is occasionally due to alterations in ribosomal proteins. Resistance to clindamycin may be inducible by macrolides in macrolide-resistant bacterial isolates. Inducible resistance can be demonstrated with a disk test (D-zone) or in broth. Less frequently encountered resistance mechanisms involve modification of the antibiotic and active efflux. There is complete cross resistance between clindamycin and lincomycin. As with many antibiotics, the incidence of resistance varies with the bacterial species and the geographical area. The incidence of resistance to clindamycin is higher among methicillin-resistant staphylococcal isolates and penicillin-resistant pneumococcal isolates than among organisms susceptible to these agents.

Antimicrobial activity

Clindamycin has been shown to have *in vitro* activity against isolates of the following organisms:

Aerobic bacteria
Gram-positive bacteria:
- *Staphylococcus aureus (methicillin-susceptible isolates)*
- *Coagulase-negative staphylococcus (methicillin-susceptible isolates)*
- *Streptococcus pneumoniae* (penicillin-susceptible isolates)
- Beta-haemolytic streptococci
- Viridans group streptococci
- *Corynebaterium* spp.

Gram-negative bacteria:
- Chlamydia trachomatis

Anaerobic bacteria
Gram-negative bacteria:
- *Bacteroides* spp.
- *Fusobacterium* spp.
- *Prevotella spp.*

Gram-positive bacteria:
- *Propionibacterium acnes*
- *Actinomyces* spp.
- *Eggerthella (Eubacterium spp.)*
- *Peptococcus spp.*
- *Peptostroptococcus spp. (Finegoldia magna, Micromonas micros)*
- *Clostridium spp. (except Clostridium difficile)*

Fungi
- *Pneumocystis jirovecii*

Protozoans
- *Toxoplasma gondii*
- *Plasmodium falciparum*

Breakpoints

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. NCCLS). Standardised susceptibility testing procedures require the use of laboratory control microorganisms to control the technical aspects of laboratory procedures.

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. Particularly in severe infections or therapy failure microbiological diagnosis with verification of the pathogen and its susceptibility to clindamycin is recommended.

Resistance is usually defined by susceptibility interpretive criteria (breakpoints) established by Clinical and Laboratory Standards Institute (CLSI) or European Committee on Antimicrobial Susceptibility Testing (EUCAST) for systemically administered antibiotics.

Clinical and Laboratory Standards Institute (CLSI) breakpoints for relevant organisms are listed below

Table 1. CLSI Susceptibility Interpretive Criteria for Clindamycin

Pathogen	**Minimal Inhibitory Concentrations (mcg/mL)**			**Disk Diffusion (Zone Diameters in mm)[a]**		
	S	**I**	**R**	**S**	**I**	**R**
Staphylococcus spp.	≤ 0.5	1-2	≥ 4	≥ 21	15-20	≤ 14
Steptocococcus spp.	≤ 0.25	0.5	≥ 1	≥ 19	16-18	≤ 15
Anaerobic bacteria[b]	≤ 2	4	≥ 8	NA	NA	NA

NA = not applicable; S = susceptible; I = intermediate; R = resistant

[a] Disk content 2 micrograms of clindamycin

[b] MIC ranges for anaerobes are based on agar dilution methodology

A report of "Susceptible" (S) indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of "Intermediate" (I) indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small, uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" (R) indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable and other therapy should be selected.

Standardised susceptibility test procedures require the use of laboratory controls to monitor and ensure the accuracy and precision of the supplies and reagents used in the assay, and the techniques of the individuals performing the test. Standard clindamycin powder should provide the MIC ranges in Table 2. For the disk diffusion technique using the 2 mcg clindamycin disk the criteria provided in Table 2 should be achieved.

Table 2. CLSI Acceptable Quality Control (QC) Ranges for Clindamycin to be used in Validation of Susceptibility Test Results.

QC Strain	**Minimum Inhibitory Concentration Range (mcg/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 49616	0.03 - 0.12	19 - 25
Bacteroides fragilis ATCC 25285	0.5 – 2[a]	NA
Bacteroides thetaiotaomicron ATCC 29741	2 – 8[a]	NA

Eggerthella lenta ATCC 43055	0.06 – 0.25[a]	NA

NA = Not applicable

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[a]MIC ranges for anaerobes are based on agar dilution methodology

The European Committee on Antimicrobial Susceptibility Testing (EUCAST) breakpoints are presented below.

Table 3. EUCAST Susceptibility Interpretive Criteria for Clindamycin

	MIC breakpoints (mg/L)		**Zone diameter breakpoints (mm)[a]**	
Organism	**S≤**	**R >**	**S≥**	**R <**
Staphylococcus spp.	0.25	0.5	22	19
Streptococcus Groups A, B, C and 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	4	4	NA	NA
Gram-negative anaerobes	4	4	NA	NA
Corynebacterium spp.	0.5	0.5	20	20

[a]Disk content 2µg of clindamycin

NA = not applicable; S = susceptible; R = resistant

EUCAST QC ranges for MIC and disk zone determinations are in the table below.

Table 4. EUCAST Acceptable Quality Control (QC) Ranges for Clindamycin to be used in Validation of Susceptibility Test Results

QC Strain	**Minimum Inhibitory Concentration Range (mcg/mL)**	**Disk Diffusion Range (Zone Diameters in mm)**
Staphylococcus aureus ATCC 29213	0.06 – 0.25	23 - 29
Steptococcus pneumoniae ATCC 49619	0.03 – 0.125	22 - 28

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Clinical Trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Serum level studies with a 150 mg oral dose of clindamycin in 24 normal adult volunteers showed that clindamycin was rapidly absorbed after oral administration. An average peak serum level of 2.5 micrograms/mL was reached in 45 minutes; serum levels averaged 1.51 micrograms/mL at 3 hours and 0.70 micrograms/mL at 6 hours. Absorption of an oral dose is virtually complete (90%). Concomitant

administration of food does not appreciably modify the serum concentrations; serum levels have been uniform and predictable from person to person and dose to dose.

Distribution

Serum level studies following multiple doses of clindamycin for up to 14 days show no evidence of accumulation or altered metabolism of drug. Multiple-dose studies in newborns and infants up to 6 months of age show that the drug does not accumulate in the serum and is excreted rapidly.

Serum half-life of clindamycin is increased slightly in patients with markedly reduced renal function. Haemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. Concentrations of clindamycin in the serum increased linearly with increased dose. Serum levels exceed the MIC (minimum inhibitory concentration) for most indicated organisms for at least six hours following administration of the usually recommended doses. Clindamycin is widely distributed in body fluids and tissues, including bones.

Metabolism

In vitro studies in human liver and intestinal microsomes indicated that clindamycin is predominantly oxidized by CPY3A4, with minor contribution from CYP3A5, to form clindamycin sulfoxide and a minor metabolite, N-desmethylclindamycin.

Excretion

The average biological half- life is 2.4 hours. Approximately 10% of the bioactivity is excreted in the urine and 3.6% in the faeces; the remainder is excreted as bio-inactive metabolites.

Doses of up to 2 g of clindamycin per day for 14 days have been well tolerated by healthy volunteers, except that the incidence of gastrointestinal side effects is greater with the higher doses.

No significant levels of clindamycin are attained in the cerebrospinal fluid, even in the presence of inflamed meninges.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The inactive ingredients are lactose monohydrate, magnesium stearate, maize starch, purified talc, titanium dioxide and gelatin with black printing ink (shellac, iron oxide black).

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

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.

6.5 NATURE AND CONTENTS OF CONTAINER

Available in PVC/Al blister packs of 100 capsules and 24 capsules

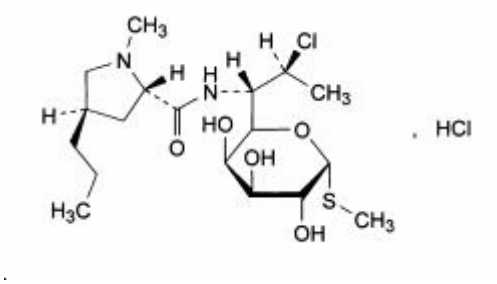
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical Structure

The structural formula of clindamycin hydrochloride is:



Molecular formula: $C_{18}H_{33}ClN_2O_5S,HCl$

Molecular Weight: 461.5

pKa value: 7.6

CAS Number

21462-39-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 (Prescription Only Medicine)

8 SPONSOR

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
www.arrotex.com.au

9 DATE OF FIRST APPROVAL

22/08/2014

10 DATE OF REVISION

4 March 2026

Summary Table of Changes

Section Changed	Summary of New Information
4.4	Addition of 'Kounis syndrome' as an example of severe hypersensitivity reaction.
4.8	Addition of post-marketing adverse reactions 'Kounis syndrome', 'cutaneous vasculitis', and 'symmetrical drug-related intertriginous and flexural exanthema'.
All	Minor editorial changes

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