NEW ZEALAND DATA SHEET

1 PRODUCT NAME

CLINDAMYCIN LU 150 mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

CLINDAMYCIN LU capsules contain clindamycin hydrochloride, equivalent to 150 mg of clindamycin.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Capsules, hard.

The capsules are No.2 apple green in colour and imprinted with CLD 150.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Clindamycin hydrochloride has been shown to be effective in the treatment of the following infections when caused by susceptible anaerobic bacteria or susceptible strains of Gram-positive bacteria such as streptococci, staphylococci and pneumococci:

1. Upper respiratory infections including tonsillitis, pharyngitis, sinusitis, otitis media and scarlet fever.

2. Lower respiratory infections including bronchitis, pneumonia, empyema and lung abscess.

3. Skin and soft tissue infections including acne, furuncles, cellulitis, impetigo, abscesses, and wound infections. For specific skin and soft tissue infections like erysipelas and paronychia (panaritium).

4. Bone and joint infections including osteomyelitis and septic arthritis.

5. Pelvic infections including endometritis, cellulitis, vaginal cuff infection tubo-ovarian abscesses, salpingitis and pelvic inflammatory disease when given in conjunction with an antibiotic of appropriate Gram-negative aerobic spectrum. In cases of cervicitis due to Chlamydia trachomatis, monotherapy with clindamycin has been shown to be effective in eradicating the organism.

6. Intra-abdominal infections including peritonitis and abdominal abscess when given in conjunction with an antibiotic of appropriate Gram-negative aerobic spectrum.

7. Septicaemia and endocarditis - the effectiveness of clindamycin in the treatment of selected cases of endocarditis has been documented when clindamycin is determined to be bactericidal to the infecting organism by in vitro testing of appropriate achievable serum concentrations.

8. Dental infections such as periodontal abscess and periodontitis.

9. As an alternative therapy when used in combination with quinine for the treatment of multidrug resistant Plasmodium falciparum infection.

4.2 Dose and method of administration

Dose

If significant diarrhoea occurs during therapy, this antibiotic should be discontinued (see section 4.4).

To avoid the possibility of oesophageal irritation, Clindamycin hydrochloride capsules should be taken with a full glass of water.

Adults

• Serious Infections: 150 mg – 300 mg every six hours.
• More severe infections: 300 mg – 450 mg every six hours.

Children

Clindamycin should be dosed based on total body weight regardless of obesity. The maximum daily dose in obese children should not exceed the adult dose.

• Serious Infections: 8 – 16 mg/kg/day divided into three or four equal doses.
• More severe infections: 16 – 25 mg/kg/day divided into three or four equal doses.

CLINDAMYCIN LU capsules should only be used for children who are able to swallow capsules.

The use of capsules may not be suitable to provide the exact mg/kg doses required for the treatment of children.

For the treatment of anaerobic infections

Clindamycin hydrochloride Phosphate Solution for Injection should be used initially. This may be followed by oral therapy with Clindamycin hydrochloride capsules at the discretion of the physician.

For the treatment of Pelvic Inflammatory Disease - Inpatient treatment

Clindamycin phosphate 900 mg (IV) q8h daily plus an antibiotic with an appropriate Gram-negative aerobic spectrum administered IV; e.g. gentamicin in patients with normal renal function. Continue (IV) drugs for at least 4 days and at least 48 hours after the patient improves. Then continue oral clindamycin hydrochloride 450 mg q6h daily to complete 10- 14 days total therapy.

For the treatment of Cervicitis due to *Chlamydia trachomatis*

Clindamycin hydrochloride by mouth 450 mg 4 times daily for 10-14 days.

For the treatment of β-haemolytic streptococcal infections

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

For the treatment of multi-drug resistant *Plasmodium falciparum* infection

Limited data from uncontrolled studies using a variety of doses suggest that clindamycin, orally at a dose of 5-10 mg/kg twice daily for minimum of 5 days, is useful alternative therapy when used in combination with quinine, for the treatment of multi-drug resistant *Plasmodium falciparum* infection.

4.3 Contraindications

Clindamycin is contraindicated in patients previously found to be sensitive to clindamycin, lincomycin or any of the ingredients listed under section 6.1.

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 generalised exanthematous pustulosis (AGEP) have been reported in patients receiving clindamycin therapy. If a hypersensitivity or severe skin reaction occurs, clindamycin should be discontinued and appropriate therapy should be initiated (see section 4.3 and section 4.8). The usual agents (adrenaline, corticosteroids, antihistamines, colloid infusion) should be available for emergency treatment of serious reactions.

As has been reported with other antibiotics, clindamycin therapy has been associated with severe colitis, which may end fatally. It should not be used in patients with non-bacterial infections. Studies

indicate a toxin(s) produced by Clostridia is one primary cause of antibiotic associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*. The colitis is usually characterised by mild watery diarrhoea to severe, persistent diarrhoea leukocytosis, fever, severe abdominal cramps which may be associated with the passage of blood and mucous and if allowed to progress may produce peritonitis, shock and toxic megacolon. Endoscopic examination may reveal pseudomembranous colitis.

Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases, appropriate therapy with a suitable oral antibacterial agent effective against *Clostridioides 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 (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.

Stool culture for *C. difficile* and stool assay for *C. difficile* toxin may be helpful diagnostically.

When significant diarrhoea occurs, the drug should be discontinued or, if necessary, continued only with close observation of the patient. Large bowel endoscopy has been recommended.

Antiperistaltic agents such as opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition. Vancomycin has been found to be effective in the treatment of antibiotic associated pseudomembranous colitis produced by *C. difficile*. The usual adult dose is 500 mg to 2 g of vancomycin orally per day in three to four divided doses administered for seven to ten days. Cholestyramine or colestipol resins bind vancomycin *in vitro*.

If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug.

Diarrhoea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of therapy with clindamycin.

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

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

Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated.

Systemic corticoids and corticoid retention enemas may help relieve the colitis. Other causes of colitis should also be considered.

A careful inquiry should be made concerning previous sensitivities to medicines and other allergens.

Paediatric use

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

Use in meningitis

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

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

CLINDAMYCIN LU should be prescribed with caution in atopic individuals.

During prolonged therapy, periodic liver 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.

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

Clindamycin dosage modification is not necessary in patients with renal disease. In patients with moderate to severe liver disease, prolongation of the half-life of clindamycin has been found, but a pharmacokinetic study has shown that, when given every eight hours, accumulation of clindamycin should rarely occur. Therefore, dosage reduction in liver disease is not considered necessary.

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

4.5 Interaction with other medicines and other forms of interaction

Clindamycin 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.

Clindamycin is metabolised 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. Therefore, clinically important interactions between clindamycin and co-administered drugs metabolised by these CYP enzymes are unlikely.

4.6 Fertility, pregnancy and lactation

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.

Breast-feeding
Clindamycin has been reported to appear in human breast milk in ranges from <0.5 to 3.8 micrograms/mL. Clindamycin has the potential to cause adverse effects on the breastfed infant's gastrointestinal flora such as diarrhoea 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 need 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 effect of clindamycin on the ability to drive or operate machinery has not been systematically evaluated.

4.8 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 by decreasing medical seriousness.

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			Vaginal infection
Blood and lymphatic system disorders	Eosinophilia			Agranulocytosis, neutropenia, thrombocytopenia, leucopenia
Immune system disorders				Anaphylactoid reaction
Nervous system disorders		Dysgeusia		
Gastrointestinal disorders	Diarrhoea, abdominal pain	Vomiting, nausea		Oesophagitis‡, oesophageal 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), acute generalised exanthematous pustulosis (AGEP), dermatitis exfoliative, dermatitis bullous, rash morbilliform
Musculoskeletal and connective tissue disorders				Polyarthritis
Renal and urinary disorders				Renal dysfunction (as evidenced by azotaemia, oliguria, and/or proteinuria)
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 only to oral formulation.

Post-Marketing Experience
The following additional adverse reactions have been reported during post-marketing experience.

Infections and infestations
Frequency not known: C. difficile colitis.

Immune system disorders
Frequency not known: Anaphylactic shock, anaphylactic reaction, hypersensitivity.

Skin and subcutaneous tissue disorders
Frequency not known: Angioedema.

Renal and urinary disorders
Frequency not known: Acute kidney injury.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/}

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).

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 intravenously 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 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. Oxygen and intravenous corticosteroids should also be administered as indicated.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

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 streptogramins B (MLSB 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 test) 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 most isolates of the following organisms:

Aerobic bacteria

Gram-positive bacteria:

Staphylococcus aureus (methicillin-susceptible isolates)
Coagulase-negative Staphylococci (methicillin-susceptible isolates)
Streptococcus pneumoniae (penicillin-susceptible isolates)
Streptococci groups A, B, C, and G
Viridans groups Streptococci
Corynebacterium spp.

Atypical bacteria:

Chlamydia trachomatis

Anaerobic bacteria

Gram-negative bacteria:

Bacteroides spp.
Fusobacterium spp.
Gardnerella vaginalis
Prevotella spp.

Gram-positive bacteria:

Propionibacterium acnes
Actinomyces (Eubacterium) spp.
Eggerthella (Eubacterium) spp.
Peptococcus spp.
Peptostreptococcus spp. *(Finegoldia magna, Micromonas micros)*
Clostridioides spp. (except *C. 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. CLSI or EUCAST). 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
Streptococcus 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 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 usually achievable concentrations 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 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 49619	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.
ATCC® is a registered trademaek of the American Type Culture Collection
[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 2 µg 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
Streptococcus pneumoniae ATCC 49619	0.03–0.125	22-28

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5.2 Pharmacokinetic properties

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 2.50 micrograms/mL was reached in 45 minutes; serum levels averaged 1.51 micrograms/mL at three hours and 0.70 micrograms/mL at six 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. Serum level studies following multiple doses of Clindamycin hydrochloride HCl 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. *In vitro* studies in human liver and intestinal microsomes indicated that clindamycin is predominantly oxidised by CYP3A4, with minor contribution from CYP3A5, to form clindamycin sulfoxide and a minor metabolite, N-desmethylclindamycin. 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 bioinactive metabolites. Clindamycin is mainly eliminated by hepatic metabolism and biliary excretion.

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.

Obese paediatric patients aged 2 to less than 18 years

An analysis of pharmacokinetic data in obese paediatric patients aged 2 to less than 18 years demonstrated that clindamycin clearance and volume of distribution normalised by total body weight are comparable regardless of obesity.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Lactose
Povidone
Sodium starch glycolate
Purified talc
Magnesium stearate.
Hard Gelatin Capsules size 2 P Lt Green Op / PLt Green Op (proprietary ingredient number: 109543)- Tartrazine, Brilliant blue FCF, Titanium dioxide, Sodium laurilsulfate, Purified water and Gelatin.

TekPrint SB-0007P White Ink (proprietary ingredient number: 2216)- Shellac, Dehydrated alcohol, Isopropyl alcohol, Butyl alcohol, Propylene glycol, Sodium hydroxide, Povidone and Titanium dioxide.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30ºC, protect from heat, light, and moisture.

6.5 Nature and contents of container

Blister packs of 24, 50 or 100 capsules*.
* Not all pack sizes available.

6.6 Special precautions for disposal

Not stated.

7 MEDICINE SCHEDULE

Prescription medicine.

8 SPONSOR

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9 DATE OF FIRST APPROVAL

11 /12/2023

10 DATE OF REVISION OF THE TEXT

Not applicable

SUMMARY TABLE OF CHANGES

Not applicable