

Generic Name: Clindamycin hydrochloride
Trade Name: DALACIN C
CDS Effective Date: October 30, 2020
Supersedes: June 13, 2018
Approved by BPOM:

PT. Pfizer Indonesia Local Product Document

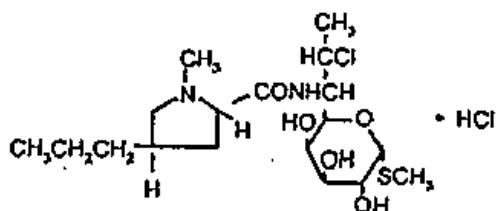
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DESCRIPTION

Clindamycin hydrochloride is the hydrated hydrochloride salt of clindamycin. Clindamycin is a semi synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent compound lincomycin.

DALACIN C HCl capsules contain clindamycin hydrochloride equivalent to 150 mg or 300 mg of clindamycin.

The structural formula is represented below:



The chemical name for clindamycin hydrochloride is Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-progyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo- α -D-galacto-octopyranoside monohydrochloride.

PHARMACOLOGICAL 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 (MLS_B phenotype). Resistance is occasionally due to

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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)
- Beta-hemolytic streptococci groups A, B, C, and G
- Viridans group streptococci
- *Corynebacterium* spp.

Gram-negative bacteria

- *Chlamydia trachomatis*

Anaerobic bacteria

Gram-positive bacteria

- *Actinomyces* spp.
- *Clostridium* spp. (except *Clostridium difficile*)
- *Eggerthella (Eubacterium)* spp.
- *Peptococcus* spp.
- *Peptostreptococcus* spp. (*Finegoldia magna*, *Micromonas micros*)
- *Propionibacterium acnes*

Gram-negative bacteria

- *Bacteroides* spp.
- *Fusobacterium* spp.

Breakpoints

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.

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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

<i>Pathogen</i>	Minimal Inhibitory Concentrations (mcg/mL)			Disk Diffusion (Zone Diameters in mm) ^a		
	S	I	R	S	I	R
<i>Staphylococcus</i> spp.	≤0.5	1–2	≥4	≥21	15–20	≤14
<i>Streptococcus</i> 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 that 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.

Standardized 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)
<i>Staphylococcus aureus</i> ATCC 29213	0.06–0.25	NA
<i>Staphylococcus aureus</i> ATCC 25923	NA	24–30
<i>Streptococcus pneumoniae</i> ATCC 49619	0.03–0.12	19–25

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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)
<i>Bacteroides fragilis</i> ATCC 25285	0.5–2 ^a	NA
<i>Bacteroides thetaiotaomicron</i> ATCC 29741	2–8 ^a	NA
<i>Escherichia coli</i> ATCC 25922	0.06–0.25 ^a	NA

NA=Not applicable.
 ATCC® is a registered trademark 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

Organism	MIC breakpoints (mg/L)		Zone diameter breakpoints (mm) ^a	
	S≤	R>	S≥	R<
<i>Staphylococcus</i> spp.	0.25	0.5	22	19
<i>Streptococcus</i> Groups A, B, C and G	0.5	0.5	17	17
<i>Streptococcus pneumoniae</i>	0.5	0.5	19	19
<i>Viridans group streptococci</i>	0.5	0.5	19	19
Gram-positive anaerobes	4	4	NA	NA
Gram-negative anaerobes	4	4	NA	NA
<i>Corynebacterium</i> 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)
<i>Staphylococcus aureus</i> ATCC 29213	0.06–0.25	23–29
<i>Streptococcus pneumoniae</i> ATCC 49619	0.03–0.125	22–28

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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)
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Pharmacokinetic Properties

Pharmacokinetic studies in elderly volunteers (61-79 years) and younger adults (18-39 years) indicate that age alone does not alter clindamycin pharmacokinetics (clearance, elimination half-life, volume of distribution, and area under the serum concentration time curve) after IV administration of clindamycin phosphate. After oral administration of clindamycin hydrochloride, elimination half-life is increased to approximately 4.0 hours (range 3.4 –5.1 h) in the elderly compared to 3.2 hours (range 2.1 - 4.2 h) in younger adults. The extent of absorption, however, is not different between age groups and no dosage alteration is necessary for the elderly with normal hepatic function and normal (age-adjusted) renal function.

In vitro studies in human liver and intestinal microsomes indicated that clindamycin is predominantly oxidized by CYP3A4, with minor contribution from CYP3A5, to form clindamycin sulfoxide and a minor metabolite, N-desmethylclindamycin.

Obese Pediatric Patients Aged 2 to Less than 18 Years and Obese Adults Aged 18 to 20 Years

An analysis of pharmacokinetic data in obese pediatric patients aged 2 to less than 18 years and obese adults aged 18 to 20 years demonstrated that clindamycin clearance and volume of distribution normalized by total body weight are comparable regardless of obesity.

Preclinical Safety Data

Carcinogenesis:

Long term studies in animals have not been performed with clindamycin to evaluate carcinogenic potential.

Mutagenesis:

Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative.

Impairment of Fertility:

Fertility studies in rats treated orally with up to 300 mg/kg/day (approximately 1.1 times the highest recommended adult human dose based on mg/m²) revealed no effects on fertility or mating ability.

In oral embryo fetal development studies in rats and subcutaneous embryo fetal development studies in rats and rabbits, no developmental toxicity was observed except at doses that produced maternal toxicity.

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INDICATIONS AND USAGE

Clindamycin is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria.

Clindamycin is also indicated in the treatment of serious infections due to susceptible strains of gram-positive aerobic bacteria such as streptococci, pneumococci, and staphylococci; and susceptible strains of *Chlamydia trachomatis*.

Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, penicillin is inappropriate. Because of the risk of colitis, as described in the **WARNINGS**, before selecting clindamycin the physician should consider the nature of the infection and the suitability of less toxic alternatives (e.g., erythromycin).

Anaerobes: Serious respiratory tract infections such as empyema, anaerobic pneumonitis and lung abscess; serious skin and soft tissue infections; septicemia; intra-abdominal infections such as peritonitis and intra-abdominal abscess (typically resulting from anaerobic organisms resident in the normal gastrointestinal tract); gynecology infections such as endometritis, pelvic cellulitis postsurgical vaginal cuff and infection, nongonococcal tubo-ovarian abscess, salpingitis and pelvic inflammatory disease when given in conjunction with an antibiotic of appropriate gram negative aerobic spectrum. In case of cervicitis due to *Chlamydia trachomatis*, single drug therapy with clindamycin has been shown to be effective in eradicating the organism.

Streptococci: Serious respiratory tract infections; serious skin and soft tissue infections.

Staphylococci: Serious respiratory tract infections; serious skin and soft tissue infections.

Pneumococci: Serious respiratory tract infections.

Dental Infection such as periodontal abscess and periodontitis.

Toxoplasmic encephalitis in patients with AIDS. In patients who are intolerant to conventional treatment, clindamycin in combination with pyrimethamine has been shown to be efficacious.

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

In Vitro Susceptibility Testing: A standardized disk testing procedure is recommended for determining susceptibility of aerobic bacteria to clindamycin. A description is contained in the DALACIN C Susceptibility Disk Insert. Using this method, the laboratory can designate isolates as resistant intermediate, or susceptible. Tube or agar dilution methods may be used for both anaerobic and aerobic bacteria. When the directions in the DALACIN C Susceptibility Powder Insert are followed, an

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MIC of 1.6 mcg/mL may be considered susceptible; MICs of 1.6 to 4.8 mcg/mL may be considered intermediate and MICs greater than 4.8 mcg/mL may be considered resistant.

For anaerobic bacteria the minimal inhibitory concentration (MIC) of clindamycin can be determined by agar dilution and broth dilution (including microdilution) techniques. If MICs are not determined routinely, the disk broth method is recommended for routine use. THE KIRBY-BAUER DISK DIFFUSION METHOD AND ITS INTERPRETIVE STANDARDS ARE NOT RECOMMENDED FOR ANAEROBES.

CONTRAINDICATIONS

DALACIN C is contraindicated in patients previously found to be sensitive to clindamycin or lincomycin.

WARNINGS

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) 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 **CONTRAINDICATIONS** section and **UNDESIRABLE EFFECTS** section).

Clindamycin therapy, like therapy with other broad spectrum antibiotics, has been associated with pseudomembranous colitis which may end fatally. Therefore it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in the **INDICATIONS AND USAGE** section. Diarrhea, colitis and pseudomembranous colitis have observed to begin up to several weeks following cessation of clindamycin therapy. Consequently, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of clindamycin.

Treatment with antibiotics alters the normal flora of the colon and may permit overgrowth clostridia. Studies indicate that a toxin produced by Clostridia is one primary cause of "antibiotic-associated colitis".

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated.

Mild cases of colitis may respond to drug discontinuation alone. Moderate to severe cases should be managed promptly with fluids, electrolytes and protein supplementation as indicated. Vancomycin has been found to be effective in the treatment of antibiotic-associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dosage is 2 grams of vancomycin orally per day three to four divided doses administered for 7 to 10 days. Cholestyramine or colestipol resin binds vancomycin *in vitro*. If both the resins and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug.

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

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

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD.

Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Usage in Pregnancy - Oral and subcutaneous reproductive toxicity studies in rats and rabbits revealed no evidence of impaired fertility or harm to the fetus due to clindamycin, except at doses that caused maternal toxicity. Animal reproduction studies are not always predictive of human response. Clindamycin crosses the placenta in humans. After multiple doses, amniotic fluid concentrations were approximately 30% of maternal blood concentrations.

In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters, has not been associated with an increased frequency of congenital abnormalities. There are no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy.

Clindamycin should be used in pregnancy only if clearly needed.

Usage in Newborn and Infants — When DALACIN C is administered to newborns and infants, appropriate monitoring of organ system function is desirable.

Usage in Nursing Mother — Clindamycin has been reported to appear in human breast milk in ranges from < 0.5 to 3.8 mcg/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. 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.

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

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

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.

PRECAUTIONS

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

DALACIN C should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis and atopic individuals.

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

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

The use of DALACIN C occasionally results in overgrowth of non-susceptible organisms—particularly yeasts. Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Patient 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.

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.

UNDESIRABLE EFFECTS

All undesirable effects listed in the label are presented by MedDRA system organ class (SOC). Within each SOC, the undesirable effects are presented in the order of decreasing medical seriousness.

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Adverse Reactions Table

System Organ Class	Common ≥1/100 to <1/10	Uncommon ≥1/1000 to <1/100	Rare ≥1/1000 0 to <1/1000	Frequency Not Known (cannot be estimated from the available data)
Infections and infestations	pseudomembranous colitis*			<i>clostridium difficile</i> colitis*, <i>vaginal infection</i> *
Blood and the lymphatic system disorders	eosinophilia			agranulocytosis*, neutropenia*, thrombocytopenia*, leukopenia*,
Immune system disorders				anaphylactic shock*, anaphylactoid reactions*, anaphylactic reaction*, hypersensitivity*
Nervous system disorders		dysgeusia		
Cardiac disorders		cardio-respiratory arrest [§]		
Vascular disorders	thrombophlebitis [†]	hypotension [§]		
Gastrointestinal disorders	diarrhoea	abdominal pain, vomiting, nausea		oesophageal ulcer*, oesophagitis*
Hepatobiliary disorders				jaundice*
Skin and subcutaneous tissue disorders	rash maculo-papular	urticaria	erythema multiforme, pruritus	toxic epidermal necrolysis (TEN)*, Stevens-Johnson syndrome (SJS)*, drug reaction with eosinophilia and systemic symptoms (DRESS)*, acute generalised exanthematous pustulosis (AGEP)*, angioedema*, dermatitis exfoliative*, dermatitis bullous*, rash morbilliform*
Investigations	liver function test abnormal			

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System Organ Class	Common ≥1/100 to <1/10	Uncommon ≥1/1000 to <1/100	Rare ≥1/1000 0 to <1/1000	Frequency Not Known (cannot be estimated from the available data)
* ADR identified post-marketing				
† ADRs apply only to injectable formulations.				
‡ ADRs apply only to oral formulations.				
§ Rare instances have been reported following too rapid intravenous administration (see DOSAGE AND ADMINISTRATION section).				

INTERACTION WITH OTHER MEDICAMENTS 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 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. Therefore, clinically important interactions between clindamycin and co-administered drugs metabolized by these CYP enzymes are unlikely.

DOSAGE AND ADMINISTRATION

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

Adults: *Serious infections*—150-300 mg every 6 hours. *More severe infections*—300-450 mg every 6 hours.

Pelvic Inflammation Disease: Clindamycin phosphate 900 mg IV every 6 hours; plus gentamicin: IV or IM, 2 mg/kg initially followed by 1.5 mg/kg every 8 hours in patients with normal renal function. Continue drugs IV for at least 48 hours after patients improve. Then continue with doxycycline 100 mg orally, twice daily to complete 10-14 days of total therapy. Continuation of clindamycin 450 mg orally, 4 times daily to complete 10-14 days of total therapy, may be considered as an alternative.

For cervicitis due to *Chlamydia trachomatis*; 450 mg 4 times daily for 10-14 days

For treatment of Toxoplasmic encephalitis in patients with AIDS: Parenteral (IV) 600-1200 mg every 6 hours for 3 weeks, followed by oral clindamycin 300 mg every 6 hours of 450 mg every 8 hours 3 weeks. The dose of pyrimethamine is 100-200 mg

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loading dose in 2 divided doses for 1-2 days, followed by 75 mg/day. Folinic acid 10-20 mg/day should be given with higher doses of pyrimethamine.

Children: Clindamycin should be dosed based on total body weight regardless of obesity. 8 to 16 mg/kg/day divided into three or four equal doses.
To avoid the possibility of esophageal irritation DALACIN C capsules should be taken with a full glass of water.

Clindamycin capsules are not suitable for children who are unable to swallow them whole.

Serious infections due to anaerobic bacteria are usually treated with DALACIN C Sterile Solution. However, in clinically appropriate circumstances, the physician may elect to initiate treatment or continue treatment with DALACIN C capsules.

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

SUPPLY

DALACIN C capsules are available in the following strengths, colors and sizes:
150 mg capsule with a scarlet opaque cap and lavender body: Box of 3 blisters @ 10 capsules, Reg. No: DKL7419808301A1
300 mg capsule with opaque maroon cap and body: Box of 3 blisters @ 10 capsules, Reg. No: DKL9019808301B1

Store at maximum temperature 30°C

HARUS DENGAN RESEP DOKTER

DALACIN C capsules are manufactured by:
PT. Pfizer Indonesia, Jakarta, Indonesia