

NOVELL-CLINDAMYCIN 150 MG Capsule

NAME OF THE MEDICINAL PRODUCT Novell-Clindamycin Capsule 150 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Clindamycin Hydrochloride equivalent to 150 mg of Clindamycin.

PHARMACEUTICAL FORM

Hard capsule no. 1, pink opaque cap and maroon opaque body colour.
Capsule Content: White Granules

CLINICAL PARTICULARS

Therapeutic Indication

Clindamycin 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 aerobic 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, specific skin and soft tissue infections caused by susceptible organisms like erysipelas and paronychia (panaritium).
4. Bone and joint infections including osteomyelitis and septic arthritis.
5. Gynecological infections including endometritis, cellulitis, vaginal cuff infection, tubo-ovarian abscess, salpingitis, and pelvic inflammatory disease when given in conjunction with an antibiotic of appropriate gram-negative spectrum.
6. Intra-abdominal infections including peritonitis and abdominal abscess when given in conjunction with an antibiotic of appropriate gram-negative spectrum.
7. Septicemia 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. 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.
10. Pneumocystis jirovecii (previously classified as Pneumocystis carinii) pneumonia in patients with AIDS. In patients who are intolerant to, or do not respond adequately to conventional treatment, clindamycin may be used in combination with primaquine.

Limited data from uncontrolled studies using a variety of doses suggest that clindamycin, either orally or parenterally at a dose of 20 mg/kg/day for a minimum of 5 days is useful alternative therapy when used alone or in combination with quinine or amodiaquine, for the treatment of multi-drug resistant Plasmodium falciparum infection.

Posology and Method of Administration

Dosage and route of administration should be determined by the severity of the infection, the condition of the patient, and the susceptibility of the causative micro-organisms.

Adults:

600-1800 mg/day divided in 2, 3 or 4 equal doses.

Children over 1 month of age:

Doses of 8-25 mg/kg/day in 3 or 4 equal doses. Clindamycin should be dosed based on total body weight regardless of obesity.

Clindamycin capsules are not suitable for children who are unable to swallow them whole. The capsules do not provide exact mg/kg doses therefore it may be necessary to use other clindamycin formulations in some cases.

To avoid possibility of esophageal irritation, capsules should be taken with a full glass of water.

BETA-HEMOLYTIC STREPTOCOCCAL INFECTIONS

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

ACUTE STREPTOCOCCAL TONSILLITIS/PHARYNGITIS

In the treatment of acute streptococcal tonsillitis/pharyngitis, clindamycin hydrochloride capsules 300 mg may be taken twice daily for 10 days.

TOXOPLASMIC ENCEPHALITIS IN PATIENTS WITH AIDS

Clindamycin hydrochloride by mouth 600-1200 mg every 6 hours for two weeks followed by 300-600 mg by mouth every 6 hours. The usual total duration of therapy is 8 to 10 weeks. The dose of pyrimethamine is 25 to 75 mg by mouth daily for 8 to 10 weeks. Folic acid 10 to 20 mg/day should be given with higher doses of pyrimethamine.

PNEUMOCYSTIS CARINII PNEUMONIA IN PATIENTS WITH AIDS

Clindamycin hydrochloride 300 to 450 mg by mouth every 6 hours for 21 days and primaquine 15 to 30 mg dose by mouth once daily for 21 days.

If significant diarrhea occurs during therapy, this antibiotic should be discontinued.

Contraindications

Hypersensitive to Clindamycin or lincomycin or to any component of the formulation.

Special Warning 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) 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.

- Clindamycin Hydrochloride should be given carefully to patients with gastrointestinal disturbance history, especially colitis and in atopic patients.

- As is the case for almost all antibiotic therapy, clindamycin therapy has been associated with severe colitis, which may end fatally.

The clinical spectrum varies from mild, watery diarrhea to severe, persistent diarrhea, leukocytosis, fever, severe abdominal cramps which may be associated with the passage of blood and mucus which, if allowed to progress, may produce peritonitis, shock and toxic megacolon.

The diagnosis of antibiotic-associated colitis is usually made by the recognition of the clinical symptoms. It can be substantiated by endoscopic demonstration of pseudomembranous colitis and may be further confirmed by culture of the stool for *Clostridium difficile* on selective media and assay of the stool specimen for the toxin(s) of *C. difficile*.

Onset of antibiotic-associated colitis has occurred during the administration or even two or three weeks following administration of the antibiotic. The disease is likely to take a more severe course in older patients or in patients who are debilitated. In case of occurrence of mild antibiotic-associated colitis, discontinuance of clindamycin is recommended. Treatment with cholestyramine and colestipol resins is recommended as these products have been shown to bind the toxin *in vitro*. The suggested dose of colestipol is 5 g three times daily, and the suggested dose of cholestyramine is 4 g three times daily. When severe antibiotic-associated colitis occurs, this has to be treated with appropriate fluid, electrolyte and protein supplementation.

Studies have also indicated that a toxin(s) produced by *Clostridia* (especially *C. difficile*) is (are) the principal direct cause of antibiotic-associated colitis. These studies also indicated that this toxigenic *Clostridium* is usually sensitive *in vitro* to vancomycin. When 125 to 500 mg vancomycin 4 times daily is administered, there is a rapid observed disappearance of the toxin from fecal samples and a coincident clinical recovery from the diarrhea.

In rare cases colitis may reoccur after cessation of vancomycin treatment. Cholestyramine or colestipol resins bind to 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.

As an alternative therapy oral bacitracin 25,000 units q.i.d. for 7-10 days could be considered. Drugs which cause bowel stasis should be avoided.

C. 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.

- 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.

- Overgrowth of nonsusceptible organisms, particularly yeasts, may occur. If superinfections occur, appropriate measures should be taken as indicated by the patient's clinical situation.

- If therapy is prolonged, liver function tests 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.

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

Interaction with Other Medicinal Products 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.

Macrolides may induce clindamycin resistance in certain macrolide-resistant strains, therefore clindamycin should not be administered with a macrolide (see Section Pharmacodynamic properties).

Fertility, pregnancy and lactation

Use 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 limited number of pregnant women, the systemic administration of clindamycin during the second and third trimesters has not been associated with an increased frequency of congenital abnormalities. However, there are no adequate and well-controlled studies using clindamycin in pregnant women during the first trimester of pregnancy and this drug should be used during pregnancy only if clearly needed.

Use in Nursing Mothers

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 blooding 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.

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.

Undesirable Effects

All undesirable effects listed in the label are presented by MedDRA system organ class (SOC) and CIOMS frequency category listed in order of decreasing medical seriousness within each frequency category and SOC.

System Organ Class	Common $\geq 1/100$ to $<1/10$	Uncommon $\geq 1/1,000$ to $<1/100$	Rare $\geq 1/10,000$ to $<1/1,000$	Frequency Not Known (cannot be estimated from available data)
Infections and infestations	<i>pseudomonas</i> colitis*			<i>clostridium difficile</i> colitis*, vaginal infection*
Blood and lymphatic system disorders	eosinophilia			agranulocytosis*, neutropenia*, thrombocytopenia*, leukopenia*
Immune system disorders				anaphylactic shock*, anaphylactoid reaction*, anaphylactic reaction*, hypersensitivity*
Nervous system disorders		dysgeusia		
Cardiac disorders		cardio-respiratory arrest		
Vascular disorders	thrombophlebitis†	hypotension		
Gastrointestinal disorders	diarrhea	abdominal pain, vomiting, nausea		esophageal ulcer*‡, esophagitis*‡
Hepatobiliary disorders				jaundice*
Skin and subcutaneous tissue disorders	rash maculo-papular		erythema multiforme, pruritus	toxic epidermal necrolysis (TEN)*, Stevens-Johnson syndrome (SJS)*, drug reaction with eosinophilia and systemic symptoms (DRESS)*, acute generalized exanthematous pustulosis (AGEP)*, angioedema*, dermatitis exfoliative*, dermatitis bullous*, rash morbilliform*
Renal and urinary disorders				acute kidney injury*
General disorders and administration site conditions		pain†, injection site abscess†		injection site irritation*††
Investigations	liver function test abnormal			

* ADRs identified post-marketing

† ADRs apply only to injectable formulations

‡ ADRs apply only to oral formulations

Overdose

Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Pharmacotherapeutic group: Lincosamide antibiotics, ATC Code J01FF01

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.

Depending on the sensitivity of the micro-organism and the concentration of the antibiotic, clindamycin may be either bactericidal or bacteriostatic.

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. (*Finexgoldia magna*, *Micromonas micros*)
- *Propionibacterium acnes*

Gram-negative bacteria

- *Bacteroides* spp.
- *Fusobacterium* spp.
- *Gardnerella vaginalis*
- *Prevotella* spp.

Fungi

- *Pneumocystis jirovecii*

Protozoans

- *Toxoplasma gondii*
- *Plasmodium falciparum*

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.

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
<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.

^aDisk content 2 micrograms of clindamycin.

^bMIC 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 micro-organism 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 (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
<i>Bacteroides fragilis</i> ATCC 25285	0.5-2 ^a	NA
<i>Bacteroides thetaiotaomicron</i> ATCC 29741	2-8 ^a	NA
<i>Eggerthella lenta</i> ATCC 43055	0.06-0.25 ^a	NA

NA=Not applicable.

ATCC® is a registered trademark of the American Type Culture Collection.

aMIC 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>Staphylococcus</i> Groups A, B, C and G	0.5	0.5	17	17
<i>Streptococcus pneumoniae</i>	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
<i>Corynebacterium</i> spp.	0.5	0.5	20	20

^aDisk content 2 mcg 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

Organism	Minimum Inhibitory Concentration Range (mcg/mL)	Disk Diffusion (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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Miscellaneous organisms including:

Plasmodium falciparum and *Pneumocystis jirovecii* (previously classified as *Pneumocystis carinii*) (in combination with primaquine).

The following organisms are generally resistant to clindamycin:

- Aerobic gram-negative bacilli
- *Streptococcus faecalis*
- *Nocardia* species
- *Neisseria meningitidis*
- Strains of methicillin-resistant *Staphylococcus aureus* and strains of *Haemophilus influenzae* (depending on the areas where antibiotic resistance is known to occur).

Although clindamycin hydrochloride is active as well *in vivo* as *in vitro*, clindamycin phosphate and clindamycin palmitate do not show any *in vitro* effect. However, both substances are *in vivo* rapidly hydrolyzed to the active base.

Pharmacokinetic Properties

Serum level studies with a 150 mg oral dose of clindamycin hydrochloride in 24 normal adult volunteers showed that clindamycin was rapidly absorbed after oral administration. An average peak serum level of 2.50 mcg/mL was reached in 45 minutes; serum levels averaged 1.51 mcg/mL at 3 hours and 0.70 mcg/mL at 6 hours. Absorption of an oral dose is virtually complete (90%), and the 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 for up to 14 days show no evidence of accumulation or altered metabolism of drug.

Half-life is somewhat increased in patients with markedly reduced renal or hepatic function. Dosage schedule need not be modified in the presence of mild or moderate renal or hepatic disease. Hemodialysis 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 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 bone tissue ±40% (20%-75%) of the serum level is reached, in the mother milk 50%-100%, in the synovial fluid 50%, in sputum 30%-75%, in the peritoneal liquid 50%, in the fetal blood 40%, in the pus 30%, in the pleural liquid 50%-90%. However clindamycin does not penetrate in the liquor cerebrospinalis, even not in case of meningitis.

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. The average biological half-life is 2.4 hours. Approximately 10% of the bioactivity is excreted in the urine and 3.6% in the feces; the remainder is excreted as bioactive metabolites. Doses of up to 2 grams 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.

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.

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.

PHARMACEUTICAL PARTICULARS

List of excipients

- Capsule Content
- Lactose Monohydrate
- Maize Starch
- Talc
- Magnesium Stearate

Capsule Shell

- Gelatin
- FD&C Blue 1
- FD&C Red 3
- Titanium Dioxide

Shelf life

36 months

Special precaution for storage

Store below 30°C

Nature and contents of container

10 capsules per blister, 5 blisters per box
Clindamycin 150 mg Capsules are packed in Aluhard/PVC blisters. The material of Aluhard is made from PTP Foil Aluminum. The material of PVC Blister is made from transparent PVC rigid film.

PRESCRIPTION ONLY MEDICINE

PRODUCT OWNER:



PT. Novell Pharmaceutical Laboratories
Jl. Pos Pengumben Raya No. 8,
Sukabumi Selatan, Kebon Jeruk,
Jakarta Barat 11560
Indonesia

DISTRIBUTED BY:



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