

CLINDAMYCIN HYDROCHLORIDE - clindamycin hydrochloride capsule, gelatin coated

Zydus Pharmaceuticals USA Inc.

Clindamycin Hydrochloride Capsules, USP

To reduce the development of drug-resistant bacteria and maintain the effectiveness of clindamycin hydrochloride and other antibacterial drugs, clindamycin hydrochloride should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

WARNING

***Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin hydrochloride 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*.**

Because clindamycin hydrochloride therapy has been associated with severe colitis which may end fatally, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in the INDICATIONS AND USAGE section. It should not be used in patients with nonbacterial infections such as most upper respiratory tract infections.

***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.**

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.

Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

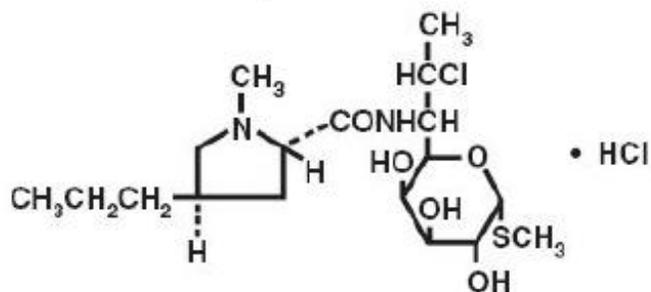
DESCRIPTION

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

Clindamycin hydrochloride capsules contain clindamycin hydrochloride, USP equivalent to 75 mg or 150 mg or 300 mg of clindamycin.

Each capsule also contains the following inactive ingredients: colloidal silicon dioxide, FD&C Blue # 1, FD&C Red # 3, gelatin, lactose monohydrate, magnesium stearate, talc and titanium dioxide.

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-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*- α -D-galacto-octopyranoside monohydrochloride.

CLINICAL PHARMACOLOGY

Human Pharmacology

Absorption

Pharmacokinetic 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 concentration of 2.50 mcg/mL was reached in 45 minutes; serum concentration 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 concentrations have been uniform and predictable from person to person and dose to dose. Pharmacokinetic studies following multiple doses of clindamycin hydrochloride capsules for up to 14 days show no evidence of accumulation or altered metabolism of drug. 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.

Distribution

Concentrations of clindamycin in the serum increased linearly with increased dose. Serum concentrations 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). No significant concentrations of clindamycin are attained in the

cerebrospinal fluid, even in the presence of inflamed meninges.

Metabolism

In vitro studies in human liver and intestinal microsomes indicated that clindamycin is predominantly metabolized by Cytochrome P450 3A4 (CYP3A4), 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 feces; the remainder is excreted as bioinactive metabolites.

Specific Populations

Patients with Renal Impairment

Serum half-life of clindamycin is increased slightly in patients with markedly reduced renal function. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.

Elderly Patients

Pharmacokinetic studies in elderly volunteers (61 to 79 years) and younger adults (18 to 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, the average elimination half-life is increased to approximately 4 hours (range 3.4 to 5.1 h) in the elderly compared to 3.2 hours (range 2.1 to 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 function¹.

Microbiology

Mechanism of Action

Clindamycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is bacteriostatic.

Resistance

Resistance to clindamycin is most often caused by modification of specific bases of the 23S ribosomal RNA. Cross-resistance between clindamycin and lincomycin is complete. Because the binding sites for these antibacterial drugs overlap, cross-resistance is sometimes observed among lincosamides, macrolides and streptogramin B. Macrolide-inducible resistance to clindamycin occurs in some isolates of macrolide-resistant bacteria. Macrolide-resistant isolates of staphylococci and beta-hemolytic streptococci should be screened for induction of clindamycin resistance using the D-zone test.

Antimicrobial Activity

Clindamycin has been shown to be active against most of the isolates of the following microorganisms, both *in vitro* and in clinical infections [see *Indications and Usage (1)*]:

Gram-positive bacteria

Staphylococcus aureus (methicillin-susceptible strains)

Streptococcus pneumoniae (penicillin-susceptible strains)

Streptococcus pyogenes

Anaerobic bacteria

Clostridium perfringens

Fusobacterium necrophorum

Fusobacterium nucleatum

Peptostreptococcus anaerobius

Prevotella melaninogenica

The following in vitro data are available, but their clinical significance is unknown. At least 90 percent of the following bacteria exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for clindamycin against isolates of a similar genus or organism group. However, the efficacy of clindamycin in treating clinical infections due to these bacteria has not been established in adequate and well-controlled clinical trials.

Gram-positive bacteria

Staphylococcus epidermidis (methicillin-susceptible strains)

Streptococcus agalactiae

Streptococcus anginosus

Streptococcus mitis

Streptococcus oralis

Anaerobic bacteria

Actinomyces israelii

Clostridium clostridioforme

Eggerthella lenta

Finegoldia (Peptostreptococcus) magna

Micromonas (Peptostreptococcus) micros

Prevotella bivia

Prevotella intermedia

Propionibacterium acnes

Susceptibility Testing

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: <https://www.fda.gov/STIC>.

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 streptococci, pneumococci, and staphylococci. Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, a penicillin is inappropriate. Because of the risk of colitis, as described in the **BOXED WARNING**, 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); infections of the female pelvis and genital tract such as endometritis, nongonococcal tubo-ovarian abscess, pelvic cellulitis and postsurgical vaginal cuff infection.

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.

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

To reduce the development of drug-resistant bacteria and maintain the effectiveness of clindamycin hydrochloride and other antibacterial drugs, clindamycin hydrochloride should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

Clindamycin hydrochloride capsules are contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.

WARNINGS

See **BOXED WARNING**.

***Clostridium difficile* associated diarrhea**

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Clindamycin hydrochloride, 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.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Anaphylactic and Severe Hypersensitivity Reactions

Anaphylactic shock and anaphylactic reactions have been reported (see **ADVERSE REACTIONS**).

Severe hypersensitivity reactions, including severe skin reactions such as toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and Stevens-Johnson syndrome (SJS), some with fatal outcome, have been reported (see **ADVERSE REACTIONS**).

In case of such an anaphylactic or severe hypersensitivity reaction, discontinue treatment permanently and institute appropriate therapy.

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

Usage in Meningitis

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

PRECAUTIONS

General

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.

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

Clindamycin hydrochloride capsules should be prescribed with caution in atopic individuals.

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

The use of clindamycin hydrochloride capsules occasionally results in overgrowth of

nonsusceptible organisms particularly yeasts. Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Clindamycin dosage modification may not be necessary in patients with renal disease. In patients with moderate to severe liver disease, prolongation of clindamycin half-life has been found. However, it was postulated from studies that when given every eight hours, accumulation should rarely occur. Therefore, dosage modification in patients with liver disease may not be necessary. However, periodic liver enzyme determinations should be made when treating patients with severe liver disease.

Prescribing clindamycin hydrochloride capsules in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Information for Patients

Patients should be counseled that antibacterial drugs including clindamycin hydrochloride capsules should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When clindamycin hydrochloride capsules are prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by clindamycin hydrochloride or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Laboratory Tests

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

Drug Interactions

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 increase plasma concentrations of clindamycin and inducers of these isoenzymes may reduce plasma concentrations of clindamycin. In the presence of strong CYP3A4 inhibitors, monitor for adverse reactions. 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term studies in animals have not been performed with clindamycin to evaluate carcinogenic potential. Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative.

Fertility studies in rats treated orally with up to 300 mg/kg/day (approximately 1.6 times the highest recommended adult human dose based on mg/m²) revealed no effects on fertility or mating ability.

Pregnancy

Teratogenic effects

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.

Clindamycin should be used during the first trimester of pregnancy only if clearly needed. There are no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy. Because animal reproduction studies are not always predictive of the human response, this drug should be used during pregnancy only if clearly needed.

Reproduction studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (3.2 and 1.6 times the highest recommended adult human dose based on mg/m², respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (1.3 and 0.7 times the highest recommended adult human dose based on mg/m², respectively) revealed no evidence of teratogenicity.

Nursing Mothers

Limited published data based on breast milk sampling reports that clindamycin appears in human breast milk in the range of less than 0.5 to 3.8 mcg/mL. Clindamycin has the potential to cause adverse effects on the breast-fed infant's gastrointestinal flora. 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. Monitor the breast-fed infant for possible adverse effects on the gastrointestinal flora, such as diarrhea, candidiasis (thrush, diaper rash) or rarely, blood in the stool indicating possible antibiotic-associated colitis.

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 breast-fed child from clindamycin or from the underlying maternal condition.

Pediatric Use

When clindamycin hydrochloride capsules are administered to the pediatric population (birth to 16 years), appropriate monitoring of organ system functions is desirable.

Geriatric Use

Clinical studies of clindamycin did not include sufficient numbers of patients age 65 and over to determine whether they respond differently from younger patients. However, other reported clinical experience indicates that antibiotic-associated colitis and diarrhea (due to *Clostridium difficile*) seen in association with most antibiotics occur more frequently in the elderly (> 60 years) and may be more severe. These patients should be carefully monitored for the development of diarrhea.

Pharmacokinetic studies with clindamycin have shown no clinically important differences between young and elderly subjects with normal hepatic function and normal (age-adjusted) renal function after oral or intravenous administration.

ADVERSE REACTIONS

The following reactions have been reported with the use of clindamycin.

Infections and Infestations: *Clostridium difficile* colitis

Gastrointestinal

Abdominal pain, pseudomembranous colitis, esophagitis, nausea, vomiting and diarrhea (see **BOXED WARNING**). The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment (see **WARNINGS**). Esophageal ulcer has been reported. An unpleasant or metallic taste has been reported after oral administration.

Hypersensitivity Reactions

Generalized mild to moderate morbilliform-like (maculopapular) skin rashes are the most frequently reported adverse reactions. Vesiculobullous rashes, as well as urticaria, have been observed during drug therapy. Severe skin reactions such as Toxic Epidermal Necrolysis, some with fatal outcome, have been reported (See **WARNINGS**). Cases of Acute Generalized Exanthematous Pustulosis (AGEP), erythema multiforme, some resembling Stevens-Johnson syndrome, anaphylactic shock, anaphylactic reactions and hypersensitivity have also been reported.

Skin and Mucous Membranes

Pruritus, vaginitis, angioedema and rare instances of exfoliative dermatitis have been reported (see *Hypersensitivity Reactions*).

Liver

Jaundice and abnormalities in liver function tests have been observed during clindamycin therapy.

Renal

Although no direct relationship of clindamycin to renal damage has been established, renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed.

Hematopoietic

Transient neutropenia (leukopenia) and eosinophilia have been reported. Reports of agranulocytosis and thrombocytopenia have been made. No direct etiologic relationship to concurrent clindamycin therapy could be made in any of the foregoing.

Immune System

Drug reaction with eosinophilia and systemic symptoms (DRESS) cases have been reported.

Musculoskeletal

Cases of polyarthrititis have been reported.

OVERDOSAGE

Significant mortality was observed in mice at an intravenous dose of 855 mg/kg and in rats at an oral or subcutaneous dose of approximately 2618 mg/kg. In the mice, convulsions and depression were observed.

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

DOSAGE AND ADMINISTRATION

If significant diarrhea occurs during therapy, this antibiotic should be discontinued (see **BOXED WARNING**).

Adults

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

Pediatric Patients (for children who are able to swallow capsules):

Serious infections - 8 to 16 mg/kg/day (4 to 8 mg/lb/day) divided into three or four equal doses. *More severe infections* - 16 to 20 mg/kg/day (8 to 10 mg/lb/day) divided into three or four equal doses.

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

Clindamycin hydrochloride 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 the clindamycin palmitate oral solution in some cases.

Serious infections due to anaerobic bacteria are usually treated with clindamycin injection. However, in clinically appropriate circumstances, the physician may elect to initiate treatment or continue treatment with clindamycin hydrochloride capsules.

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

HOW SUPPLIED

Clindamycin hydrochloride capsules, USP are available in the following strengths, colors and sizes:

Clindamycin hydrochloride capsules, USP equivalent to 75 mg of clindamycin are white to off white granular powder filled in size '2' hard gelatin capsules with blue colored cap printed with "Z-89" in black ink and blue colored body printed with "75 mg" in black ink and are supplied as follows.

NDC 68382-234-08 in bottles of 16 capsules

NDC 68382-234-01 in bottles of 100 capsules

NDC 68382-234-05 in bottles of 500 capsules

Clindamycin hydrochloride capsules, USP equivalent to 150 mg of clindamycin are white to off white granular powder filled in size '1' hard gelatin capsules with blue colored cap printed with "Z-90" in black ink and blue colored body printed with "150 mg" in black ink and are supplied as follows.

NDC 68382-235-08 in bottles of 16 capsules

NDC 68382-235-01 in bottles of 100 capsules

NDC 68382-235-05 in bottles of 500 capsules

Clindamycin hydrochloride capsules, USP equivalent to 300 mg of clindamycin are white to off white granular powder filled in size '0' hard gelatin capsules with blue colored cap printed with "Z-91" in black ink and blue colored body printed with "300 mg" in black ink and are supplied as follows.

NDC 68382-236-08 in bottles of 16 capsules

NDC 68382-236-01 in bottles of 100 capsules

NDC 68382-236-05 in bottles of 500 capsules

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

REFERENCES

1. Smith RB, Phillips JP: Evaluation of CLEOCIN HCl and CLEOCIN Phosphate in an Aged Population. Upjohn TR 8147-82-9122-021, December 1982.

"CLEOCIN" is a registered trademark of Pharmacia & Upjohn Company.

Manufactured by:

Cadila Healthcare Ltd.

Ahmedabad, India

Distributed by:

Zydus Pharmaceuticals (USA) Inc.

Pennington, NJ 08534

Rev.: 06/19

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 68382-234-01 in bottle of 100 Capsules

Clindamycin Hydrochloride Capsules USP, 75 mg

Rx only

100 Capsules

ZYDUS

GTIN : 00000000000000
Lot: xxxxxx
Exp: DDMMYYYY
SR No : 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
(18 x 41 mm)

The image shows a detailed product label for Clindamycin Hydrochloride Capsules, USP, 75 mg*. The label is rectangular with a white background and a purple and green header. On the left side, there is a vertical barcode with the number 'N' above it and '3 6 8 3 8 2 2 3 4 0 1 8' printed vertically to its left. The main text on the label includes the NDC number 'NDC 68382-234-01' in a purple box, the product name 'Clindamycin Hydrochloride Capsules, USP' in large black font, and the strength '75 mg*' in a green box. Below this, it says '100 Capsules Rx only' and features the Zydus Pharmaceuticals logo. On the right side, there is a block of text providing dosage information, storage instructions, and manufacturer details. A red arrow points from the 'No Varnished Area' text to a dashed red box on the left side of the label.

NDC 68382-234-01

Clindamycin Hydrochloride Capsules, USP

75 mg*

100 Capsules
Rx only

zydus
pharmaceuticals

*Each capsule contains :
Clindamycin hydrochloride USP
equivalent to clindamycin.....75 mg
Usual adult dosage -150 mg four times
daily. See package insert for complete
prescribing information.
Store at 20°-25°C (68°-77°F)
[see USP Controlled Room Temperature].
Dispense in tight, light-resistant containers
as described in the USP.
**KEEP THIS AND ALL DRUGS OUT OF
THE REACH OF CHILDREN.**
Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India
Distributed by:
Zydus Pharmaceuticals (USA) Inc.
Pennington, NJ 08534

Rev: 10/18

NDC 68382-235-01 in bottle of 100 Capsules

Clindamycin Hydrochloride Capsules USP, 150 mg

Rx only

100 Capsules

ZYDUS

GTIN : 00000000000000
Lot: xxxxxx
Exp: DDMMYYYY
SR. No : 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
(18 x 50.5 mm)

The image shows a product label for Clindamycin Hydrochloride Capsules, USP, 150 mg*. The label is rectangular with a white background and a purple header. The header contains the NDC number 68382-235-01. The main text reads "Clindamycin Hydrochloride Capsules, USP" in large black font, with "150 mg*" in a purple box below it. The Zydus logo is at the bottom left. On the right side, there is detailed information including the amount per capsule, dosage instructions, storage conditions, and manufacturer details. A barcode is on the left side, and a vertical revision date "Rev: 10/18" is on the far right. A dashed red box highlights a specific area on the left side of the label, with an arrow pointing to it from the text "Over Coding Template" and "No Varnished Area (Do Not Print) (18 x 50.5 mm)".

NDC 68382-235-01

Clindamycin Hydrochloride Capsules, USP

150 mg*

100 Capsules
Rx only

zydus
pharmaceuticals

*Each capsule contains :
Clindamycin hydrochloride USP
equivalent to clindamycin.....150 mg

Usual adult dosage -150 mg four times
daily. See package insert for complete
prescribing information.

Store at 20°-25°C (68°-77°F)
[see USP Controlled Room Temperature].

Dispense in tight, light-resistant
containers as described in the USP.

**KEEP THIS AND ALL DRUGS OUT
OF THE REACH OF CHILDREN.**

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Distributed by:
Zydus Pharmaceuticals (USA) Inc.
Pennington, NJ 08534

Rev: 10/18

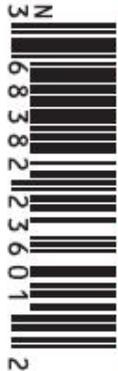
3 N
6838223501
5

NDC 68382-236-01 in bottle of 100 Capsules
Clindamycin Hydrochloride Capsules USP, 300 mg
Rx only
100 Capsules
ZYDUS

GTIN : 00000000000000
 Lot : xxxxxx
 Exp : DDMMYYYY
 SR. No : 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)
 (18 x 50.5 mm)



NDC 68382-236-01

Clindamycin Hydrochloride Capsules, USP

300 mg*

100 Capsules
Rx only



*Each capsule contains :
 Clindamycin hydrochloride USP equivalent to clindamycin.....300 mg

Usual adult dosage -300 mg every six hours. See package insert for complete prescribing information.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Dispense in tight, light-resistant containers as described in the USP.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

Distributed by:
 Zydus Pharmaceuticals (USA) Inc.
 Pennington, NJ 08534

Rev: 10/18

CLINDAMYCIN HYDROCHLORIDE

clindamycin hydrochloride capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68382-234
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN HYDROCHLORIDE (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	75 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN (UNII: 2G86QN327L)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (BLUE (CAP)) , BLUE (BLUE (BODY))	Score	no score
Shape	CAPSULE (CAPSULE)	Size	18mm
Flavor		Imprint Code	Z;89
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-234-08	16 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
2	NDC:68382-234-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
3	NDC:68382-234-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065217	11/17/2017	

CLINDAMYCIN HYDROCHLORIDE

clindamycin hydrochloride capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68382-235
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN HYDROCHLORIDE (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	150 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (BLUE (CAP)) , BLUE (BLUE (BODY))	Score	no score
Shape	CAPSULE (CAPSULE)	Size	20mm
Flavor		Imprint Code	Z;90
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-235-08	16 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
2	NDC:68382-235-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
3	NDC:68382-235-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065217	11/23/2017	

CLINDAMYCIN HYDROCHLORIDE

clindamycin hydrochloride capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68382-236
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN HYDROCHLORIDE (UNII: T200Q1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	300 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (BLUE (CAP)) , BLUE (BLUE (BODY))	Score	no score
Shape	CAPSULE (CAPSULE)	Size	21mm
Flavor		Imprint Code	Z;91
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68382-236-08	16 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
2	NDC:68382-236-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
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Marketing Information

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ANDA	ANDA065217	11/23/2017	

Labeler - Zydus Pharmaceuticals USA Inc. (156861945)

Registrant - Zydus Pharmaceuticals USA Inc. (156861945)

Revised: 11/2022

Zydus Pharmaceuticals USA Inc.