CLINDAMYCIN HYDROCHLORIDE- clindamycin hydrochloride capsule
Northwind Pharmaceuticals

Patient Information

Patients should be counseled that antibacterial drugs, including clindamycin hydrochloride, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When clindamycin hydrochloride is 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.

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

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

Pregnancy Category B

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.

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

Nursing Mothers

Clindamycin has been reported to appear in breast milk in the range of 0.7 to 3.8 mcg/mL.

Pediatric Use

When clindamycin hydrochloride is 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

ADVERSE REACTIONS

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

Gastrointestinal: Abdominal pain, pseudomembranous colitis, esophagitis, nausea, vomiting, and diarrhea. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment.

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. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, and a few cases of anaphylactoid reactions have also been reported.

Skin and Mucous Membranes: Pruritus, vaginitis, and rare instances of exfoliative dermatitis have been reported.

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 in rare instances.

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.

Musculoskeletal: Rare instances of polyarthritis have been reported

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

Adults

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

Pediatric Patients

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.

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

Label Display

NDC: 51655-0530-24

CLINDAMYCIN HCL 300MG

30 Capsules

Lot: Exp: Rx only

Store at 20C to 25C (68-77F)

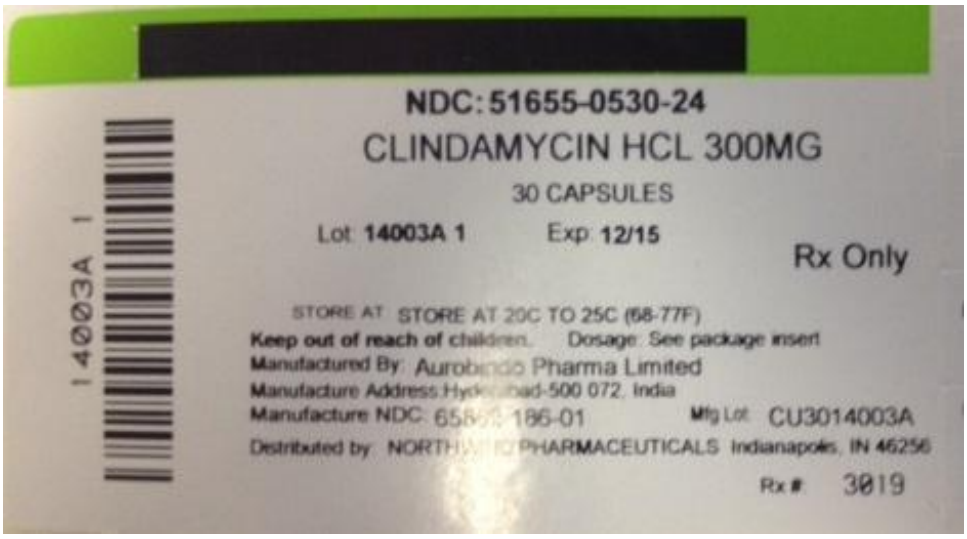
Keep out of reach of children. Dosage: See package insert

Manufactured by: Aurobindo Pharma Limited

Manufacture Address: Hyderabad-500-072, India

Manufacture NDC: 65862-186-01 Mfg. Lot: CU3014003A

Distributed by Northwind Pharmaceuticals Indianapolis, IN 46256



CLINDAMYCIN HYDROCHLORIDE

clindamycin hydrochloride capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51655-530(NDC:65862-186)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CLINDAMYCIN HYDROCHLORIDE (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	300 mg

Product Characteristics			
Color	blue	**Score**	no score
Shape	capsule	**Size**	21mm
Flavor		**Imprint Code**	C;40
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-530-24	30 in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065442	06/01/2014	

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
EPM Packaging		079124340	repack(51655-530)

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