CLINDAMYCIN

CLINDAL

℞ CAPSULE
ANTIBACTERIAL

FORMULATION
Each capsule contains:
Clindamycin (as hydrochloride), USP ……150 mg
Clindamycin (as hydrochloride), USP …….. 300 mg

PRODUCT DESCRIPTION
- Clindamycin hydrochloride (Clindal) 150 mg Capsule is a white to off-white, crystalline powder contained in a blue / white # 1 capsule.
- Clindamycin hydrochloride (Clindal) 300 mg Capsule is a white to off-white, crystalline granular powder contained in a blue / blue # 0 capsule.

PHARMACODYNAMICS AND PHARMACOKINETICS
Microbiology: Clindamycin has been shown to have an *in vitro* activity against isolates of the following organisms:

Aerobic gram-positive cocci, including:
Staphylococcus aureus;
Staphylococcus epidermidis (penicillinase and *nonpenicillinase producing strains)*;
When tested by *in vitro* methods, some staphylococcal strains originally resistant to erythromycin rapidly develop resistance to clindamycin;
Streptococci (except *Streptococcus faecalis*);
Pneumococci
Anaerobic gram-negative bacilli, including:
Bacteroides species (including *Bacteroides fragilis* group and *Bacteroides melaninogenicus* group);
Fusobacterium species
Anaerobic gram-positive non-sporeforming bacilli, including:
Propionibacterium
Eubacterium
Actinomyces species
Anaerobic and microaerophilic gram-positive cocci, including:
Peptococcus species
Peptostreptococcus species;
Microaerophilic streptococci
Clostridia spp: Clostridia are more resistant than most anaerobes to clindamycin. Most *Clostridium perfringens* are susceptible, but other species, e.g., *Clostridium sporogenes* and *Clostridium tertium* are frequently resistant to clindamycin.

Susceptibility testing should be done.

Cross resistance has been demonstrated between clindamycin and lincomycin. Antagonism has been demonstrated between clindamycin and erythromycin.

About 90% of a dose of clindamycin hydrochloride is absorbed from the gastrointestinal tract; concentrations of 2 to 3 micrograms/mL occur within 1 hour after a 150-mg oral dose, with average concentrations of about 700 nanograms/mL after 6 hours. After doses of 300 mg and 600 mg, peak plasma concentrations of 4 and 8 micrograms/mL, respectively, have been reported. Absorption is not significantly diminished by food in the stomach but the rate of absorption may be reduced.

Clindamycin is widely distributed in body fluids and tissues, including bone, but it does not reach the CSF in significant concentrations. It diffuses across the placenta into the fetal circulation and has been reported to appear in breast milk. High concentrations occur in bile. It accumulates in leucocytes and macrophages.

Over 90% of clindamycin in the circulation is bound to plasma proteins. The half-life is 2 to 3 hours, although this may be prolonged in preterm neonates and in patients with severe renal impairment.

Clindamycin undergoes metabolism, presumably in the liver, to the active N-demethyl and sulfoxide metabolites, and also to some inactive metabolites. About 10% of a dose is excreted in the urine as active drug or metabolites and about 4% in the faeces; the remainder is excreted as inactive metabolites. Excretion is slow, and takes place over several days. It is not effectively removed from the blood by dialysis.

INDICATIONS
Clindamycin is used in the treatment of serious anaerobic infections especially those caused by *Bacteroides fragilis*. It has been recommended as an alternative to penicillin in some severe staphylococcal and streptococcal infections, including staphylococcal osteomyelitis. Because of its potential toxicity, clindamycin should only be used when there is no suitable alternative.

DOSAGE AND ADMINISTRATION
Adult: Serious infection: 150 mg to 300 mg 6-hourly, or as prescribed by a physician.

CONTRAINDICATIONS
Clindamycin hydrochloride is contraindicated in patients previously found to be sensitive to clindamycin or lincomycin or to any component of the formulation.

PRECAUTIONS
Clindamycin should not be given to patients known to be hypersensitive or who have experienced reactions with Lincomycin. It should not be used to patients with diarrheal states and it should be used with caution in patients with impaired liver and renal function.
Since clindamycin is reported to possess neuromuscular blocking activity, it should be used with care with other drugs of similar activity.

PREGNANCY AND LACTATION
Clindamycin crosses the placenta in humans. After multiple doses, amniotic fluid concentrations were approximately 30% of maternal blood concentrations. Clindamycin should be used in pregnancy only if clearly needed.
Clindamycin has been reported to appear in human breast milk in ranges from 0.7 to 3.8 µg/mL. Because of the potential for serious adverse reactions in nursing infants, clindamycin should not be taken by nursing mothers.

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

ADVERSE DRUG REACTIONS
Infections and Infestations
Pseudomembranous colitis, Clostridium difficile colitis, Vaginal infection

Blood and the lymphatic system disorders
Eosinophilia, Agranulocytosis, Neutropenia, Thrombocytopenia, Leukopenia

Immune system disorders
Anaphylactic shock, Anaphylactoid reactions, Anaphylactic reactions, Hypersensitivity

Nervous system disorders
Dysgeusia

Cardiac disorders
Cardio-respiratory arrest

Vascular disorders
Thrombophlebitis, Hypotension

Gastrointestinal disorders
Diarrhea, 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 generalized exanthematous pustulosis (AGEP), Angioedema, Dermatitis exfoliative, Dermatitis bullous, Rash morbilliform

Renal and urinary disorders
Acute kidney injury

Investigations
Liver function test abnormal

OVERDOSE AND TREATMENT:
Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. Treatment is symptomatic and supportive.

DOSAGE FORMS AND PACKAGING:
150 mg Capsule: Blister Pack x 10's (Box of 100's)
300 mg Capsule: Blister Pack x 10's (Box of 100's)

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:
150 mg Capsule: DR-XY28449
300 mg Capsule: DR-XY24058

DATE OF FIRST AUTHORIZATION:
150 mg Capsule: 25 March 2003
300 mg Capsule: 03 April 1998

DATE OF REVISION:
August 2023

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Manufactured by:
HIZON LABORATORIES, INC.
Assumption Road, Sumulong Highway,
Antipolo City

For:

ONE PHARMA

ONE PHARMA MARKETING INC.
L51, B21, Abel Nosce St.,
BF Resort Village, Talon II,
Las Piñas City, Metro Manila