TIDACT® CAPSULE

TDC
draft - 04 Sep 19

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 is chemically known as 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.

Description:
A violet colored cap and yellow colored body hard gelatine capsule with the mark "TDC", and containing white powder.

Ingredient(s):
Each capsule contains:
Clindamycin Hydrochloride ..... 150mg(potency)

Pharmacodynamics:
1. Clindamycin inhibits protein synthesis in susceptible bacteria by binding to the 50s subunits of bacterial ribosomes and preventing peptide bond formation. It is bacteriostatic or bactericidal, depending on the concentration.

Pharmacokinetics:
1. Clindamycin is active against more aerobic Gram-positive bacteria including Streptococci, Staphylococci, *Bacillus anthracis* and *Corynebacterium diphtheriae*. It has good activity against a wide range of anaerobic bacteria. Susceptible Gram-positive anaerobes include Eubacterium, Propionibacterium, Peptococcus, Peptostreptococcus, and most strains of *Clostridium perfringens* and *Clostridium tetani*. The Gram-negative anaerobes that are susceptible to Clindamycin are *Fusobacterium sp.*and *Bacteroides sp*. including *B. fragilis* group.

2. About 90% of a dose of Clindamycin Hydrochloride is absorbed from the gastrointestinal tract and peak plasma concentrations are achieved more rapidly than with Lincomycin. Concentrations of about 2.5µg/mL occur within 1 hour after a 150mg dose with average concentrations of about 0.7µg/mL after 6 hours. After doses of 300 and 600mg, peak plasma concentrations of 4 and 8µg/mL, respectively, have been reported. The biological half-life is about 1.5hours. Absorption is not significantly diminished by food but the rate of absorption may be reduced. Between 80 and 90% of Clindamycin in the circulation is bound to plasma proteins.

3. Clindamycin is widely distributed in body fluids and tissues including bone but it does not reach the cerebrospinal fluid 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 the bile. Clindamycin undergoes metabolism, presumably in the liver, to the active N-dimethyl 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% is excreted in the feces. It is not effectively removed from the blood by dialysis.

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Indication(s):
Serious infections caused by susceptible anaerobic bacteria or strains of streptococci, pneumococci and staphylococci. 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, non-gonococcal tubo-ovarian abscess, pelvic cellulitis and post-surgical 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.

Dosage and Administration:

Adults:		
Serious infections	-	150 to 300mg every 6 hours.
More severe infections	-	300 to 450mg every 6 hours.
Children:		
Serious infections	-	8 to 16mg/kg/day divided to three or four equal doses.
More severe infections	-	16 to 20mg/kg/day divided to three or four equal doses.

To be dispensed on physician's prescription.

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Route of administration:
Oral

Contraindication(s):
Contraindicated in patients with a history of hypersensitivity to Clindamycin or Lincomycin.

Precaution(s) / Warning(s):
1. Tidact Capsule should be used with caution in individuals with a history of gastrointestinal disease, particularly colitis.

2. It should not be used in patients with diarrheal states.

3 Caution should be exercised in patients with impaired liver and renal functions.

4. Since Clindamycin is reported to possess neuromuscular blocking activity, it should be used cautiously with other drugs having similar activity.

5. Safety for use in pregnancy has not been established. Clindamycin has been reported to appear in breast milk in ranges of 0.7 - 3.8mcg/ml.

Clindamycin 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.
It should not be used in patients with nonbacterial infections, such as most upper respiratory tract infections.
Its use in newborns is contraindicated.

Drug Interactions:
1. Clindamycin and Erythromycin should not be administered concurrently as studies have shown antagonism *in vitro*.

2. The concurrent use of kaolin-containing anti-diarrheal preparations markedly reduces the rate of absorption of Clindamycin but not the extent of absorption.

Side Effect(s) / Adverse Reaction(s):
Clindamycin may cause diarrhea which can be severe and persistent, nausea, vomiting, abdominal cramps, and abnormality of taste. Severe pseudomembranous colitis has occurred in some patients and occasionally has been fatal. Hypersensitivity reaction including skin rashes and urticaria may occur, and transient leucopenia and eosinophilia, abnormalities of liver function tests, and jaundice have been reported. Agranulocytosis, thrombocytopenia, and erythema multiforme have been observed.

Symptoms and Treatment for Overdosage, and Antidote(s):
There is no specific antidote for its overdose; therefore, management of the patients should consist of symptomatic and supportive therapy.

Shelf-Life:
3 years from the date of manufacture.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Packing(s):
Plastic bottle of 300's, 1000's and 1500's (for export only)
Blister packing of 10's x 10 and 10's x 50.

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Manufacturer and Product Registration Holder:
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