10 x 2mL ampoule

CLINDAMYCIN

Rx

CLINDAMAN

150mg/mL (300mg/2mL)
Solution for Injection (IM/IV)

ANTIBACTERIAL

Description: Clindamycin Phosphate is a clear colorless solution for injection filled in a clear glass with a blue neck line ampoule.

Composition: Each mL contains 178. 23 mg clindamycin phosphate equivalent to 150 mg clindamycin.

Pharmacodynamics: Clindamycin is a lincosamide antibiotic with a primarily bacteriostatic action against gram-positive including streptococci, staphylococci, *Bacillus anthracis*, and *Corynebacterium diptheriae* and a wide range of anaerobic bacteria. Susceptible gram-positive anaerobes include *Eubacterium*, *Propionibacterium, Peptococcus,* and *Peptostreptococcus* spp., and many strains of *Clostridium perfringens* and *C.I tetani*. Among Gram-negative anaerobes susceptible to clindamycin are *Fusobacterium* spp., *Veillonella*, and *Bacteroide*s spp., including the *B. fragilis* group.

Clindamycin is usually considered bacteriostatic by binding to the 50 S subunits of bacterial ribosomes and preventing peptide bond formation, cause inhibition of protein synthesis in susceptible bacteria. Clindamycin may be bactericidal in high concentrations. When used against highly susceptible organisms Clindamycin may be bacterial antibiotic.

Pharmacokinetics:
Absorption: rapidly absorbed from the Gastrointestinal tract (approx 90%); skin (approx. 4-5%); and systemically as an intravaginal preparation (approx 5%). Food may reduce rate of absorption. Time to peak plasma concentration: W/in 60 min (oral); 1-3 hr (IM).
Distribution: widely distributed in body fluids and tissues, including bone. Crosses the placenta and enters breast milk. Volume of distribution: Approx 2 L/kg. Plasma protein binding: >90%.
Metabolism: undergoes hepatic metabolism to the active N-demethyl and sulfoxide metabolites and some inactive metabolites.
Excretion: via urine as active drug or metabolites (approx 10%); faeces (approx 4%); and the remainder as inactive metabolites. Plasma half-life: 2-3 hr.

Indications: For treatment of bacterial infections caused by susceptible microorganism i.e.

1. As an adjunctive treatment of chronic bone and joint infections, and acute hematogenous osteomyelitis caused by staphylococci.
2. Female pelvic infections, including endometritis, non-gonococcal tubo-ovarian abscess, pelvic cellulitis, and postsurgical vaginal cuff infections caused by susceptible anaerobes.
3. Intra-abdominal infections such as peritonitis and abscesses caused by susceptible anaerobes.
4. Pneumonia including serious respiratory tract infections (such as empyema, pneumonitis, and lung abscesses) caused by susceptible anaerobes.
5. Septicemia caused by streptococci and staphylococci.
6. Skin and soft tissue infections caused by susceptible anaerobes, streptococci, and staphylococci.

Dosage and Administration:
Usual adult and adolescent dose:
Intramuscular or intravenous
- Serious infections: 600-1200 mg/day in 2,3 or 4 equal doses
- More severe infections: 1200-1700 mg/day in 2,3 or 4 equal doses
- For more serious infections, these doses may have to be increased. In life-threatening situations due to either aerobes or anaerobes these doses may be increased. Doses of as much as 4800 mg daily have been given intravenously to adults.

(Single intramuscular injections of greater than 600 mg are not recommended and dosage should not exceed 2.7 gm daily)

Usual pediatric dose:
Intramuscular or intravenous
- 20 to 40 mg/kg/day in 3 or 4 equal doses. The higher doses would be used for more severe infections. As an alternative to dosing on body weight basis, pediatric patients may be dosed on the basis of square meters body surface: 350mg/m2/day for serious infections and 450 mg/m2/day for more severe infections.

Adverse Drug Reactions:
Hypersensitivity reactions (skin rashes, redness, itching, etc.), nausea, vomiting, abdominal pain or cramps, taste disturbances, oesophagitis, oesophageal ulceration, rashes, urticaria, erythema multiforme, Stevens-Johnson syndrome, drug rash w/ eosinophilia and systemic symptoms (DRESS), exfoliative and vesiculobullous dermatitis, leucopenia, agranulocytosis, eosinophilia, thrombocytopenia, polyarthritis, renal dysfunction (e.g. azotemia, oliguria, proteinuria), local irritation, skin dryness, contact dermatitis, cervicitis, vaginitis, vag candidiasis, vulvovaginal irritation, sterile abscess and thrombophlebitis.
Potentially Fatal: Clostridium difficile-associated diarrhoea (CDAD) or pseudomembranous colitis (severe abdominal or stomach cramps and pain, abdominal tenderness; diarrhea, watery and severe which may also be bloody; fever), toxic epidermal necrolysis (TEN).

Overdose and treatment: If overdose is suspected immediately consult a physicain, other healthcare professionals or contact a nearest hospital.

Incompatibilities: Clindamycin phosphate is physically incompatible with ampicillin sodium, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, and magnesium sulfate.

Dilution for IV use and IV infusion rates: The concentration of clindamycin in diluent for infusion should not exceed 18 mg per ml. Infusion rates should not exceed 30 mg per minute.
Preparations: To prepare initial dilution for intravenous use, each dose must be diluted as follows:

dose (mg)	diluent (ml)	duration of administration (min)
300	50	10
600	50	20
900	50-100	30

Precautions and Contraindications: Diarrhea, which can be severe and persisent, nausea, vomiting, abdominal cramps and abnormality of taste.
Hypersensitivity reactions including skin rashes and urticaria, leucopenia and eosinophilia, abnormalities of liver function tests and jaundice have been reported. Agranulocytosis, thrombocytopenia, erythema multiform. Anaphylactic reactions may occur. Immediate emergency treatment should be applied. Thrombophlebitis may occur after intravenous administration. Patients with renal and/or hepatic disease should be treated with caution and serum clindamycin levels monitored during therapy.
Contraindicated to patients with hypersensitivity to clindamycin or lincomycin. Give special precautions to patients history of GI disease particularly colitis, atopic individuals. Not intended for the treatment of CNS infections. Severe renal and/or hepatic impairment. Pregnancy and lactation.

Interactions: Clindamycin has been shown to have neuromuscular blocking properties that mayenhance 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, the two drugs should not be administered concurrently. Food may reduce rate of absorption.

Warning:
- Single dose. Discard any remaining portion.
- *Clostridum difficile* associated diarrhea
- Severe Skin Reactions
- Benzyl Alcohol in Pediatric Patients ("Gasping Syndrome")
- Use in meningitis

Pregnancy: Teratogenic effects
Pregnancy Category B
Reproduction studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (2.1 and 1.1 times the highest recommended adult human dose based on mg/m2, respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (0.9 and 0.5 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.

Reporting Of Suspected Adverse Drug Reaction: To show continued monitoring of benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

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

Storage:
Store at temperatures not exceeding 30°C. Keep out of reach of children.

Availability: Box of 10 x 2mL ampoules, (150mg/mL (300mg/2mL).

Manufactured by:
VESCO PHARMACEUTICAL COMPANY LIMITED
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Date of Revision of Package Insert: