

# Dalatic

Clindamycin Phosphate USP Injection

**Composition : Dalatic 300 Injection (IV/IM) :** Each 2ml Sterile Injectable Solution Contains Clindamycin 300mg as Clindamycin Phosphate USP.

**Dalatic 600 Injection (IV/IM) :** Each 4ml Sterile Injectable Solution Contains Clindamycin 600mg as Clindamycin Phosphate USP.

**Pharmacology :** Clindamycin is a lincosamide antibiotic with a primarily bacteriostatic action against Gram-positive aerobes and a wide range of anaerobic bacteria. Lincosamides such as clindamycin bind to the 50S subunit of the bacterial ribosome similarly to macrolides such as erythromycin and inhibit the early stages of protein synthesis. The action of clindamycin is predominantly bacteriostatic although high concentrations may be slowly bactericidal against sensitive strains. Clindamycin is widely distributed in body fluids and tissues including bone, but it does not reach the cerebrospinal fluid in significant concentrations. High concentrations occur in bile. It accumulates in leucocytes and macrophages. Over 90% of clindamycin in the circulation is bound to plasma proteins. Clindamycin is predominantly metabolized by Cytochrome P450 3A4 (CYP3A4). Clindamycin undergoes metabolism to the active N-demethyl and sulphoxide metabolites and also some inactive metabolites. After intramuscular injection of clindamycin phosphate, peak concentrations of active clindamycin are reached within 3 hours in adults and 1 hour in pediatric patients. The average serum elimination half-life of active clindamycin is about 3 hours in adults and 2½ hours in pediatric patients. About 10% of the drug is excreted in the urine as active drug or metabolites and about 4% in the faeces; the remainder is excreted as inactive metabolites.

**Indications :** Clindamycin is indicated in the treatment of the following infections caused by susceptible anaerobic bacteria or susceptible strains of gram positive bacteria such as streptococci, Pneumococci and staphylococci in Lower respiratory tract infections, skin and soft tissue infections, Bone and joint infections, Pelvic infections, Intra-abdominal infections, Septicemia, Dental infections and also indicated for the treatment of AIDS associated Pneumonia.

**Dosage and administration : Dosage of Dalatic Injection (IV/IM) : Adults :** For Serious infections : 600-1200 mg/day in 2-4 equal doses. More severe infections, 1200-2700 mg/day in 2-4 equal doses. For more Serious infections, these doses may have to 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. **Neonates (less than 1 month) :** 15 to 20 mg/kg/day in 3 to 4 equal doses. **Paediatric patients (1 month of age to 16 years) :** 20 to 40mg/kg/day in 3 or 4 equal doses. The higher doses would be used for more severe infections. **Dilution of Clindamycin injection for intravenous use : Dilution and Infusion Rates :** Clindamycin phosphate must be diluted prior to IV administration. The concentration of clindamycin in diluent for infusion should not exceed 18 mg/ml. Infusion rates should not exceed 30 mg/minute. The usual infusion dilutions and rates are as follows :

Dose	Diluent (Dextrose 5% or NaCl 0.9%)	Infusion Duration
300mg	50ml	10 min
600mg	50ml	20 min
900mg	50-100ml	30 min
1200mg	100ml	40 min

Administration of more than 1200mg in a single 1 hour infusion is not recommended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Or, as directed by the registered physician.

**Contraindication :** Clindamycin is contraindicated in patients with known hypersensitivity to the active substance or to any of the excipients of this medicine.

**Precautions :** Clindamycin should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

**Side effects :** The adverse effects have been reported with the use of clindamycin are abdominal pain, nausea, vomiting, urticaria, skin rashes, esophagitis and esophageal ulcer, diarrhoea.

**Use in pregnancy and lactation :** Pregnancy Category B. No adequate and well-controlled studies in pregnant women. However, this drug should be used during pregnancy only if clearly needed. Clindamycin has been reported to appear in breast milk. Therefore, it is not recommended for nursing mothers if not clearly needed.

**Use in Child :** See dosage and administration.

**Drug Interaction :** 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.

**Overdose :** Overdosage with orally administered clindamycin is rare. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. Overdosage should be treated with simple gastric lavage. No specific antidote is known.

**Storage :** Store below 30°C in a dry place.

**Packing : Dalatic 300 Injection (IV/IM) :** Each Box Contains 5's ampoules in blister pack.

**Dalatic 600 Injection (IV/IM) :** Each Box Contains 3's ampoules in blister pack.



Manufactured by  
**DRUG INTERNATIONAL LTD.**  
Tongi, Gazipur, Bangladesh