Antibiotic

TDI SGP-002
R.O.C. Reg. No.: 032640

TIDACT Injection 150mg/mL

(Clindamycin)

Tidact Injection contains Clindamycin, a semi synthetic analogue of the natural antibiotic Lincomycin. Clindamycin is better absorbed, more potent, and less toxic than Lincomycin.

Ingredient: Each mL contains:

Clindamycin (as Phosphate) ····· 150mg (potency)

Actions:

1. Inhibits protein synthesis in susceptible bacteria by binding to the 50S subunits of bacterial ribosomes and prevents peptide bond formation.
2. Usually considered as bacteriostatic but may be bactericidal at high concentrations or when used against highly susceptible organisms.
3. Generally active in vitro against the following G(+) microorganisms: *Staph. aureus, Staph. epidermidis, Staph. pyogenes, Strep. pneumoniae,* β-hemolytic streptococci, *Strep. viridans, Corynebacterium diphtheriae,* and *Nocardia asteroids;* and to the following anaerobes: *Bacteroides* species, *Fusobacterium, Propionibacterium, Eubacterium, Actinomyces* species, *Peptococcus, Peptostreptococcus,* Microaerophilic streptococci, *Clostridium perfringens, Clostridium tetani* and *Veillonella.*
4. Widely and rapidly distributed to most fluid and tissues, except cerebrospinal fluids. High concentrations in bone, bile and urine. Excreted in breast milk.
5. Undergoes hepatic biotransformation. Clindamycin phosphate is inactive; it is hydrolyzed in vivo to active Clindamycin.
6. Half-life in normal renal function: adult, 2.4-3.0 hours; infants and children, 2.5-3.4 hours; premature infants, 6.3-8.6 hours. In end-stage of renal failure or severe hepatic impairment, 3-5 hours in adults.
7. Time to peak serum concentration: I.M., 1 hour in children and 3 hours in adults: I.V., end of infusion. Clindamycin serum level exceeds MIC for most indicated organisms for at least 6 hours after recommended doses. Levels can be maintained above the in vitro MIC for most indicated organisms by giving Clindamycin phosphate every 8 to 12 hours to adults, every 6 to 8 hours to children or by continuous I.V. infusion. Equilibrium is reached by dose 3.
8. About 10% of the total dose is eliminated in the urine and 3.6% in the feces as active drug. Not removed from the blood by hemodialysis or peritoneal dialysis.

Indications:

For the treatment of serious infections due to susceptible strains of Staphylococci, Streptococci, Pneumococci, and anaerobic bacteria.

Dosage and Administration:

Single I.M. injection should not exceed 600mg; for I.V. infusion, do not administer more than 1200mg in a single 1 hour infusion.

Adult dose: I.M. or I.V.

Ordinary infections: 600-1200mg/day in 2,3 or 4 equal doses.
Serious infections: 1200-1800mg/day in 3 or 4 equal doses.
Very serious infections: 2400-2700mg/day in 2,3 or 4 equal doses.
In life threatening situations, a maximum of 4800mg/day may be given I.V.
May be administered as a single rapid infusion on the first dose and followed by continuous I.V. infusion, as follows:

To maintain serum Clindamycin levels	Rapid infusion rate	Maintenance infusion rate
Above 4mcg/mL	10mg/min for 30 min	0.75mg/min
Above 5mcg/mL	15mg/min for 30 min	1.00mg/min
Above 6mcg/mL	20mg/min for 30 min	1.25mg/min

To prepare initial dilution for I.V. dose, each dose must be diluted as follows (it must not be administered undiluted as a bolus):

Dose	Diluent	Duration of administration
300	50	10 min
600	50	20 min
900	100	30 min
1200	100	40 min

Children dose: I.M. or I.V.

Infants up to 1 month of age: 15-20mg/kg/day in 3 or 4 equal doses.
Over 1 month of age: 20-40mg/kg/day in 3 or 4 equal doses.
May be given based on body surface area:
Serious infections: 350mg/m²/day
More serious infections: 450mg/m²/day

In β-hemolytic streptococcal infection, treatment should be continued for at least 10 days.

To be administered only by a physician.

Contraindications:

1. History of gastrointestinal disease, especially ulcerative colitis, regional enteritis, and antibiotic-associated colitis. Clindamycin may cause pseudomembranous colitis.
2. Severe hepatic function impairment. Half-life of Clindamycin is prolonged in this condition, therefore may require dosage adjustment.
3. Hypersensitivity to Lincomycins and doxorubicin.
4. Severe renal function impairment may require reduction of dosage.

Precautions:

1. Patients hypersensitive to Lincomycin and doxorubicin may also be hypersensitive to Clindamycin.
2. It is excreted in breast milk but no problems in humans have been documented.
3. It should be used with caution in infants of up to 1 month of age. This preparation contains benzyl alcohol, which has been associated with a fatal gasping syndrome in infants.
4. Clindamycin is potentially nephrotoxic. Acute kidney injury including acute renal failure has been reported. Therefore, monitoring of renal function should be considered during therapy of patients with pre-existing renal dysfunction or taking concomitant nephrotoxic drugs and monitoring of renal function should be performed if therapy is prolonged.

Pregnancy statement:

Clindamycin has not been shown to have mutagenic or carcinogenic potential. Safety for its use in pregnant women has not been clearly established.

Incompatibility:

Clindamycin phosphate is physically in compatible with ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, and magnesium sulfate.

Drug interactions:

In the study of Clindamycin-susceptible Gram-positive cocci and anaerobes, the combination of Clindamycin and gentamicin were additive, and occasionally synergistic.

Adverse Effects:

1. Gastrointestinal: Abdominal pain, nausea, vomiting and diarrhea. An unpleasant or metallic taste occasionally has been reported after intravenous administration of the higher doses of Clindamycin phosphate.
2. Hypersensitivity Reactions: Maculopapular rash and urticaria have been observed during drug therapy. Generalized mild to moderate morbilliform-like skin rashes are the most frequently reported of all adverse reactions.
3. Liver: Jaundice and abnormalities in liver function tests have been observed during Clindamycin therapy.
4. Renal: Renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed in rare instances.
5. Hematopoietic: Transient neutropenia (leukopenia) and eosinophilia, agranulocytosis, and thrombocytopenia have been reported.
6. Local reactions: Pain, induration and sterile abscess have been reported after intramuscular injection and thrombophlebitis after intravenous infusion. Reactions can be minimized or avoided by giving deep intramuscular injections and avoiding prolonged use of indwelling intravenous catheters.
7. Musculoskeletal: Rare instances of polyarthritis have been reported.
8. Cardiovascular: Rare instances of cardiopulmonary arrest and hypotension have been reported following too rapid intravenous administration.
9. Post-marketing experience - renal and urinary disorders: acute kidney injury (frequency not known).

Storage Conditions:

Store at temperatures not exceeding 30℃.

Packaging:

Box of 2mLx10Vials.

Manufacturer:
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