United Pharmaceuticals

DANALLI®
Clindamycin

Description:
DANALLI® (Clindamycin Hydrochloride) 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.
Most Gram-negative aerobic bacteria, including the Enterobacteriaceae, are resistant to Clindamycin. Clindamycin demonstrates cross resistance with lincomycin. When tested by in vitro methods, some staphylococcal strains originally resistant to erythromycin rapidly developed resistance to Clindamycin. The mechanisms for resistance are the same as for erythromycin, namely methylation of the ribosomal binding site, chromosomal mutation of the ribosomal protein and in a few staphylococcal isolates enzymatic inactivation by a plasmid-mediated adenyltransferase.
Properties:
Absorption: Following oral administration, Clindamycin is rapidly and almost completely absorbed (90% of the dose taken). Concomitant intake of food induced practically no modification in the plasma concentrations obtained.
Distribution:
- Serum concentration: in healthy adults, a peak plasma concentration of the order of 2-3 mg/L is achieved 1 hour post-oral intake of 150 mg of Clindamycin hydrochloride and the concentration is 4-5 mg/L after oral intake of 300 mg. The plasma concentration subsequently decays slowly but remains greater than 1 mg/L for over 6 hours.
Plasma concentration increases linearly with dose.
In diabetics serum concentrations rather lower than those in healthy subjects have been reported.
The mean biological half-life is 2.5 hours.
- Plasma protein binding: Binding is marked: of the order of 80 to 94%.
- Humoral and tissue diffusion: Clindamycin diffuses into the extra- and intracellular fluids at a very high tissue concentration.
Diffusion into the cerebrospinal fluid is very limited.
Metabolism: Clindamycin is metabolized in the liver.
Elimination: About 10% of the active compounds are eliminated in the urine and 3.6% in the feces. The remainder is excreted in the form of inactive compounds.
Indications:
The therapeutic indications derive from the antibacterial potency and pharmacokinetic characteristics of Clindamycin. The indications reflect both the clinical trials conducted with the medicinal product and its position in the range of antibacterials currently available.
Curative treatment
The indications are restricted to severe infections due to microorganisms defined as sensitive, in the following infections:
- ENT,
- bronchopulmonary,
- stomatologlcal,
- cutaneous,
- genital,
- osteoarticular,
- post-operative abdominal,
- septicemia,
With the exception of meningeal infections, even due to sensitive microorganisms, because of the inadequate diffusion of the antibiotic into the CSF.
Prophylactic treatment
Prophylaxis of infectious endocarditis in the course of dental treatment and investigations targeting the upper airways, in outpatient care settings, in the event of allergy to β-lactams.
The official recommendations for appropriate use of antibacterials are to be taken into account.
Dosage and Administration:
Curative treatment
- **Adults:** 600 to 2400 mg/24 hours as 2, 3 or4 divided intakes.
- **Children aged over 6 years:** 8 to 25 mg/ kg/24 hours as 3 to 4 divided intakes.
Prophylactic treatment
- Adults: 600 mg by the oral route in the hour preceding the procedure.
- Children aged over 6 years: 15 mg/kg by the oral route in the hour preceding the procedure.
Contraindications:
- In the event of allergy to lincomycin or Clindamycin.
- In children aged less than 6 years, due to the pharmaceutical form.
- Lactation.
Precautions:
- Diarrhea due to pseudomernbranous enterocolitis may occur during or after Clindamycin treatment (even several weeks post-discontinuation).The diarrhea may become serious if it is not treated with an antibiotic active against Clostridium difficile, the toxin producer. Such episodes of diarrhea require the immediate withdrawal of Clindamycin and specific antibiotic therapy. The administration of intestinal peristalsis inhibitors is contra-Indicated.
- Due to the presence of lactose, this medicinal Product is contra-indicated in the event of congenital galactosemia, glucose and galactose malabsorption syndrome and lactase deficiency.
Special precautions for use:
- Do not administer to patients presenting with enterocolitis.
- Use with caution in patients with a history of asthma or other allergies.
- An increase in serum levels and prolongation of the elimination half-life of Clindamycin have been documented in patients with liver failure.
- Long-term treatment should only be conducted under monitoring of the complete blood count, liver enzymes and renal function.
- Effects on the ability to drive and use machines: Not applicable.
Use during pregnancy and lactation:
Pregnancy: It is preferable, as a precaution, not to use Clindamycine during pregnancy.
Lactation: Due to the tolerance profile of this drug product, the lactation is contra-indicated during the treatment with this drug product.
Drug Interaction:
Combinations requiring precautions for use
- Aluminum (salts and hydroxides): Decreased gastrointestinal absorption of lincosamides. Take the gastrointestinal topical agents remotely from the lincosamides (more than 2 hours before the lincosamides, if possible).
- Cyclosporin: Decreased blood immunosuppressant concentrations with a risk of loss of immunosuppressant activity. Intensify monitoring of blood cyclosporin levels and increase the dosage if necessary.
- Specific problems of INR disequilibrium: Numerous cases of increased oral anticoagulant activity have been reported in patients receiving antibiotics. The context of marked infection or inflammation, and the patient's age and general condition appear to be risk factors. Under such circumstances, it is difficult to distinguish between the contribution of the infection and the contribution of its treatment in the emergence of INR disturbances. However, certain classes of antibiotics are more strongly involved: in particular, fluoroquinolones, macrolides, cyclines, cotrimoxazole and certain cephalosporins.
Side Effects:
Gastrointestinal Effects:
- Abdominal pain, persistent diarrhea (of Special warnings and special precautions for use).
- Nausea, vomiting.
- Esophagitis.
Hematological Effects: Neutropenia, leukopenia, agranulocytosis, thrombocytopenb purpura.
Cutaneous and allergological Effects:
- Hypersensitivity reactions such as angioedema and anaphylaxis have been reported in some subjects allergic to penicillin.
- Rare cases of erythema multiform, Stevens- Johnson or Lyell's syndrome have been associated with administration of Clindamycin.
- Pruritus, skin rash, urticaria.
Hepatotoxicity: Although no direct relationship between Clindamycin administration and hepatic dysfunction has been evidenced, a few cases of jaundice and impaired liver function (transaminases) have been reported.
Overdosage:
In cases of overdosage no specific treatment is indicated.
The serum biological half life of lincomycin is 2.4 hours. Clindamycin cannot readily be removed from the blood by dialysis or peritoneal dialysis. If an allergic adverse reaction occurs, therapy should be with the usual emergency treatments, including corticosteroids, adrenaline and antihistamines.
Storage conditions:
Store between 15 - 30ºC.
Presentation:
DANALLI® **150:** Each capsule contains Clindamycin HCl equivalent to Clindamycin 150 mg in packs of 16 capsules.
DANALLI® **300:** Each capsule contains Clindamycin HCl equivalent to Clindamycin 300 mg in packs of 16 capsules.
Hospital packs are also available.
Excipients:
Lactose, Maize starch, Talc & Magnesium Stearate.

This is a medicament

· Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
· Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
· The doctor and the pharmacist are experts in medicine, its benefits and risks.
· Do not by yourself interrupt the period of treatment prescribed for you.
· Do not repeat the same prescription without consulting your doctor.
· Keep medicament out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

The United Pharmaceutical Manufacturing Co. Ltd.
P.O. Box 69 Amman 11591, Jordan

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