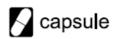
Climadan

Clindamycin



Composition:

Each capsule contains Clindamycin HCI equivalent to Clindamycin base

150 mg

Pharmacology:

CLIMADAN is a lincosamide antibiotic with a primarily bacteriostatic action against gram-positive aerobic and a wide range of anaerobic bacteria. In general, CLIMADAN is more active and causes fewer unwanted effects than lincomycin.

Microbiology:

CLIMADAN is effective against *S.pyogenes, S.pneumoniae, S.viridans, H. influenza* and *S.aureus* (either sensitive or resistant to penicillins and including the penicillinase-producing). It has been proven very effective in the treatment of infections due to anaerobic bacteria, particularly *B. fragilis*. In vitro experiments indicate that CLIMADAN is accumulated in the PMNs and macrophages, the activities of PMNs and macrophages are enhanced and subsequently, the body immune mechanisms.

Pharmacokinetics:

CLIMADAN is absorbed almost completely after oral administration. Although its absorption is not significantly diminished by food in the stomach but the rate of absorption may be reduced. Peak concentration in blood is reached within 1 hr.

The drug penetrates quickly into the tissues, body fluids, skeleton and pus. Its half-life is 2.5 hrs and primarily eliminated through the liver.

Indications:

Serious infections caused by organisms sensitive to CLIMADAN include upper and lower respiratory tract infections, otitis media, skin infections, osteomyelitis, endocarditis, anaerobic infections and others.

It is also indicated for prophylaxis of postoperative infections caused by anaerobic bacteria.

Contraindications:

Patients hypersensitive to lincomycin and clindamycin.

Patients with diarrhoea, liver and kidney functions disturbances.

Atopic individuals, e.g. the asthmatic and allergic patients.

It is not indicated for meningitis and in the treatment of mild infections caused by bacteria and viruses.

Warnings and precautions:

Look after the possibility of superinfections by resistant strains and fungi.

Regular hematologic examinations should be conducted, especially in those with liver and kidney disturbances.

When excessive diarrhoea appears during treatment, discontinue this drug immediately. In case of infections by β -hemolytic Streptococci, this drug should be continued for at least 10 days in order to reduce the chance of rheumatic fever or glomerulonephritis

As in the case for almost all antibiotic therapy, clindamycin therapy has been associated with severe colitis which may end fatally.

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.

Use in pregnancy and lactation:

Safety in the pregnant and lactating mothers has not been elucidated.

Drug interactions:

Antagonist with erythromycin.

CLIMADAN may enhance the effects of drugs with neuromuscular blocking activity and a potential danger of respiratory depression.

Side effects:

Hypersensitive reactions, e.g. pruritus, rash and urticaria.

Gastrointestinal disturbances, e.g. nausea, vomiting, diarrhea and colitis.

Post-marketing experience - renal and urinary disorders: acute kidney injury (frequency not known).

Dosage and administration:

Adults

For Serious Infections: 150 mg - 300 mg / 6-hourly. For More Severe Infections . 450 mg / 6-hourly.

Children > 1 month:

For Serious Infections: 8 - 16 mg/kg body weight/day given in 3 - 4 divided doses. For More Severe Infections: 16 - 20 mg/kg body weight/day given in 3 - 4 divided doses.

Presentation:

Box contains 10 x 10 capsules @ 150 mg.

Storage:

Store below 30°C.

ON MEDICAL PRESCRIPTION ONLY

Revision date: March 2022

Manufactured by:

PT DANKOS FARMA

JI. Rawa Gatel Blok III S, Kav. 36 - 38 Kawasan Industri Pulogadung Jakarta 13930 - Indonesia

For:

PT KALBE FARMA Tbk.

Kawasan Industri Delta Silicon JI. M.H. Thamrin Blok A3 - 1, Lippo Cikarang Bekasi 17550 – Indonesia