

Description:

DANALLI® Gel is an aqueous, nonalcoholic and emollient formulation of clindamycin phosphate with a nondrying and a soothing effect on the skin.

DANALLI® Gel is an antibacterial and anti-acne agent characterized by minimal systemic effect.

Properties:

Clindamycin is a lincosamide antibiotic with a primarily bacteriostatic action against Gram-positive aerobes and a wide range of anaerobic bacteria. It is suggested to act by reducing free fatty acid concentrations on the skin and suppressing the growth of the bacteria that is found in sebaceous glands and follicles. Following multiple applications, very low levels of clindamycin are attained in the serum due to minimal percutaneous absorption having a bioavailability of about 2%.

Indications:

DANALLI® Gel is indicated for the treatment of acne vulgaris and inflammatory acne lesions such as papules and pustules.

Dosage and administration:

Wash affected areas, prior to application, with warm water and soap; rinse and pat dry.
Apply a thin film of DANALLI® Gel twice daily to the affected areas.

Contraindications:

Clindamycin should not be used in patients with a history of sensitivity to it or to lincomycin, a history of antibiotic-associated colitis, ulcerative colitis or regional enteritis.

Precautions:

•The drug should be discontinued if significant diarrhea

occurs.

•Medical attention is needed if diarrhea, colitis and pseudomembraneous colitis develop after cessation of therapy.

•Administer with caution to patients with a history of atopic reactions.

•Use only water-base cosmetics and do not apply too heavily or too often.

•Safety and effectiveness in children under the age of 12 years have not been established.

•Contact with the eyes or the mucous membranes of the nose and mouth should be avoided. In the event of accidental contact with the eyes or mucous membranes bathe the affected area with copious amounts of cool water.

Use during pregnancy and lactation:

•Adequate and well-controlled studies in pregnant women have not been documented. Also, animal studies have not shown that clindamycin causes adverse effects on the fetus.

•It is not known whether clindamycin is distributed into breast milk. Since only a small amount is absorbed following application of clindamycin phosphate, it is unlikely to be distributed into breast milk in significant amounts.

Drug interactions:

Not known.

Side effects:

•Generally, clindamycin is well tolerated. However, contact dermatitis, hypersensitivity, gastroin-testinal disturbances, such as abdominal pain and mild diarrhea may occur.

•Also, Gram-negative folliculitis, pseudomembraneous colitis, diarrhea and bloody diarrhea were rarely reported.

Overdosage:

It is not expected that overdose would occur in normal use.

Storage conditions:

Store between 15-30°C.

Presentation:

DANALLI® Gel: Each 1 gram contains Clindamycin phosphate the equivalent of Clindamycin 10 mg (1% w/w) in tubes of 30 gm.

Excipients:

Carbopol 934P, Allantoin, Propylene Glycol, Polyethylene Glycol 400, Methylparaben, Sodium Hydroxide & Purified Water.

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

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