

ADACLIN[®] Gel

Adapalene USP 0.1 % w/w

Clindamycin Phosphate USP 1% w/w

PRESENTATION:

10 g

MOLECULAR INTRODUCTION:

The chemical name of adapalene is 6-[3-(4-damantyl)-4-methoxyphenyl]-2-naphthoic acid. It is a white to off-white powder, which is soluble in tetrahydrofuran, very slightly soluble in ethanol, and practically insoluble in water. The molecular formula is C₂₈H₂₈O₃ and molecular weight is 412.53.

The chemical name for clindamycin phosphate is Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo-α-D-galacto-octopyranoside 2-(dihydrogen phosphate). It has a molecular weight of 504.96, and the molecular formula is C₁₈H₃₄ClN₂O₈PS. Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

MECHANISM OF ACTION:

Adapalene is a chemically stable, retinoid-like compound. Biochemical and pharmacological profile studies have demonstrated that adapalene is a modulator of cellular differentiation, keratinization, and inflammatory processes all of which represent important features in the pathology of acne vulgaris.

Mechanistically, adapalene binds to specific retinoic acid nuclear receptors but does not bind to the cytosolic receptor protein. Although the exact mode of action of adapalene is unknown, it is suggested that topical adapalene may normalize the differentiation of follicular epithelial cells resulting in decreased microcomedone formation. Topical clindamycin works by killing the bacteria that cause acne. It also has anti-inflammatory effects. Usually, you'll start seeing improvement of your skin within 4 to 6 weeks. Adapalene has a significant anti-inflammatory effect that enhances the therapeutic action of clindamycin on inflammatory acne lesions.

INDICATIONS AND USAGE:

ADACLIN GEL is a third-generation topical retinoid primarily used in the treatment of mild-moderate acne and is also used (off-label) to treat keratosis pilaris as well as other skin conditions.

ADACLIN GEL is indicated for the topical treatment of comedon, papular and postular acne of the face, chest or back or as indicated by the physician.

ADACLIN Gel –a combination of adapalene to clindamycin has a larger and faster effect on acne lesions. It is indicated that this combination can be used at the onset of therapy, to obtain a better clinical response than that obtained by using the antibiotic alone.

PHARMACOKINETICS:

Absorption of adapalene through human skin is low. Only trace amounts (<0.25 ng/mL) of parent substance have been found in the plasma of acne patients following chronic topical application of adapalene in controlled clinical trials. Excretion appears to be primarily by the biliary route.

DOSAGE & ADMINISTRATION:

ADACLIN Gel should be applied once a day to affected areas after washing in the evening before bed time. A thin film of the gel should be applied, avoiding eyes, lips, and mucous membranes.

During the early weeks of therapy, an apparent exacerbation of acne may occur. This is due to the action of the medication on previously unseen lesions and should not be considered a reason to discontinue therapy. Therapeutic results should be noticed after eight to twelve weeks of treatment.

CONTRAINDICATIONS:

ADACLIN GEL should not be administered to individuals who are hypersensitive to adapalene or Clindamycin or any of the components in the vehicle gel.

WARNINGS:

Use of ADACLIN Gel should be discontinued if hypersensitivity to any of the ingredients is noted. Patients with sunburn should be advised not to use the product until fully recovered.

Adverse effects:

Erythema, Scaling, Dryness, Pruritus and burning may occur. These are most likely to occur during the first 2-4 weeks of treatment, are mostly mild to moderate in intensity, and will usually lessen with continued use of the medication.

Drug Interaction:

Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid. However, other retinoids or drugs with a similar mode of action should not be used concurrently with adapalin.

Pregnancy and Nursing Mother:

Pregnancy category C. There are no studies in pregnant women. Adapalin should be used during pregnancy only if the potential benefit justifies the potential risk.

Study has not been performed in pregnancy and nursing mother. Should only be used if the potential benefit outweighs the risk.

Precaution:

Safety and efficacy in children below the age of 12 years have not been studied.

Exposure to sunlight, including sunlamps, should be minimized during the use of Adapalene C. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, also may be irritating to while under treatment with Adapalene C.

Adapalene C Gel should not come into contact with the eyes, lips, mouth and mucous membranes, angles of the nose or broken skin (cuts and abrasions).

USP:

Adapalene enhance the efficacy of topical clindamycin. The overall efficacy of the treatment will be enhanced as compared to clindamycin alone.

Significantly larger and faster effects on acne lesions

Can be used at the onset of therapy

Better clinical response than that obtained by using the antibiotic alone.

Adapalene with significant anti-inflammatory effect enhances the therapeutic action of clindamycin on inflammatory acne.

Application of adapalene enhances the penetration of clindamycin into the skin and enhances the effects of clindamycin.

Research results:

In conclusion, the combination regimen of clindamycin topical lotion 1% plus adapalene gel 0.1% was significantly more effective than clindamycin plus vehicle for the treatment of mild to moderate acne vulgaris in reducing both inflammatory and noninflammatory lesions. The combination with adapalene resulted in a significantly greater and faster efficacy response than that of clindamycin plus vehicle, with no significant tolerability burden.

Results showed that the addition of adapalene gel 0.1% produced a faster and a clinically significant enhancement of the efficacy of clindamycin topical lotion 1% therapy for acne vulgaris. There were significantly greater reductions in total, inflammatory, and non-inflammatory lesions in the adapalene plus clindamycin group than in the clindamycin plus vehicle group.

एडाक्लिन

Manufactured by:

Deurali-Janta Pharmaceuticals Pvt. Ltd.



679, Budhanilkantha Sadak, Bansbari - 03 | G.P.O. Box: 4239, Kathmandu, Nepal

Tel: +977-01- 4018777 | E-mail: mplaning@deuralijanta.com

Website: www.deuralijanta.com

® Registered Trade Mark

01 p ADG 20