Acnicot Gel

(Clindamycin phosphate USP / Tretinoin USP)

ایکنی کوٹ جل

(کلینڈامائیسین/ٹریٹنوئن)

COMPOSITION: Each gm contains:
Clindamycin Phosphate USP …..... 1.2% w/w
Tretinoin USP ……..... 0.025% w/w
Manufacturer's Specs.

PHARMACOLOGY:
MECHANISM OF ACTION: Clindamycin Phosphate: Clindamycin binds to the 50s ribosomal subunits of susceptible bacteria and prevents elongation of peptide chains by interfering with peptidyl transfer, thereby suppressing bacterial protein synthesis. **Tretinoin:** Although the exact mode of action of tretinoin is unknown, current evidence suggests that topical tretinoin decreases cohesiveness of follicular epithelial cells with decreased microcomedone formation. Additionally, tretinoin stimulates mitotic activity and increased turnover of follicular epithelial cells causing extrusion of the comedones.

PHARMACOKINETIC: In an open-label, multiple-dose study treating 12 subjects with moderate to severe acne, the percutaneous absorption of tretinoin following 14 consecutive daily applications of approximately 4g of clindamycin phosphate and tretinoin gel was minimal. Quantifiable tretinoin plasma concentrations ranged from 1.0 to 1.6ng/ml, with unquantifiable plasma concentrations in 50% to 92% of subjects at any given timepoint following administration. The plasma concentrations of the key tretinoin metabolites, 13- cis -retinoic acid and 4-oxo-13-cis retinoic acid, ranged from 1.0 to 1.4ng/ml and from 1.6 to 6.5ng/ml, respectively. Plasma concentrations for clindamycin generally did not exceed 3.5ng/ml, with the exception of one subject whose plasma concentration reached 13.1ng/ml.

INDICATIONS: Acnicot Gel is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

CONTRA-INDICATIONS: Acnicot Gel is contra-indicated in patients with regional enteritis, ulcerative colitis, or history of antibiotic-associated colitis.

DOSAGE AND ADMINISTRATION: At bedtime, squeeze a pea-sized amount of medication onto one fingertip, dot onto the chin, cheeks, nose, and forehead, then gently rub over the entire face. Acnicot Gel should be kept away from the eyes, the mouth, angles of the nose, and mucous membranes. **Acnicot** Gel is not for oral, ophthalmic, or intravaginal use.

WARNINGS AND PRECAUTIONS:
Colitis: Systemic absorption of clindamycin has been demonstrated following topical use of this product. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical clindamycin. When significant diarrhea occurs, **Acnicot** Gel should be discontinued.
Ultraviolet Light and Environmental Exposure: Exposure to sunlight, including sun lamps, should be avoided during the use of **Acnicot** Gel, and patients with sunburn should be advised not to use the product until fully recovered because of heightened susceptibility to sunlight as a result of the use of tretinoin.

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Adverse Reactions: Skin redness, dryness, peeling, mild burning/stinging, or worsening of acne may occur during the first 2 to 4 weeks of using the medication. These effects usually decrease with continued use. A daytime moisturizer may be helpful for very. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Your doctor may want you to decrease how often you use the medication or stop using it.

DRUG INTERACTIONS: Some products that may interact with this drug include: erythromycin products used on the skin, hair perming solutions, products that contain alcohol / lime / menthol (such as astringents, toners, shaving lotions), medicated or abrasive soaps and cleansers, products containing alpha hydroxy acid, products containing glycolic acid, products containing sulfur / resorcinol / salicylic acid, soaps and cosmetics with a strong drying effect, other drugs that may increase the sensitivity to sunlight (e.g., fluoroquinolones such as ciprofloxacin, tetracyclines, thiazide water pills such as hydrochlorothiazide, sulfa drugs such as sulfamethoxazole, phenothiazines such as chlorpromezine).
Concomitant Topical Medication: Concomitant topical medication, medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices or lime should be used with caution. When used with **Acnicot** Gel, there may be increased skin irritation.
Erythromycin: ACNICOT Gel should not be used in combination with erythromycin-containing products due to its clindamycin component. In vitro studies have shown antagonism between these two antimicrobials. The clinical significance of this in vitro antagonism is not known.
Neuromuscular Blocking Agents: Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, **Acnicot** Gel should be used with caution in patients receiving such agents.

USE IN SPECIFIC POPULATIONS:
Pregnancy: Acnicot Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nursing Mothers: Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother when **Acnicot** Gel is administered to a nursing woman.
Pediatric Use: Safety and effectiveness of **Acnicot** Gel in pediatric patients under the age of 12 have not been established.

INSTRUCTIONS: FOR EXTERNAL USE ONLY. Store below 30° C. Protect from heat and light. Keep out of the reach of children.

PRESENTATION: Acnicot Gel (Clindamycin phosphate 1.2% and tretinoin 0.025%) is supplied in pack size of 20g.

ہدایات: صرف بیرونی استعمال کیلئے۔ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی اور روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.

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