

Acnalen® (topical) 0.1 %

Category

Anti acne agent (Synthetic retinoic acid analog; derivative of naphthoic acid)

Indications

Acne vulgaris (treatment): Adapalene is most effective for treating mild to moderate acne vulgaris.

It is hypothesized that by selectively binding to certain nuclear retinoic acid receptors and not others, **Adapalene** enhances keratinocyte differentiation without inducing epidermal hyperplasia and severe irritation, such as is seen with retinoic acid.

Contraindications

- * Dermatitis, seborrheic or Eczema (skin irritation may be increased.)
- * Sensitivity to Adapalene or other ingredients of the formulation

Precautions

▲ Possibility that acne may worsen during the first 3 weeks of therapy; not stopping medication unless irritation, dryness, or other symptoms become severe; checking with physician if improvement not seen by 8 to 12 weeks

▲ Alerting doctor if excessive skin irritation occurs or is bothersome; using moisturizers creams, or lotions as necessary to reduce skin irritation or dryness

▲ Avoiding or minimizing exposure of treated areas to direct and artificial sunlight, wind, or extremely cold temperatures; using sunscreens or sunblocking agents of at least SPF 15 and protective clothing over treated areas.

▲ Medication should not be applied to open wounds or windburned, sunburned, or otherwise irritated skin. If skin irritation occurs or is bothersome, Adapalene should be discontinued until skin irritation subsides.

▲ Contact with the eyes, lips, and mucous membranes of inner nose should be avoided.

Pregnancy

FDA Pregnancy Category C, although problems have not been reported with topical Adapalene in the dose used for acne, it is recommended that pregnant women not use Adapalene, based on data for other topical retinoids. As a general precaution, women of reproductive age may want contraception counseling before initiating treatment.

Breast-feeding

It is not known whether Adapalene is distributed into breast milk.

Pediatrics

Safety and efficacy in children up to 12 years of age have not been established.

Geriatrics

Acne vulgaris is not likely to occur in this age group.¹

Side/Adverse Effects

Those indicating need for medical attention:

Burning sensation or stinging of skin; erythema; pruritus; scaling (dryness and peeling of skin)

Note: These adverse effects are commonly seen within the first 4 weeks of use and usually lessen over time. If these effects are severe, dosage frequency of Adapalene should be reduced or the medication discontinued until the severe skin irritation subsides.

Twenty percent of patients report transient burning and itching of skin upon application of Adapalene.

Those indicating need for medical attention only if they continue or are bothersome:

Acne flares (worsening of acne)

Note: Acne flares are more commonly seen in the first month of treatment and decrease in frequency and severity thereafter.^{1,2}

Drug interactions

* Acne products, topical, or topical products containing a peeling agent, such as Antibiotics, topical, such as Clindamycin, topical Erythromycin, topical Benzoyl peroxide (When used together for clinical effect, it is recommended that these medications be used at different times of the day, such as morning and night, to minimize possible skin irritation. If irritation results.), Resorcinol, Salicylic acid, Sulfur

* Alcohol-containing products or products containing strong drying agents, such as After-shave lotions, Cosmetics or soaps with a strong drying effect and Shaving creams or lotions

* Hair products, skin-irritating, such as hair permanents or hair removal products

* Products containing lime or spices

* Soaps or skin cleansers, abrasive

Dosage and Administration

Usual adult and adolescent dose:

Acne vulgaris: to the involved areas of the skin, once a day as a thin film applied to clean, dry skin at least one hour before bedtime.

Usual pediatric dose:

Safety and efficacy have not been established.

Patient Consultation

*Importance of not using more medication than amount prescribed

*Not applying medication to windburned or sunburned skin or on open wounds

*Avoiding contact with the eyes, lips, and mucous membranes of inner nose

*After applying a thin film of medication to skin, the medication should be rubbed in gently and well. Hands should be washed to remove any remaining medication ¹

Storage, strength(s) and packaging:

Store between 15 and 30°C (59 and 86°F).

Each tube contains 30 grams of Acnalene gel (0.1%).

Manufactured by Aburaihan Pharmaceutical Co.

References:

1. USPDI 2007

2. Physician's Desk Reference 2007(PDR 61 Edition)