Adapalene Gel 0.3% is a retinoid indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

How should I use Adapalene Gel, 0.3%?

Apply a thin film of Adapalene Gel, 0.3% to the entire face and any other affected area. Use every evening, after washing with a soap that does not contain a medicine and pat dry.

Avoid exposure to sunlight and sunlamps. Wear protective clothing over treated areas. Use sunscreen when sun exposure cannot be avoided. Use of sunscreen products and protective clothing over treated areas is recommended and effective. See full prescribing information needed to use Adapalene safely and effectively. See full prescribing information needed to use Adapalene safely and effectively.

Avoid use if skin is sensitive to sun, should be warned to exercise caution. Use with caution, especially when using products containing sulfur, resorcinol, or lime.

Adapalene Gel 0.3% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The safety and efficacy of Adapalene Gel, 0.3% has not been established in children 12 years of age and younger.

What should I tell my doctor before using Adapalene Gel, 0.3%?

You should avoid skin products that may dry or irritate your skin such as harsh soaps, astringents, cosmetics that have strong skin drying effects and products containing high levels of alcohol.

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What should I tell my doctor before using Adapalene Gel, 0.3%?
8.4 Pediatric Use
Safety and efficacy data have not been established in pediatric patients below the age of
12.

8.5 Geriatric Use
Clinical studies of Adapalene Gel, 0.3% did not include subjects 65 years of age and
over, and there are no adequate and well-controlled studies to determine whether
older adults respond differently from younger adults. In general, geriatric patients
should be prescribed a dosage in keeping with their renal function and the severity
of their condition.

10 OVERDOSAGE
Adapalene Gel, 0.3% is intended for topical use only. If the medication is applied
externally, advise the patient to wash the affected area with soap and water, rinse
completely, and dry thoroughly.

11 DESCRIPTION
Adapalene Gel, 0.3% contains Adapalene; Adapalene 0.3% (3 mg/g) in a topical
base of gel comprised of methylparaben, propylene glycol, purified water, and
sodium hydroxide. This product contains sodium hydroxide, which is indicated to
neutralize the pH of the formula.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Adapalene is a synthetic retinoid and nuclear receptor agonist that does not bind to
lysosomal receptor protein. Structural and biochemical/pharmacological studies have
demonstrated that adapalene is a regulator of cellular differentiation, keratinization,
and inflammatory processes. However, the significance of these findings with regard
to the mechanism of action of adapalene for the treatment of acne is unknown.

12.2 Pharmacodynamics
Clinical pharmacodynamic studies have not been conducted for Adapalene Gel, 0.3%.

12.3 Pharmacokinetics
Systemic exposure of adapalene following topical application of Adapalene Gel was eval-
uated in a clinical study. Sixteen female patients were treated once daily for 16 days with
2 grams of Adapalene Gel, 0.3% applied to the face, chest, and back, concomitant with
approximately 0.2% benzoyl peroxide (0.2% w/w) adapalene gel containing 1000 ppm
of benzoyl peroxide. Plasma adapalene concentrations in 5 patients treated for 16
days was approximately 0.03 ng/mL. No metabolites were detected at the limit of
detection. Adapalene was rapidly cleared from plasma and was not detectable 12 hours
after the last application for all but one subject. Exposure of potential circulating metabolites of adapalene was not measured. Exposure of adapalene appears to be primarily by the
oral route.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity studies with adapalene were conducted in mice at topical oral doses of
0.4, 1.3, and 4.0 mg/kg/day, and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/day. These
doses are approximately 0.1, 0.3, and 1.5 times the MRHD (0.3 mg/g) in humans when
compared on a weight per weight basis. No increased incidence of benign or malignant
tumors in animals was observed. Adapalene did not cause an increased risk of skin
tumors in CD-1 mice. The results of a 16-month study in rats at oral doses of 0.15, 0.5,
and 1.5 mg/kg/day (0.3 mg/g) of adapalene; or 1.5 mg/kg/day (0.4 mg/g) of
adapalene in females, reveal the similarity in results observed in female rats. These
doses of adapalene are approximately 0.3, 1.0, and 3.0 times the MRHD (0.3 mg/g) in
humans when compared on a weight per weight basis. There was an increased incidence
of benign neoplasms in the adrenal glands of female rats. The results of a two-year oral
study, increased incidence of benign and malignant pheochromocytomas and tumors
in the adrenal glands of male rats was observed.

14 CLINICAL STUDIES
14.1 Clinical Studies
Clinical studies of Adapalene Gel, 0.3% did not include subjects 65 years of age and
over, and there are no adequate and well-controlled studies to determine whether
older adults respond differently from younger adults. In general, geriatric patients
should be prescribed a dosage in keeping with their renal function and the severity
of their condition.

15 ADVERSE REACTIONS
15.1 Cutaneous Reactions
Adapalene Gel, 0.3% was associated with skin redness and irritation in 20% of the
patients that used the medication. The most common dermatologic side effects reported
by patients were erythema, scaling, and pruritus. Adapalene Gel, 0.3% patients
treated only the face and trunk, once daily for 12 weeks. Seventy-eight (78) patients
had plasma adapalene levels evaluated at Weeks 2, 8, and 12. Of the 209 plasma samples
analyzed, adapalene concentrations were below the limit of detection (0.03 ± 0.03 ng/mL)
of the method in all samples. Levels of adapalene below the limit of quantification (LOQ: 0.02 ng/mL) of the method were found. Of these 209 samples, 15 were taken after
Week 8 and 51 after Week 12. Thirty-nine (39) patients had plasma adapalene levels
analyzed after 12 weeks. Thirty-one (31) patients had plasma adapalene levels analyzed
after 12 weeks. Forty-three (43) patients had plasma adapalene levels analyzed after
12 weeks. Thirty-one (31) patients had plasma adapalene levels analyzed after 12 weeks.

8.1 General Information
Adapalene Gel, 0.3% or Adapalene Gel, 0.1% was applied to the face and optionally
to the trunk, once daily for 12 weeks. Seventy-eight (78) patients had plasma adapalene levels evaluated at Weeks 2, 8, and 12. Of the 209 plasma samples analyzed,
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9.1 Black Perforation
Where indicated, 9.1 Black Perforation is added to the table of contents and the back
of the book to denote an item that is not a Usual and Customary cost, but may be
covered by an insurance policy. 9.1 Black Perforation is used in the Product
Information Section of the book to indicate a color break. Actual colors will be matched
on Plus Book and/or approved Color Standards.

9.2 Black Perforation Color Break
This proof is to show size, copy placement and color. Actual colors will be matched
on Plus Book and/or approved Color Standards.

3/11/2014

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