

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EPIDUO Gel safely and effectively. See full prescribing information for EPIDUO Gel.

EPIDUO® (adapalene and benzoyl peroxide) Gel 0.1% / 2.5%

For topical use

Initial U.S. Approval: 2008

-----**INDICATIONS AND USAGE**-----

EPIDUO gel is a combination of adapalene, a retinoid, and benzoyl peroxide, and is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. (1)

-----**DOSAGE AND ADMINISTRATION**-----

EPIDUO gel is not for oral, ophthalmic, or intravaginal use. (2)
Apply a thin film of EPIDUO gel to affected areas of the face and/or trunk once daily after washing. Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek). Avoid the eyes, lips and mucous membranes. (2)

-----**DOSAGE FORMS AND STRENGTHS**-----

Each gram of EPIDUO gel contains 1 mg (0.1%) adapalene and 25 mg (2.5%) benzoyl peroxide. (3)

-----**CONTRAINDICATIONS**-----

None. (4)

-----**WARNINGS AND PRECAUTIONS**-----

Ultraviolet Light and Environmental Exposure: Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided. (5.1)

Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of EPIDUO. (5.2)

-----**ADVERSE REACTIONS**-----

Most commonly reported adverse events ($\geq 1\%$) in patients treated with EPIDUO gel were dry skin, contact dermatitis, application site burning, application site irritation and skin irritation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Galderma Laboratories, L.P. at 1-866-735-4137 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 01/2011

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

EPIDUO gel is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

For topical use only; EPIDUO gel is not for oral, ophthalmic, or intravaginal use.

Apply a thin film of EPIDUO gel to affected areas of the face and/or trunk once daily after washing. Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek). Avoid the eyes, lips and mucous membranes.

3 DOSAGE FORMS AND STRENGTHS

Each gram of EPIDUO gel contains 1 mg (0.1%) adapalene and 25 mg (2.5%) benzoyl peroxide in a white to very pale yellow, opaque, aqueous based gel.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Ultraviolet Light and Environmental Exposure

Exposure to sunlight, including sunlamps, should be minimized during the use of EPIDUO gel. Patients with high levels of sun exposure and those with inherent sensitivity to sun should exercise particular caution. Use of sunscreen products and protective apparel, (e.g., hat) are recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, may be irritating to patients under treatment with EPIDUO gel. [See 13 NONCLINICAL TOXICOLOGY]

5.2 Local Cutaneous Reactions

Erythema, scaling, dryness, and stinging/burning may be experienced with use of EPIDUO gel. These are most likely to occur during the first four weeks of treatment, are mostly mild to moderate in intensity, and usually lessen with continued use of the medication. Irritant and allergic contact dermatitis may occur. Depending upon the severity of these adverse reactions, patients should be instructed to use a moisturizer, reduce the frequency of the application of EPIDUO gel, or discontinue use. The product should not be applied to cuts, abrasions, eczematous or sunburned skin. As with other retinoids, use of "waxing" as a depilatory method should be avoided on skin treated with EPIDUO gel.

Avoid concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have strong skin-drying effect and products with high concentrations of alcohol, astringents, spices, or limes).

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

During clinical trials, 1401 subjects were exposed to EPIDUO gel. A total of 1036 subjects with acne vulgaris, 12 years and older, were treated once daily for 12 weeks to 12 months. Related adverse reactions reported within 12 weeks of treatment and in at least 1% of subjects treated with EPIDUO gel and those reported in subjects treated with the vehicle gel are presented in Table 1:

Table 1. Drug Related Adverse Reactions Reported in Clinical Trials by At Least 1% of Subjects Treated For 12 Weeks

System Organ Class/ Preferred Term	EPIDUO gel N = 564	Vehicle gel N = 489
Subjects with AE (s)	14%	4%
Dry Skin	7%	2%
Contact dermatitis	3%	<1%
Application site burning	2%	<1%
Application site irritation	1%	<1%
Skin irritation	1%	0%

Local tolerability evaluations, presented in Table 2, were conducted at each study visit in clinical trials by assessment of erythema, scaling, dryness, burning, and stinging.

Table 2 Incidence of Local Cutaneous Irritation in Controlled Clinical Trials (N = 553)

Treatment Emergent Signs and Symptoms

	Maximum Severity During Treatment			End of Treatment Severity (12 Weeks)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Erythema	27%	13%	1%	8%	2%	1%
Scaling	35%	11%	1%	9%	1%	<1%
Dryness	41%	13%	1%	10%	2%	<1%
Stinging/burning	41%	15%	3%	7%	2%	1%

Analysis over the 12-week period showed that local tolerability scores for erythema, scaling, dryness, and stinging/burning peaked at Week 1 of therapy and decreased thereafter.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of EPIDUO Gel: eyelid edema, sunburn, blister, pain of skin, pruritus, swelling face, conjunctivitis, skin discoloration, rash, eczema and allergic contact dermatitis. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

7 DRUG INTERACTIONS

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

No formal drug-drug interaction studies were conducted with EPIDUO gel.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C. There are no well-controlled trials in pregnant women treated with EPIDUO gel. Animal reproduction studies have not been conducted with the combination gel or benzoyl peroxide. Furthermore, such studies are not always predictive of human response; therefore, EPIDUO gel should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

No teratogenic effects were observed in rats treated with oral doses of 0.15 to 5.0 mg adapalene/kg/day, up to 25 times (mg/m²/day) the maximum recommended human dose (MRHD) of 2 grams of EPIDUO gel. However, teratogenic changes were observed in rats and rabbits when treated with oral doses of ≥ 25 mg adapalene/kg/day representing 123 and 246 times MRHD, respectively. Findings included cleft palate, microphthalmia, encephalocele and skeletal abnormalities in rats; and umbilical hernia, exophthalmos and kidney and skeletal abnormalities in rabbits.

Dermal teratology studies conducted in rats and rabbits at doses of 0.6-6.0 mg adapalene/kg/day [25-59 times (mg/m²) the MRHD] exhibited no fetotoxicity and only minimal increases in supernumerary ribs in both species and delayed ossification in rabbits.

8.3 Nursing Mothers

It is not known whether adapalene or benzoyl peroxide is excreted in human milk following use of EPIDUO gel. Because many drugs are excreted in human milk, caution should be exercised when EPIDUO gel is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of EPIDUO gel in pediatric patients under the age of 12 have not been established.

8.5 Geriatric Use

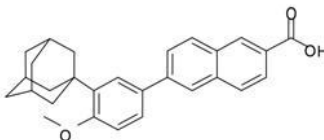
Clinical studies of EPIDUO gel did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

11 DESCRIPTION

EPIDUO (adapalene and benzoyl peroxide) gel, 0.1%/2.5% is a white to very pale yellow, opaque gel for topical use containing adapalene 0.1% and benzoyl peroxide 2.5%.

Adapalene, a synthetic retinoid, is a naphthoic acid derivative with retinoid-like properties. The chemical name for adapalene is (6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid). It has the following structural formula:

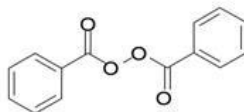
Adapalene:



Molecular formula: C₂₈H₂₈O₃ Molecular weight: 412.5

Benzoyl Peroxide is a highly lipophilic oxidizing agent that localizes in both bacterial and keratinocyte cell membranes. The chemical name for benzoyl peroxide is dibenzoyl peroxide. It has the following structural formula:

Benzoyl Peroxide:



Molecular formula: C₁₄H₁₀O₄ Molecular weight: 242.23

EPIDUO gel contains the following inactive ingredients: acrylamide/sodium acryloyldimethyltaurate copolymer, docusate sodium, edetate disodium, glycerin, isohexadecane, poloxamer 124, polysorbate 80, propylene glycol, purified water, and sorbitan oleate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Adapalene

Adapalene binds to specific retinoic acid nuclear receptors but does not bind to cytosolic receptor protein. Biochemical and pharmacological profile studies have demonstrated that adapalene is a modulator 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.

Benzoyl peroxide

Benzoyl peroxide is an oxidizing agent with bactericidal and keratolytic effects.

12.2 Pharmacodynamics

Pharmacodynamics of EPIDUO gel is unknown.

12.3 Pharmacokinetics

A pharmacokinetic study was conducted in 24 subjects with acne vulgaris who were treated once daily for 30 days with 2 grams/day of EPIDUO gel applied to 1000 cm² of acne involved skin, (face, chest, and upper back).

Two subjects (20%) had quantifiable adapalene plasma concentrations above the limit of quantification (LOQ = 0.1ng/mL). The highest adapalene C_{max} and AUC_{0-24h} was 0.21 ng/mL and 1.99 ng•h/mL, respectively. Excretion of adapalene appears to be primarily by the biliary route.

13 Benzoyl peroxide is absorbed by the skin where it is converted to benzoic acid and eliminated in the urine.

13.1 NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity, photocarcinogenicity, genotoxicity, or fertility studies were conducted with EPIDUO gel. Carcinogenicity studies with adapalene have been conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day (1.2, 3.9, and 12 mg/m²/day), and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/day (0.9, 3.0, and 9.0 mg/m²/day). In terms of body surface area, the highest dose levels are 9.8 (mice) and 7.4 times (rats) the MRHD of 2 grams of EPIDUO gel. In the rat study, an increased incidence of benign and malignant pheochromocytomas in the adrenal medulla of male rats was observed.

No significant increase in tumor formation was observed in rodents topically treated with 15-25% benzoyl peroxide carbopol gel (6-10 times the concentration of benzoyl peroxide in EPIDUO gel) for two years. Rats received maximum daily applications of 138 (males) and 205 (females) mg benzoyl peroxide/kg. In terms of body surface area, these levels are 27-40 times the MRHD. Similar results were obtained in mice topically treated with 25% benzoyl peroxide carbopol gel for 56 weeks followed by intermittent treatment with 15% benzoyl peroxide carbopol gel for rest of the 2 years study period, and in mice topically treated with 5% benzoyl peroxide carbopol gel for two years.

The role of benzoyl peroxide as a tumor promoter has been well established in several animal species. However, the significance of this finding in humans is unknown.

In a photocarcinogenicity study conducted with 5% benzoyl peroxide carbopol gel, no increase in UV-induced tumor formation was observed in hairless mice topically treated for 40 weeks.

No photocarcinogenicity studies were conducted with adapalene. However, animal studies have shown an increased tumorigenic risk with the use of pharmacologically similar drugs (e.g., retinoids) when exposed to UV irradiation in the laboratory or sunlight. Although the significance of these findings to humans is not clear, patients should be advised to avoid or minimize exposure to either sunlight or artificial irradiation sources.

Adapalene did not exhibit mutagenic or genotoxic effects *in vitro* (Ames test, Chinese hamster ovary cell assay, mouse lymphoma TK assay) or *in vivo* (mouse micronucleus test).

Bacterial mutagenicity assays (Ames test) with benzoyl peroxide has provided mixed results, mutagenic potential was observed in a few but not in a majority of investigations. Benzoyl peroxide has been shown to produce single-strand DNA breaks in human bronchial epithelial and mouse epidermal cells, it has caused DNA-protein cross-links in the human cells, and has also induced a dose-dependent increase in sister chromatid exchanges in Chinese hamster ovary cells.

In rat oral studies, 20 mg adapalene/kg/day (120 mg/m²/day; 98 times the MRHD based on mg/m²/day comparison) did not affect the reproductive performance and fertility of F₀ males and females, or growth, development and reproductive function of F₁ offspring.

No fertility studies were conducted with benzoyl peroxide.

14 CLINICAL STUDIES

The safety and efficacy of EPIDUO gel applied once daily for the treatment of acne vulgaris were assessed in two 12-week, multicenter, controlled clinical studies of similar design, comparing EPIDUO gel to the gel vehicle in acne subjects. Treatment response was defined as the percent of subjects who had a two grade improvement and rated 'Clear' and 'Almost Clear' at Week 12 based on the Investigator's Global Assessment (IGA) and mean absolute change from baseline at Week 12 in both inflammatory and non-inflammatory lesion counts. An IGA score of 'Clear' corresponded to residual hyperpigmentation and erythema may be present. An IGA score of 'Almost Clear' corresponded to a few scattered comedones and a few small papules.

In Study 1, 517 subjects were randomized to EPIDUO gel, adapalene 0.1% in vehicle gel, benzoyl peroxide 2.5% in vehicle gel, or vehicle gel. The median age of these 517 subjects was 15 years old and 60% were males.

At baseline subjects had between 20 to 50 inflammatory lesions and 30 to 100 non-inflammatory lesions. The majority of subjects had a baseline IGA score of 'Moderate' which corresponded to more than half of the face is involved, many comedones, papules and pustules. The efficacy results at week 12 are presented in Table 3.

In Study 2, 1668 subjects were randomized to EPIDUO gel, adapalene 0.1% in vehicle gel, benzoyl peroxide 2.5% in vehicle gel, or vehicle gel. The median age of subjects was 16 years old and 49% were males. At baseline subjects had between 20 to 50 inflammatory lesions and 30 to 100 non-inflammatory lesions as well as an Investigator Global Assessment score of 'Moderate'. The efficacy results at week 12 are presented in Table 3.

Table 3: Clinical Efficacy of EPIDUO Gel at Week 12

Study 1				
	EPIDUO gel (N = 149)	Adapalene 0.1% in Vehicle gel (N = 148)	Benzoyl Peroxide 2.5% in Vehicle gel (N = 149)	Vehicle gel (N = 71)
IGA: Two Grade Improvement and Clear or Almost Clear	32 (21.5%)	18 (12.2%)	18 (12.1%)	4 (5.6%)
Inflammatory Lesions: Mean Absolute (Percent) Change	16.0 (52.4%)	11.4 (39.9%)	10.5 (35.8%)	9.5 (31.8%)
Non-inflammatory Lesions: Mean Absolute (Percent) Change	23.4 (45.9%)	15.2 (29.6%)	13.7 (32.2%)	13.2 (27.8%)

Study 2

	EPIDUO gel (N = 415)	Adapalene 0.1% in Vehicle gel (N = 420)	Benzoyl Peroxide 2.5% in Vehicle gel (N = 415)	Vehicle gel (N = 418)
IGA: Two Grade Improvement and Clear or Almost Clear	125 (30.1%)	83 (19.8%)	92 (22.2%)	47 (11.3%)
Inflammatory Lesions: Mean Absolute (Percent) Change	15.4 (53.4%)	12.3 (41.7%)	13.7 (47.6%)	8.7 (30.2%)
Non-inflammatory Lesions: Mean Absolute (Percent) Change	24.6 (48.1%)	21.0 (40.8%)	19.2 (37.2%)	11.3 (23.2%)

In both Studies 1 and 2 the treatment effect was smaller in subjects with a small number of baseline lesions than in subjects with a large number of baseline lesions.

16 HOW SUPPLIED/STORAGE AND HANDLING

EPIDUO (adapalene and benzoyl peroxide) gel 0.1% / 2.5% is white to very pale yellow in color and opaque in appearance, and is supplied as follows:

45 gram tube NDC 0299-5908-45

Storage and handling

- Store at 25°C; excursions permitted to 15° – 30°C (59° – 86°F).
- Protect from light.
- Keep out of reach of children.
- Keep away from heat.
- Keep tube tightly closed.

17 PATIENT COUNSELING INFORMATION

[See FDA- approved patientlabeling (Patient Information)]

Information for Patients

- Advise patients to cleanse the area to be treated with a mild or soapless cleanser; pat dry. Apply EPIDUO gel as a thin layer, avoiding the eyes, lips and mucous membranes.
- Advise patients not to use more than the recommended amount and not to apply more than once daily as this will not produce faster results, but may increase irritation.
- EPIDUO gel may cause irritation such as erythema, scaling, dryness, stinging or burning.
- Advise patients to minimize exposure to sunlight, including sunlamps.
Recommend the use of sunscreen products and protective apparel, (e.g., hat) when exposure cannot be avoided.
- EPIDUO gel may bleach hair and colored fabric.

Patient Information
EPIDUO® (Ep-E-Do-Oh)
(adapalene and benzoyl peroxide)
gel 0.1%/2.5%

Important: For use on the skin only (topical). Do not use EPIDUO gel in or on your mouth, eyes, or vagina.

Read this Patient Information leaflet about EPIDUO gel before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your treatment or your medical condition. If you have any questions about EPIDUO gel, talk with your doctor or pharmacist.

What is EPIDUO gel?

EPIDUO gel is a prescription medicine for skin use only (topical) used to treat acne vulgaris in people 12 years of age and older.

Acne vulgaris is a condition in which the skin has blackheads, whiteheads and pimples.

It is not known if EPIDUO gel is safe and effective in children younger than 12 years old.

What should I tell my doctor before using EPIDUO gel?

Before you use EPIDUO gel, tell your doctor if you:

- have other skin problems, including cuts or sunburn
- have any other medical conditions
- are pregnant or planning to become pregnant. It is not known if EPIDUO gel can harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if EPIDUO gel passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use EPIDUO gel.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Especially tell your doctor if you use any other medicine for acne. Using EPIDUO gel with topical medicines that contain sulfur, resorcinol or salicylic acid may cause skin irritation.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use EPIDUO gel?

- Use EPIDUO gel exactly as your doctor tells you to use it. EPIDUO gel is for skin use only. Do not use EPIDUO gel in or on your mouth, eyes, or vagina.
- Apply EPIDUO gel 1 time a day.
- Do not use more EPIDUO gel than you need to cover the treatment area. Using too much EPIDUO gel or using it more than 1 time a day may increase your chance of skin irritation.

Applying EPIDUO gel:

- Wash the area where the gel will be applied with a mild cleanser and pat dry.

- Squeeze a small amount (about the size of a pea) of EPIDUO gel onto your fingertips and spread a thin layer over the affected area.

What should I avoid while using EPIDUO gel?

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. EPIDUO gel can make your skin sensitive to sun and the light from tanning beds and sunlamps. You should wear sunscreen and wear a hat and clothes that cover the areas treated with EPIDUO gel if you have to be in sunlight.
- You should avoid weather extremes such as wind and cold as this may cause irritation to your skin.
- You should avoid applying EPIDUO gel to cuts, abrasions and sunburned skin.
- 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.
- You should avoid the use of “waxing” as a hair removal method on skin treated with EPIDUO gel.
- EPIDUO gel may bleach your clothes or hair. Allow EPIDUO gel to dry completely before dressing to prevent bleaching of your clothes.

What are the possible side effects of EPIDUO gel?

EPIDUO gel may cause serious side effects including:

- Local skin reactions. Local skin reactions are most likely to happen during the first 4 weeks of treatment and usually lessen with continued use of EPIDUO gel. Signs and symptoms of local skin reaction include:
 - Redness
 - Dryness
 - Swelling
 - Scaling
 - Stinging or burning

Tell your doctor right away if these side effects continue for longer than 4 weeks or get worse, you may have to stop using EPIDUO gel.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of EPIDUO gel. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to GALDERMA LABORATORIES, L.P. at 1-866-735-4137

How should I store EPIDUO gel?

- Store EPIDUO gel at room temperature, 68° – 77° F (20° – 25° C)
- Keep EPIDUO gel inside container and out of light and away from heat.

Keep EPIDUO gel and all medicines out of the reach of children.

NDA 022320/S-001

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General information about EPIDUO gel

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use EPIDUO gel for a condition for which it was not prescribed. Do not give EPIDUO gel to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about EPIDUO gel. If you would like more information, talk with your doctor. You can also ask your doctor or pharmacist for information about EPIDUO gel that is written for health professionals.

What are the ingredients in EPIDUO gel?

Active ingredient: adapalene and benzoyl peroxide

Inactive ingredients: acrylamide/sodium acryloyldimethyltaurate copolymer, docusate sodium, edetate disodium, glycerin, isohexadecane, polaxamer 124, polysorbate 80, propylene glycol, purified water and sorbitan oleate

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: **January/2011**

Marketed by:
GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Manufactured by:
Galderma Production Canada Inc., Baie d'Urfé, QC, H9X 3S4 Canada
Made in Canada.
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