HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use EPIDUO FORTE safely and effectively. See full prescribing information for EPIDUO FORTE.

EPIDUO® FORTE (adapalene and benzoyl peroxide) topical gel
Initial U.S. Approval: 2015

---------- INDICATIONS AND USAGE----------
EPIDUO FORTE, is a combination of adapalene, a retinoid, and benzoyl peroxide and is indicated for the topical treatment of acne vulgaris in adults and pediatric patients 12 years of age and older. (1)

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

----------DOSAGE FORMS AND STRENGTHS----------
Topical Gel, 0.3%/2.5%. (3)

----------CONTRAINDICATIONS----------
EPIDUO FORTE is contraindicated in patients with a history of hypersensitivity reactions to benzoyl peroxide or any components of the formulation in EPIDUO FORTE.(4)

----------WARNINGS AND PRECAUTIONS----------
- *Hypersensitivity*: Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with the use of benzoyl peroxide products. (5.1)
- *Photosensitivity*: Avoid exposure to sunlight and sunlamps. Wear broad spectrum sunscreen and protective clothing when sun exposure cannot be avoided. (5.2)
- *Skin Irritation*: Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of EPIDUO FORTE and may necessitate discontinuation. (5.3)

----------ADVERSE REACTIONS----------
The most common adverse reactions (incidence ≥1%) are skin irritation, eczema, atopic dermatitis and skin burning sensation. (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: 04/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

- For topical use only. EPIDUO FORTE is not for oral, ophthalmic, or intravaginal use.
- Apply a thin layer of EPIDUO FORTE 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).
- Wash hands after application as EPIDUO FORTE may bleach hair or colored fabrics.
- Avoid the eyes, lips and mucous membranes.

3 DOSAGE FORMS AND STRENGTHS

Each gram of EPIDUO FORTE topical gel contains 3 mg (0.3%) adapalene and 25 mg (2.5%) benzoyl peroxide in a white to very pale yellow, opaque gel. EPIDUO FORTE is available in pumps containing 15 g, 30 g, 45 g, 60 g or 70 g.

4 CONTRAINDICATIONS

EPIDUO FORTE is contraindicated in patients with a history of hypersensitivity reactions to benzoyl peroxide or any components of the formulation in EPIDUO FORTE.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Hypersensitivity reactions, including anaphylaxis, angioedema, and urticaria, have been reported with the use of benzoyl peroxide products. If a serious hypersensitivity reaction occurs, discontinue EPIDUO FORTE immediately and initiate appropriate therapy.

5.2 Photosensitivity

Avoid exposure to sunlight, including sunlamps, during the use of EPIDUO FORTE. Patients with high levels of sun exposure and those with inherent sensitivity to sun should exercise particular caution. Use of broad spectrum 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 FORTE.

5.3 Skin Irritation/Contact Dermatitis

Erythema, scaling, dryness, and stinging/burning may be experienced with use of EPIDUO FORTE. 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 FORTE, 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 FORTE.

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

The following adverse reactions are discussed in greater detail elsewhere in the labeling:

• Hypersensitivity *[see Warnings and Precautions (5.1)]*

• Skin Irritation/Contact Dermatitis *[see Warnings and Precautions (5.3)]*

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 the randomized, double-blind, vehicle- and active-controlled clinical trial, 217 subjects were exposed to EPIDUO FORTE. A total of 197 subjects with acne vulgaris, 12 years and older, were treated once daily for 12 weeks. Adverse reactions reported within 12 weeks of treatment in at least 1% of subjects treated with EPIDUO FORTE and for which the rate with EPIDUO FORTE exceeded the rate for the vehicle are presented in Table 1:

Table 1. Adverse Reactions Occurring in ≥1% of Subjects with Acne Vulgaris in a 12-week Clinical Trial

	EPIDUO FORTE (N=217)	Adapalene and Benzoyl Peroxide Gel, 0.1%/2.5% (N=217)	Vehicle (N=69)
Skin irritation	4%	<1%	0%
Eczema	1%	0%	0%
Dermatitis atopic	1%	0%	0%
Skin burning sensation	1%	0%	0%

Local tolerability evaluations presented in Table 2, were conducted at each trial visit in the clinical trial by assessment of erythema, scaling, dryness, and stinging/burning, which peaked at Week 1 of therapy and decreased thereafter.

Table 2. Incidence of Local Cutaneous Irritation in 12-week Clinical Trial in Subjects with Acne Vulgaris

	Maximum Severity During Treatment		End of Treatment Severity (Final Score)	
	Moderate	Severe	Moderate	Severe
EPIDUO FORTE (N=213)				
Erythema	20%	1%	4%	<1%
Scaling	17%	1%	1%	<1%
Dryness	15%	2%	3%	<1%
Stinging/burning	19%	6%	1%	1%
Adapalene and Benzoyl Peroxide Gel, 0.1%/2.5% (N=212)				
Erythema	15%	1%	2%	<1%
Scaling	12%	<1%	2%	0%
Dryness	13%	1%	2%	0%
Stinging/burning	14%	9%	3%	0%
Vehicle (N=68)				
Erythema	6%	1%	1%	0%
Scaling	6%	0%	1%	0%
Dryness	4%	1%	1%	0%
Stinging/burning	3%	1%	0%	0%

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of EPIDUO FORTE. 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.

Skin and subcutaneous tissue disorders: sunburn, blister (including vesicles and bullae), pruritus, hyperpigmentation and hypopigmentation.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available pharmacovigilance data with EPIDUO FORTE use in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with the combination gel.

Adapalene gel, 0.3%

Available data from clinical trials with adapalene gel 0.3% use in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of adapalene to pregnant rats and rabbits during organogenesis at dose exposures 41 and 81 times, respectively, the human exposure at the maximum recommended human dose (MRHD) of 2 g resulted in fetal skeletal and visceral malformations *(see Data)*.

Benzoyl peroxide gel, 2.5%
The systemic exposure of benzoyl peroxide is unknown. Based on published literature, benzoyl peroxide is rapidly metabolized to benzoic acid (an endogenous substance), which is eliminated in the urine. Hence, maternal use is not expected to result in fetal exposure of the drug.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data
Animal Data
No malformations were observed in rats treated with oral adapalene doses of 0.15 to 5.0 mg/kg/day, up to 8 times the MRHD of 2 grams of EPIDUO FORTE based on a mg/m^2 comparison. However, malformations were observed in rats and rabbits when treated with oral doses of $\geq$ 25 mg/kg/day adapalene (41 and 81 times the MRHD, respectively, based on a mg/m^2 comparison). Findings included cleft palate, microphthalmia, encephalocele, and skeletal abnormalities in rats and umbilical hernia, exophthalmos, and kidney and skeletal abnormalities in rabbits.

Dermal adapalene embryofetal development studies in rats and rabbits at doses up to 6.0 mg/kg/day (9.7 and 19.5 times the MRHD, respectively, based on a mg/m^2 comparison) exhibited no fetotoxicity and only minimal increases in skeletal variations (supernumerary ribs in both species and delayed ossification in rabbits).

8.2 Lactation
Risk Sumary
Adapalene gel, 0.3%
There are no data on the presence of adapalene topical gel or its metabolite in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies, adapalene is present in rat milk with oral administration of the drug. When a drug is present in animal milk, it is likely that the drug will be present in human milk. It is possible that topical administration of large amounts of adapalene could result in sufficient systemic absorption to produce detectable quantities in human milk *(see Clinical Considerations)*.

Benzoyl peroxide gel, 2.5%
The systemic exposure of benzoyl peroxide is unknown. Based on the published literature, benzoyl peroxide is rapidly metabolized to benzoic acid (an endogenous substance), which is eliminated in the urine. Any amount of benzoyl peroxide excreted into human milk by a nursing mother would be expected to be rapidly metabolized by tissue and stomach esterases. There are no data on the presence of benzoyl peroxide in human milk, its effects on the breastfed infant or its effects on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EPIDUO FORTE and any potential adverse effects on the breastfed child from EPIDUO FORTE or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breastmilk, use EPIDUO FORTE on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply EPIDUO FORTE directly to the nipple and areola to avoid direct infant exposure.

8.4 Pediatric Use

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

8.5 Geriatric Use

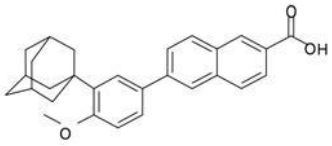
Clinical studies of EPIDUO FORTE did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

11 DESCRIPTION

EPIDUO FORTE (adapalene and benzoyl peroxide) topical gel, 0.3%/2.5% is a white to very pale yellow, opaque gel for topical use containing adapalene 0.3% 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:

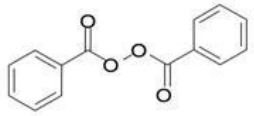
Adapalene:



Molecular formula: $C_{28}H_{28}O_3$ 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: $C_{14}H_{10}O_4$ Molecular weight: 242.23

EPIDUO FORTE 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 FORTE is unknown.

12.3 Pharmacokinetics

A pharmacokinetic trial was conducted in 26 adult and adolescent subjects (12 to 33 years of age) with severe acne vulgaris who were treated with once-daily applications during a 4-week period with, on average, 2.3 grams/day (range 1.6 - 3.1 grams/day) of EPIDUO FORTE applied as a thin layer to the face, shoulders, upper chest and upper back. After a 4-week treatment, 16 subjects (62%) had quantifiable adapalene plasma concentrations above the limit of quantification of 0.1 ng/mL, with a mean C_{max} of 0.16 ± 0.08 ng/mL and a mean $AUC_{0\text{-}24hr}$ of 2.49 ± 1.21 ng.h/mL. The most exposed subject had adapalene C_{max} and $AUC_{0\text{-}24hr}$ of 0.35 ng/mL and 6.41 ng.h/mL, respectively. Excretion of adapalene appears to be primarily by the biliary route. Benzoyl peroxide is absorbed by the skin where it is converted to benzoic acid and eliminated in the urine.

Drug Interactions

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity, genotoxicity, or fertility studies were conducted with EPIDUO FORTE.

Carcinogenicity studies with adapalene were conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day (1.2, 3.9, and 12 mg/m^2/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/m^2/day). The highest dose levels are 3.2 (mice) and 2.4 (rats) times the MRHD of EPIDUO FORTE based on a mg/m^2 comparison. In the rat study, an increased incidence of benign and malignant pheochromocytomas reported 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 FORTE) for two years. Rats received maximum daily applications of 138 (males) and 205 (females) mg/kg benzoyl peroxide (27-40 times the MRHD based on a mg/m^2 comparison). 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 year study period, and in mice topically treated with 5% benzoyl peroxide carbopol gel for two years.

Benzoyl peroxide is a tumor promoter in several animal species. The significance of this finding in humans is unknown.

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

Benzoyl peroxide caused DNA strand breaks and DNA-protein cross-links in mammalian cells, increased sister chromatid exchanges in Chinese hamster ovary cells, and was mutagenic in a few, but not all, *in vitro* bacterial mutagenicity assays (Ames tests) conducted.

In rat oral studies, 20 mg/kg/day adapalene (32 times the MRHD based on a mg/m^2 comparison) did not affect the reproductive performance and fertility of F_0 males and females or the growth, development, or reproductive function of F_1 offspring.

No fertility studies were conducted with benzoyl peroxide.

14 CLINICAL STUDIES

The safety and efficacy of EPIDUO FORTE applied once daily for 12 weeks for the treatment of acne vulgaris were assessed in a multicenter, randomized, double-blind, vehicle-controlled trial, comparing EPIDUO FORTE to vehicle gel in subjects with acne vulgaris. The trial also evaluated adapalene and benzoyl peroxide gel, 0.1%/2.5%, a lower strength product than EPIDUO FORTE (adapalene and benzoyl peroxide) topical gel, 0.3%/2.5%. In this trial, 217

subjects were treated with EPIDUO FORTE, 217 subjects with adapalene and benzoyl peroxide, gel, 0.1%/2.5% and 69 subjects with the vehicle gel.

Treatment response was defined as the percent of subjects who were rated "clear" or "almost clear' at Week 12 with at least a two-grade improvement 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 clear skin with no inflammatory or non-inflammatory lesions. An IGA score of "almost clear" corresponded to a few scattered comedones and a few small papules.

At baseline, 50% of subjects were graded as "moderate" (IGA Grade 3) and 50% were graded as "severe" (IGA Grade 4) on the IGA scale. Subjects had an average of 98 (range 51-226) total lesions of which the mean number of inflammatory lesions was 38 (range: 20-99) and the mean number of non-inflammatory lesions was 60 (range 30-149). Subjects ranged in age from 12 to 57 years, with 273 (54%) of subjects 12 to 17 years of age. Approximately equal number of males (48%) and females (52%) were enrolled.

The IGA success rate, mean reduction, and percent reduction in acne lesion counts from baseline after 12 weeks of treatment are presented in the following table.

Table 3. Clinical Efficacy of EPIDUO FORTE at Week 12 in Subjects with Acne Vulgaris

	EPIDUO FORTE (N=217)	**Adapalene and Benzoyl Peroxide Gel, 0.1%/2.5% (N=217)***	**Vehicle (N=69)**
IGA: two-grade improvement and "clear" or "almost clear"	33.7%	27.3%	11.0%
Inflammatory lesions: mean absolute (percent) reduction	27.8 (68.7%)	26.5 (69.3%)	13.2 (39.2%)
Non-inflammatory lesions: mean absolute (percent) reduction	40.5 (68.3%)	40.0 (68.0%)	19.7 (37.4%)

* This trial was not designed or powered to compare the efficacy of EPIDUO FORTE to the lower strength adapalene and benzoyl peroxide gel, 0.1%/2.5%, nor to compare the lower strength adapalene and benzoyl peroxide gel, 0.1%/2.5% to the vehicle control.

In subjects graded as "severe" (IGA Grade 4), efficacy was observed in the EPIDUO FORTE group.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

EPIDUO FORTE (adapalene and benzoyl peroxide) topical gel 0.3% / 2.5% is white to very pale yellow in color and opaque in appearance, and is supplied as follows:

15 gram pump NDC 0299-5906-15
30 gram pump NDC 0299-5906-30
45 gram pump NDC 0299-5906-45
60 gram pump NDC 0299-5906-60
70 gram pump NDC 0299-5906-70

16.2 Storage and handling

- Store at controlled room temperature 20 – 25˚C (68 – 77˚F) with excursions permitted to 15˚ – 30˚C (59˚ – 86˚F) [see USP controlled room temperature].
- Keep away from heat.
- Protect from light.
- Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA approved patient labeling (Patient Information).

Hypersensitivity
Inform patients that serious hypersensitivity reactions occurred with the use of benzoyl peroxide products. If a patient experiences a serious hypersensitivity reaction, instruct patient to discontinue EPIDUO FORTE immediately and seek medical help *[see Warnings and Precautions (5.1)]*.

Photosensitivity
Advise patients to minimize or avoid exposure to natural or artificial light, including tanning beds or UVA/B treatment. Recommend the use of broad spectrum sunscreen products and protective apparel (e.g., hat) when exposure cannot be avoided *[see Warnings and Precautions (5.2)]*.

Skin Irritation/Contact Dermatitis
Inform patients that EPIDUO FORTE may cause irritation such as erythema, scaling, dryness, stinging or burning *[see Warnings and Precautions (5.3)]*.

Lactation
Use EPIDUO FORTE on the smallest part of the skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply EPIDUO FORTE directly to the nipple and areola to avoid direct infant exposure *[see Use in Specific Populations (8.2)]*.

Administration Instructions

- Advise patients to cleanse the area to be treated with a mild or soapless cleanser; pat dry. Apply EPIDUO FORTE 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.
- Wash hands after application as EPIDUO FORTE may bleach hair and colored fabric.

Marketed by:
GALDERMA LABORATORIES, L.P.
Fort Worth, Texas 76177 USA

Made in Canada

Patient information
EPIDUO FORTE (Ep-E-Do-oh For-Tay)
(adapalene and benzoyl peroxide) topical gel

Important information: EPIDUO FORTE is for use on the skin only (topical). Do not use EPIDUO FORTE in or on your mouth, eyes, or vagina.

What is EPIDUO FORTE?

EPIDUO FORTE is a prescription medicine used on the skin (topical) to treat acne vulgaris.
It is not known if EPIDUO FORTE is safe and effective in children under 12 years of age.

Do not use EPIDUO FORTE if you have had an allergic reaction to benzoyl peroxide or any of the ingredients in EPIDUO FORTE. See the end of this Patient Information leaflet for a complete list of ingredients in EPIDUO FORTE.

Before using EPIDUO FORTE, tell your doctor about all of your medical conditions, including if you:

- have other skin problems, including cuts, abrasions, sunburn or eczema.
- are pregnant or plan to become pregnant. It is not known if EPIDUO FORTE can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if EPIDUO FORTE 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 FORTE. If you use EPIDUO FORTE while breastfeeding, use EPIDUO FORTE on the smallest area of the skin and for the shortest time needed. Do not apply EPIDUO FORTE directly to the nipple and the areola to minimize contact with your baby.

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

How should I use EPIDUO FORTE?

- Use EPIDUO FORTE exactly as your doctor tells you to use it.
- Apply EPIDUO FORTE 1 time a day.
- Do not use more EPIDUO FORTE than you need to cover the treatment area. Using too much EPIDUO FORTE or using it more than 1 time a day may increase your chance of skin irritation.

Applying EPIDUO FORTE:

- Wash the area where the gel will be applied with a mild or soapless cleanser and pat dry.
- EPIDUO FORTE comes in a pump. Depress the pump to dispense a small amount (about the size of a pea) of EPIDUO FORTE and spread a thin layer over the treatment area. Use a pea-sized amount for each area of the face (forehead, chin, and each cheek).
- Wash your hands right away after applying the gel. EPIDUO FORTE may bleach your hair or colored fabrics. Allow EPIDUO FORTE to dry completely before dressing to prevent bleaching of your clothes.

What should I avoid while using EPIDUO FORTE?

- Avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. EPIDUO FORTE can make your skin sensitive to sun and the light from tanning beds and sunlamps. Use sunscreen and wear a hat and clothes that cover the areas treated with EPIDUO FORTE if you have to be in sunlight.
- Cold weather and wind may irritate skin treated with EPIDUO FORTE.
- Avoid applying EPIDUO FORTE to cuts, abrasions, and sunburned skin.
- Avoid skin products that may dry or irritate your skin such as medicated or harsh soaps, astringents, cosmetics that make your skin dry, and products containing high levels of alcohol, spices, or limes.
- Avoid the use of “waxing” as a hair removal method on skin treated with EPIDUO FORTE.

What are the possible side effects of EPIDUO FORTE?

EPIDUO FORTE may cause serious side effects including:

- **Allergic reactions.** Stop using EPIDUO FORTE and get medical help right away if you have any of the following symptoms during treatment with EPIDUO FORTE:
  - hives, rash or severe itching
  - swelling of your face, eyes, lips, tongue, or throat
  - trouble breathing or throat tightness
  - feeling faint, dizzy, or lightheaded

- **Skin irritation.** Skin irritation is common with EPIDUO FORTE and is most likely to happen during the first 4 weeks of treatment, and usually lessen with continued use of EPIDUO FORTE. Skin reactions at the treatment area include redness, scaling, dryness, stinging, burning, itching and swelling. Tell your doctor if you get any skin reactions.
- **Sensitivity to sunlight.** See **"What should I avoid while using EPIDUO FORTE?"**

These are not all of the possible side effects of EPIDUO FORTE.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EPIDUO FORTE?

- Store EPIDUO FORTE at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep EPIDUO FORTE out of light and away from heat.

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

General information about the safe and effective use of EPIDUO FORTE.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.
Do not use EPIDUO FORTE for a condition for which it was not prescribed. Do not give EPIDUO FORTE to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for information about EPIDUO FORTE that is written for health professionals.

What are the ingredients in EPIDUO FORTE?
Active ingredient: adapalene and benzoyl peroxide
Inactive ingredients: acrylamide/sodium acryloydimethyltaurate copolymer, docusate sodium, edetate disodium, glycerin, isohexadecane, polaxamer 124, polysorbate 80, propylene glycol, purified water and sorbitan oleate.

Marketed by: GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Made in Canada

For more information, call GALDERMA LABORATORIES, L.P. at 1-866-735-4137.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised:04/2022