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TEXT FREE AREA

Adapalene and Benzoyl Peroxide
Topical Gel, 0.3% / 2.5%

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Adapalene and Benzoyl Peroxide
Topical Gel, 0.3% / 2.5%

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ADAPALENE AND BENZOYL PEROXIDE TOPICAL GEL safely and effectively. See full prescribing information for ADAPALENE AND BENZOYL PEROXIDE TOPICAL GEL.

ADAPALENE AND BENZOYL PEROXIDE topical gel

Initial U.S. Approval: 2015

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

Adapalene and benzoyl peroxide topical gel 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
- Adapalene and benzoyl peroxide topical gel is not for oral, ophthalmic or intravaginal use. (2)
- Apply a thin layer of adapalene and benzoyl peroxide topical gel 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-----

Adapalene and benzoyl peroxide topical gel is contraindicated in patients with a history of hypersensitivity reactions to benzoyl peroxide or any components of the formulation in adapalene and benzoyl peroxide topical gel. (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 adapalene and benzoyl peroxide topical gel 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 Taro Pharmaceuticals U.S.A., Inc. at 1-866-923-4914 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Revised: 12/2022

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ADVERSE REACTIONS

Adapalene and benzoyl peroxide topical gel is indicated for the topical treatment of acne vulgaris in adults and pediatric patients 12 years of age and older.

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

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

Adapalene and benzoyl peroxide topical gel is contraindicated in patients with a history of hypersensitivity reactions to benzoyl peroxide or any components of the formulation in adapalene and benzoyl peroxide topical gel.

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 adapalene and benzoyl peroxide topical gel immediately and initiate appropriate therapy.

Photosensitivity

Avoid exposure to sunlight, including sunlamps, during the use of adapalene and benzoyl peroxide topical gel. 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 adapalene and benzoyl peroxide topical gel.

Skin Irritation/Contact Dermatitis

Erythema, scaling, dryness, and stinging/burning may be experienced with use of adapalene and benzoyl peroxide topical 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 adapalene and benzoyl peroxide topical 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 adapalene and benzoyl peroxide topical 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).

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 adapalene and benzoyl peroxide topical gel. 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 adapalene and benzoyl peroxide topical gel and for which the rate with adapalene and benzoyl peroxide topical gel 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

	Adapalene and Benzoyl Peroxide Topical Gel, 0.3%/2.5% (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
Adapalene and Benzoyl Peroxide Topical Gel, 0.3%/2.5% (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%

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Patient Information

Adapalene (a dap’ a leen) and Benzoyl Peroxide (BEN-zoe-il per-OX-ide) Topical Gel

Important information:

Adapalene and benzoyl peroxide topical gel is for use on the skin only (topical). Do not use adapalene and benzoyl peroxide topical gel in or on your mouth, eyes, or vagina.

What is adapalene and benzoyl peroxide topical gel?

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

Do not use adapalene and benzoyl peroxide topical gel if you

have had an allergic reaction to benzoyl peroxide or any of the ingredients in adapalene and benzoyl peroxide topical gel. See the end of this Patient Information leaflet for a complete list of ingredients in adapalene and benzoyl peroxide topical gel.

Before using adapalene and benzoyl peroxide topical gel, 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 adapalene and benzoyl peroxide topical gel can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if adapalene and benzoyl peroxide 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 adapalene and benzoyl peroxide topical gel. If you use adapalene and benzoyl peroxide topical gel while breastfeeding, use adapalene and benzoyl peroxide topical gel on the smallest area of the skin and for the shortest time needed. Do not apply adapalene and benzoyl peroxide topical gel 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 adapalene and benzoyl peroxide topical gel?

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

Applying adapalene and benzoyl peroxide topical gel:

- Wash the area where the gel will be applied with a mild or soapless cleanser and pat dry.
- Adapalene and benzoyl peroxide topical gel comes in a pump. Depress the pump to dispense a small amount (about the size of a pea) of adapalene and benzoyl peroxide topical gel 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. Adapalene and benzoyl peroxide topical gel may bleach your hair or colored fabrics. Allow adapalene and benzoyl peroxide topical gel to dry completely before dressing to prevent bleaching of your clothes.

What should I avoid while using adapalene and benzoyl peroxide topical gel?

- Avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. Adapalene and benzoyl peroxide topical gel 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 adapalene and benzoyl peroxide topical gel if you have to be in sunlight.

Pharmacist: Please cut or tear at dotted line and provide this patient package insert to your customer.

