

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

DUAC (clindamycin phosphate and benzoyl peroxide) gel, for topical use
Initial U.S. Approval: 2000

INDICATIONS AND USAGE

DUAC is a combination of clindamycin phosphate (a lincosamide antibacterial) and benzoyl peroxide indicated for the topical treatment of inflammatory acne vulgaris in patients 12 years and older. (1)

Limitation of Use

When compared with the use of benzoyl peroxide alone in the same vehicle, DUAC has not demonstrated any additional benefit for the treatment of non-inflammatory acne. (1)

DOSAGE AND ADMINISTRATION

- Before applying DUAC, gently wash the skin, rinse with warm water, and pat dry (2)
- Apply a thin layer of DUAC (clindamycin phosphate and benzoyl peroxide) gel, 1.2%/5%, to the face once daily, in the evening. (2)
- Avoid application of DUAC to the eyes, mouth, lips, mucous membranes, or areas of broken skin (2)
- DUAC is not for oral, ophthalmic, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Gel: Each gram of gel contains 12 mg of clindamycin phosphate (1.2%) and 50 mg of benzoyl peroxide (5%). (3)

CONTRAINDICATIONS

DUAC is contraindicated in patients (4):

- Who have demonstrated hypersensitivity to clindamycin, benzoyl peroxide, any components of DUAC, or lincomycin.
- With a history of regional enteritis, ulcerative colitis, pseudomembranous colitis, or antibiotic-associated colitis.

WARNINGS AND PRECAUTIONS

- **Colitis:** If significant diarrhea occurs, DUAC should be discontinued and diagnostic stool cultures for *Clostridium difficile* and stool assay for *C. difficile* toxin should be considered. (5.1)
- **Increased Risk of Photosensitivity:** Minimize sun exposure and use of tanning beds or sun lamps following topical application of DUAC. Use sunscreen, as appropriate. (5.2)

ADVERSE REACTIONS

The most common local adverse reactions ($\geq 5\%$) are erythema, peeling, dryness, and burning. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Stiefel Laboratories, Inc. at 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- **Erythromycin:** Avoid using DUAC in combination with erythromycin-containing products due to DUAC's clindamycin component. (7.1)
- **Topical Drugs Used to Treat Acne:** If irritancy or dermatitis occurs with concomitant use of DUAC with another topical drug to treat acne, reduce frequency of application or temporarily interrupt treatment and resume once the irritation subsides. Treatment should be discontinued if the irritation persists (7.2).
- **Neuromuscular Blocking Drugs:** Concomitant use of DUAC with neuromuscular blocking drugs should be used with caution (7.3).
- **Topical Sulfone Products:** The concomitant use of DUAC with topical sulfone products may cause skin and facial hair to temporarily change color (yellow/orange) (7.4).

USE IN SPECIFIC POPULATIONS

Lactation: If DUAC is used during lactation, mothers should wash their hands after applying DUAC to avoid transferring the drug to the breast/nipple area and other areas with increased risk for potential ingestion by the breastfeeding child, and to avoid accidental ingestion by the breastfeeding child (8.2).

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

Revised: 10/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

DUAC is indicated for the topical treatment of inflammatory acne vulgaris in patients 12 years and older.

Limitations of Use

When compared with the use of benzoyl peroxide alone in the same vehicle, DUAC has not demonstrated any additional benefit for the treatment of non-inflammatory acne vulgaris.

2 DOSAGE AND ADMINISTRATION

Before applying DUAC, gently wash the skin, rinse with warm water, and pat dry.

Apply a thin layer of DUAC (clindamycin phosphate and benzoyl peroxide) gel, 1.2%/5%, to the face once daily, in the evening. Avoid application of DUAC to the eyes, mouth, lips, mucous membranes, or areas of broken skin.

DUAC is not for oral, ophthalmic, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Gel: Each gram of gel contains 12 mg of clindamycin phosphate (1.2%) and 50 mg of benzoyl peroxide (5%) in 45-gram tubes. The gel is white to slightly yellow, and opaque.

4 CONTRAINDICATIONS

DUAC is contraindicated in patients:

- Who have demonstrated hypersensitivity to clindamycin, benzoyl peroxide, any components of DUAC, or lincomycin. Anaphylaxis, as well as other allergic reactions leading to hospitalization, have been reported in postmarketing use with DUAC [*see Adverse Reactions (6.2)*].
- With a history of regional enteritis, ulcerative colitis, pseudomembranous colitis, or antibiotic-associated colitis [*see Warnings and Precautions (5.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Colitis

If significant diarrhea occurs, DUAC should be discontinued and diagnostic stool cultures for *Clostridium difficile* and stool assay for *C. difficile* toxin should be considered.

Systemic absorption of clindamycin has been demonstrated following topical use of clindamycin.

- Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.
- Severe colitis has occurred following oral and parenteral administration of clindamycin (DUAC is only approved for topical use) with an onset of up to several weeks following cessation of therapy. Antiperistaltic drugs such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate a toxin(s) produced by Clostridia is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus.

5.2 Increased Risk of Photosensitivity

Minimize sun exposure and use of tanning beds or sun lamps following topical application of DUAC [see *Nonclinical Toxicology (13.1)*]. Use sunscreen, as appropriate. Patients who have considerable sun exposure due to their occupation and those with inherent sensitivity to the sun should increase sun protective measures.

Benzoyl peroxide, a component of DUAC, may cause increased sensitivity to sunlight and light from tanning beds or sun lamps.

6 ADVERSE REACTIONS

The following adverse reaction is described in more detail in the *Warnings and Precautions* section of the labeling:

- Colitis [see *Warnings and Precautions (5.1)*].
- Photosensitivity [see *Warnings and Precautions (5.2)*].

6.1 Clinical Trials Experience

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

During Trials 1, 2, 3, 4, and 5 [see *Clinical Studies (14)*], 397 subjects were treated with topical DUAC (clindamycin phosphate and benzoyl peroxide) gel once daily for 11 weeks for the treatment of moderate to moderately severe facial acne vulgaris. All subjects were graded for facial local skin reactions (erythema, peeling, burning, and dryness) on the following scale: 0 = absent, 1 = mild, 2 = moderate, and 3 = severe. The percentage of DUAC-treated subjects that had symptoms present before treatment (at baseline) and during treatment is presented in Table 1.

Table 1. Local Skin Reactions in 397 DUAC-Treated Subjects with Moderate to Moderately Severe Facial Acne Vulgaris (Trials 1, 2, 3, 4, and 5)¹

Symptom	Before Treatment (Baseline)			During DUAC Treatment		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Erythema	28%	3%	0	26%	5%	0
Peeling	6%	<1%	0	17%	2%	0
Dryness	6%	<1%	0	15%	1%	0
Burning	3%	<1%	0	5%	<1%	0

¹ Percentage of subjects with a local skin reaction (number of subjects in the DUAC group with the symptom divided by the number of enrolled subjects in the DUAC group).

6.2 Postmarketing Experience

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

- Anaphylaxis, and other allergic reactions leading to hospitalization.
- Urticaria, application site reactions, including discoloration.

7 DRUG INTERACTIONS

7.1 Erythromycin

Avoid using DUAC in combination with erythromycin-containing products due to DUAC's clindamycin component. In vitro studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this in vitro antagonism is not known.

7.2 Topical Drugs Used to Treat Acne

The concomitant use of DUAC with other topical drugs to treat acne may have a cumulative irritancy effect, especially with the use of peeling, desquamating, or abrasive drugs. If irritancy or dermatitis occurs with concomitant use of DUAC with another topical drug to treat acne, reduce frequency of application or temporarily interrupt treatment with DUAC and/or the other topical drug and resume treatment once the irritation subsides. DUAC and/or the other topical treatment should be discontinued if the irritation persists.

7.3 Neuromuscular Blocking Drugs

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking drugs. DUAC should be used with caution in patients receiving other neuromuscular blocking drugs.

7.4 Topical Sulfone Products

The concomitant use of topical drugs containing benzoyl-peroxide (including DUAC) with topical sulfone products may cause skin and facial hair to temporarily change color (yellow/orange).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Systemic concentration following topical administration of DUAC is minimal, and maternal use is not expected to result in fetal exposure to clindamycin or benzoyl peroxide (the components of DUAC) [see *Clinical Pharmacology* (12.3)]. Available data over decades of use with DUAC and

other topical clindamycin and benzoyl peroxide products in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.

In animal reproduction studies, clindamycin did not cause adverse developmental outcomes when administered to mice and rats during early pregnancy through organogenesis at doses up to 120 and 240 times, respectively, the amount of clindamycin at the maximum recommended human dose (MRHD) of 2.5 grams of DUAC on a mg/m² basis (*see Data*). Reproduction studies have not been conducted in animals with DUAC or benzoyl peroxide.

The systemic exposure of benzoyl peroxide is unknown. Based on published literature, benzoyl peroxide is metabolized to benzoic acid (an endogenous substance), which is eliminated in the urine [*see Clinical Pharmacology (12.3)*]. Hence, maternal use is not expected to result in fetal exposure of benzoyl peroxide.

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

Data

Animal Data: Animal reproduction studies were not conducted with DUAC or benzoyl peroxide. Clindamycin palmitate administration during the period of organogenesis in pregnant mice and rats at oral doses up to 600 mg/kg/day (120 and 240 times the MRHD of the clindamycin component in DUAC, respectively, based on mg/m² dose comparison) did not cause fetal malformations or fetotoxicity. Clindamycin palmitate administration to rats at oral doses up to 300 mg/kg/day (120 times the MRHD, based on mg/m² dose comparison) from early pregnancy through lactation and weaning of offspring did not affect prenatal or postnatal development of offspring.

No animal reproduction studies using oral, parenteral, or topical benzoyl peroxide, or DUAC have been conducted.

8.2 Lactation

Risk Summary

Systemic concentration following topical administration of DUAC is minimal, and breastfeeding is not expected to result in exposure of the child to DUAC [*see Clinical Pharmacology (12.3)*]. It is not known whether clindamycin or benzoyl peroxide are present in human milk following topical administration of DUAC. There are no data on the effects of topical clindamycin and benzoyl peroxide on the breastfed child or effects on milk production.

If DUAC is used during lactation, mothers should wash their hands after applying DUAC to avoid transferring the drug to the breast/nipple area and other areas with increased risk for potential ingestion by the breastfeeding child, and to avoid accidental ingestion by the breastfeeding child.

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

8.4 Pediatric Use

The safety and effectiveness of DUAC for the topical treatment of inflammatory acne vulgaris in pediatric patients 12 years and older has been established. The use of DUAC for this pediatric indication is based on adequate and well-controlled studies in pediatric patients 12 years of age and older and adults with inflammatory acne vulgaris.

Safety and effectiveness of DUAC in pediatric patients below the age of 12 have not been established.

8.5 Geriatric Use

Clinical studies of DUAC did not include sufficient numbers of subjects 65 years of age and over to determine whether they respond differently from younger adult subjects.

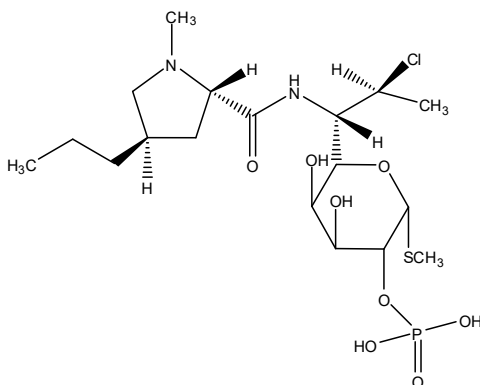
11 DESCRIPTION

DUAC (clindamycin phosphate and benzoyl peroxide) gel, 1.2%/5% is a fixed combination product with two active ingredients in a white to slightly yellow, opaque, aqueous gel.

Clindamycin Phosphate

Clindamycin phosphate is a water-soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

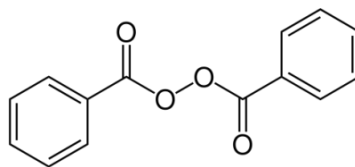
Clindamycin phosphate is $C_{18}H_{34}ClN_2O_8PS$. The structural formula for clindamycin phosphate is represented below:



Clindamycin phosphate has a molecular weight of 504.97 and its chemical name is methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*- α -D-*galacto*-octopyranoside 2-(dihydrogen phosphate).

Benzoyl Peroxide

Benzoyl peroxide is C₁₄H₁₀O₄. It has the following structural formula:



Benzoyl peroxide has a molecular weight of 242.23.

DUAC

Each gram of DUAC contains 12 mg of clindamycin phosphate (1.2%) (equivalent to 10 mg of clindamycin (1%)) and 50 mg (5%) benzoyl peroxide in a base consisting of carbomer homopolymer (type C), dimethicone, disodium lauryl sulfosuccinate, edetate disodium, glycerin, methylparaben, poloxamer 182, purified water, silicon dioxide, and sodium hydroxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Clindamycin

Clindamycin is a lincosamide antibacterial [see *Microbiology* (12.4)].

Benzoyl Peroxide

Benzoyl peroxide is an oxidizing agent with bactericidal and keratolytic effects, but the precise mechanism of action for the topical treatment of inflammatory acne vulgaris is unknown.

12.2 Pharmacodynamics

The pharmacodynamics of DUAC are unknown.

12.3 Pharmacokinetics

A comparative study of clindamycin pharmacokinetics after the use of topical DUAC and after the use of clindamycin topical solution, 1% alone in 78 subjects indicated that mean plasma clindamycin levels during the 4-week dosing period were less than 0.5 ng/mL for both treatment groups.

Benzoyl peroxide has been shown to be absorbed by the skin where it is converted to benzoic acid. Less than 2% of the benzoyl peroxide dose is expected to enter systemic circulation as benzoic acid.

12.4 Microbiology

Clindamycin binds to the 50S ribosomal subunits of susceptible bacteria and prevents elongation of peptide chains by interfering with peptidyl transfer; thereby, suppressing protein synthesis.

In Vivo Activity

No microbiology testing was performed in the clinical studies of DUAC.

In Vitro Activity

The clindamycin and benzoyl peroxide components individually have been shown to have in vitro activity against *Propionibacterium acnes*, an organism which has been associated with acne vulgaris; however, the clinical significance of this in vitro activity is not known.

Resistance

There are reports of an increase of *P. acnes* resistance to clindamycin in the treatment of acne. In patients with *P. acnes* resistant to clindamycin, the clindamycin component may provide no additional benefit beyond the use of benzoyl peroxide alone.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In a 2-year dermal carcinogenicity study in mice, treatment with DUAC at doses up to 8,000 mg/kg/day (16 times the MRHD for clindamycin phosphate and benzoyl peroxide based on mg/m² dose comparison) did not cause an increase in skin tumors. However, topical treatment with another product that contained 1% clindamycin and 5% benzoyl peroxide at doses of 100, 500, or 2,000 mg/kg per day caused a dose-dependent increase in the incidence of keratoacanthoma at the treated skin site of male rats in a 2-year dermal carcinogenicity study in rats.

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

Mutagenesis

Genotoxicity studies were not conducted with clindamycin phosphate and benzoyl peroxide gel. Clindamycin phosphate was not genotoxic in the Ames test or in a rat micronucleus test. Benzoyl peroxide caused DNA strand breaks in a variety of mammalian cell types, was mutagenic in a few, but not all, Ames tests, and caused sister chromatid exchanges in Chinese hamster ovary cells.

Impairment of Fertility

Animal fertility studies were not conducted with DUAC or benzoyl peroxide. Clindamycin palmitate administration to rats at oral doses up to 300 mg/kg/day (120 times the MRHD based on mg/m² dose comparison) did not impair fertility.

14 CLINICAL STUDIES

In 5 randomized, double-blind clinical trials in 1,319 subjects with inflammatory acne vulgaris, 397 subjects were treated with DUAC (clindamycin phosphate and benzoyl peroxide) gel, 396 subjects were treated with topical benzoyl peroxide, 349 subjects were treated with topical clindamycin, and 177 subjects were treated with a topical vehicle control. Subjects were instructed to wash their face, wait 10 to 20 minutes, and then apply study drug to the entire face once daily in the evening.

Subjects were evaluated and acne lesions counted at each clinical visit at Weeks 2, 5, 8, 11. The primary efficacy measures were the lesion counts, and the investigator's global assessment evaluated at Week 11.

DUAC applied once daily for 11 weeks was significantly more effective than benzoyl peroxide, clindamycin, and vehicle in the treatment of inflammatory lesions of moderate to moderately severe facial acne vulgaris in 3 of the 5 trials (Trials 1, 2, and 5). Percent reductions in inflammatory lesion counts after treatment for 11 weeks in these 5 trials are shown in Table 2.

Table 2. Mean Percent Reduction in Inflammatory Lesion Counts in Patients with Inflammatory Lesions of Moderate to Moderately Severe Facial Acne Vulgaris (Trials 1 to 5)

Topical Treatment	Trial 1 (n = 120)	Trial 2 (n = 273)	Trial 3 (n = 280)	Trial 4 (n = 288)	Trial 5 (n = 358)
DUAC (clindamycin phosphate and benzoyl peroxide) gel	65%	56%	42%	57%	52%
Benzoyl peroxide	36%	37%	32%	57%	41%
Clindamycin	34%	30%	38%	49%	33%
Vehicle	19%	-0.4%	29%		29%

The DUAC group showed greater overall improvement in the investigator's global assessment than the benzoyl peroxide, clindamycin, and vehicle groups in 3 of the 5 trials (Trials 1, 2, and 5).

Clinical trials have not adequately demonstrated the effectiveness of DUAC versus benzoyl peroxide alone in the treatment of non-inflammatory lesions of acne.

16 HOW SUPPLIED/STORAGE AND HANDLING

DUAC (clindamycin phosphate and benzoyl peroxide) gel is white to slightly yellow, and opaque. It is supplied as follows:

- 45-gram tube NDC 0145-2371-05

Prior to Dispensing: Store in a cold place, preferably in a refrigerator, between 2°C and 8°C (36°F and 46°F). Do not freeze.

Dispensing Instructions for the Pharmacist

- Dispense DUAC with a 60-day expiration date.
- Specify “Store at room temperature up to 25°C (77°F). Do not freeze.”
- Keep tube tightly closed.

17 PATIENT COUNSELING INFORMATION

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

Colitis

Advise patients to contact their healthcare provider if significant diarrhea occurs [*see Warnings and Precautions (5.1)*].

Photosensitivity

Advise patients to minimize sun exposure (including use of tanning beds or sun lamps) following topical application of DUAC. To minimize exposure to sunlight, hat or other clothing should be worn. Use sunscreen, as appropriate [*see Warnings and Precautions (5.2)*].

Hypersensitivity Reactions

Advise patients who develop hypersensitivity reactions such as severe swelling or shortness of breath to discontinue use and contact their health care provider immediately [*see Contraindications (4)*].

Topical Drugs Used to Treat Acne

Advise patients that DUAC may cause irritation such as erythema, scaling, itching, or burning, especially when used in combination with other topical acne therapies [*see Drug Interactions (7.2)*].

Discoloration of Skin, Hair, and Fabric

- DUAC may bleach hair or colored fabric.
- The concomitant use of DUAC with topical sulfone products may cause skin and facial hair to temporarily change color (yellow/orange) [*see Drug Interactions (7.4)*].

Lactation

Advise breastfeeding mothers to wash their hands after applying DUAC to avoid transfer of the drug to the breast/nipple area and other areas with increased risk for potential ingestion by the breastfeeding child, and to avoid accidental ingestion by the child [*see Use in Specific Populations (8.2)*].

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PATIENT INFORMATION DUAC (doo-ack) (clindamycin phosphate and benzoyl peroxide) gel
Important: For use on the skin only (topical use). Do not get DUAC in or on your mouth, eyes, vagina, or lips.
What is DUAC? DUAC is a prescription medicine used on the skin (topical) to treat inflamed acne in people 12 years and older. It is not known if DUAC is safe and effective in children under 12 years of age.
Do not use DUAC if you have: • had an allergic reaction to clindamycin, lincomycin, benzoyl peroxide, or any of the ingredients in DUAC. See the end of this Patient Information leaflet for a complete list of ingredients in DUAC. • Crohn's disease, ulcerative colitis, or had an inflammation of the colon (colitis) with past antibiotic use.
Before you use DUAC, tell your healthcare provider about all of your medical conditions, including if you: • plan to have surgery with general anesthesia. DUAC may affect how certain medicines work that may be given during surgery. • are sensitive to sunlight • are pregnant or plan to become pregnant. It is not known if DUAC will harm your unborn baby. • are breast feeding or plan to breastfeed. It is not known if DUAC passes into your breastmilk. If you breastfeed during treatment with DUAC: ○ Wash your hands after applying DUAC to avoid getting DUAC on the breast and nipple area or other areas of your body where the baby might get DUAC into their mouth. ○ Talk to your healthcare provider about the best way to feed your baby during treatment with DUAC. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you: • take a medicine that contains erythromycin. DUAC should not be used with erythromycin. • use other topical acne medicines on the skin. Other topical acne medicines may increase the irritation of your skin when used with DUAC. If you get skin irritation, you may need to apply less frequently, temporarily stop, or permanently stop DUAC or the other acne medicine. • use topical medicines called sulfones. Using DUAC with sulfones may cause skin and facial hair to temporarily change color (yellow or orange). Ask your healthcare provider if you are not sure if you take or use any of these medicines. Know the medicines you take and keep a list of them to show to your healthcare provider or pharmacist when you get a new medicine.
How should I use DUAC? • Use DUAC exactly as your healthcare provider tells you to use it. • Before you apply DUAC, wash your face gently with a mild soap, rinse with warm water, and pat the skin dry. • Apply a thin layer of DUAC to your face 1 time a day, in the evening. • Wash your hands with soap and water after applying DUAC. • Do not get DUAC in your mouth, eyes, nose, vagina, or lips, or in cuts or open wounds.
What should I avoid while using DUAC? • Limit your time in sunlight. Avoid using tanning beds or sun lamps during treatment with DUAC. If you have to be in sunlight, wear a wide-brimmed hat or other protective clothing and use sunscreen. • Avoid getting DUAC on your hair or colored fabric. DUAC may bleach hair or colored fabric.
What are the possible side effects of DUAC? DUAC can cause serious side effects including:

• Inflammation of the colon (Colitis). Stop using DUAC and tell your healthcare provider right away if you get severe stomach (abdominal) cramps, watery diarrhea, or bloody diarrhea during treatment, or within several weeks after stopping treatment with DUAC. Use sunscreen, as appropriate. • Sensitivity to sunlight. DUAC may make your skin more sensitive to the sun and the light from tanning beds and sun lamps. See “What should I avoid while using DUAC?” • Allergic reactions. Stop using DUAC and tell your healthcare provider or get help right away if you get any of the following symptoms: ○ severe itching ○ swelling of your face, eyes, lips, tongue, or throat ○ trouble breathing The most common side effects of DUAC are skin reactions and include redness, peeling, dryness, and burning. These are not all of the possible side effects of DUAC. 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 DUAC? • Store DUAC at room temperature, between 68°F and 77°F (20°C and 25°C). • Do not freeze DUAC. • The expiration date of DUAC is 60 days from the date when you get your prescription from the pharmacy. • Throw away DUAC after the expiration date. • Keep the tube tightly closed. Keep DUAC and all medicines out of the reach of children.
General information about the safe and effective use of DUAC. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DUAC for a condition for which it was not prescribed. Do not give DUAC to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DUAC that is written for health professionals.
What are the ingredients in DUAC? Active ingredients: clindamycin phosphate 1.2% and benzoyl peroxide 5% Inactive ingredients: carbomer homopolymer (type C), dimethicone, disodium lauryl sulfosuccinate, edetate disodium, glycerin, methylparaben, poloxamer 182, purified water, silicon dioxide, and sodium hydroxide.  Stiefel Stiefel Laboratories, Inc. Research Triangle Park, NC 27709 Trademark owned by or licensed to the GSK Group of companies. ©2026, GSK group of companies or its licensor DUA:3PIL For more information, call 1-888-825-5249.

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

Revised: October 2026