

# Clinidamycin Phosphate and Benzoyl Peroxide Gel 1.2%/2.5%



NDC 7450-0164

## HIGHLIGHTS OF PRESCRIBING INFORMATION

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

### CLINDAMYCIN PHOSPHATE and BENZOYL PEROXIDE gel, for topical use

United States Approval: 2000

**INDICATIONS AND USAGE**  
Clindamycin phosphate and benzoyl peroxide gel is a lincomycin antibiotic and benzoyl peroxide indicated for the topical treatment of acne vulgaris. (1)

**DOSE AND ADMINISTRATION**  
Apply a pea-sized amount of clindamycin phosphate and benzoyl peroxide gel to the face once daily. (2)  
Not for oral, ophthalmic, or intravaginal use. (2)

**DOSE FORMS AND STRENGTHS**  
Clindamycin phosphate and benzoyl peroxide gel contains clindamycin phosphate 1.2% and benzoyl peroxide 2.5% in a topical gel in 50 gram pumps. (3)

**CONTRAINDICATIONS**  
Clindamycin phosphate and benzoyl peroxide gel is contraindicated to:  
Patients who have demonstrated hypersensitivity (e.g., anaphylaxis) to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin. (4)

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- Patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis. (4)
- WARNINGS AND PRECAUTIONS**  
Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in death. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. Clindamycin phosphate and benzoyl peroxide gel should be discontinued if significant diarrhea occurs. (5.1)  
Ultraviolet Light and Environmental Exposure: Minimize sun exposure following drug application. (5.2)

**ADVERSE REACTIONS**  
The following selected adverse reactions occurred in less than 0.2% of patients: application site pain (0.1%); application site irritation (0.1%); and application site irritation (0.1%). (5.1)

To report SUSPECTED ADVERSE REACTIONS, contact Taro Pharmaceuticals U.S.A., Inc., at 1-866-622-4914 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

**DRUG INTERACTIONS**  
Clindamycin phosphate and benzoyl peroxide gel should not be used in combination with erythromycin-containing products because of its clindamycin component. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling. Issued: 06/2018

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## FULL PRESCRIBING INFORMATION

**1 INDICATIONS AND USAGE**  
Clindamycin phosphate and benzoyl peroxide gel is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

**2 DOSE AND ADMINISTRATION**  
Apply a pea-sized amount of clindamycin phosphate and benzoyl peroxide gel to the face once daily. Use of clindamycin phosphate and benzoyl peroxide gel beyond 12 weeks has not been evaluated. Concentrated topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, exfoliating, or abrasive agents. Clindamycin phosphate and benzoyl peroxide gel is not for oral, ophthalmic, or intravaginal use.

**3 DOSE FORMS AND STRENGTHS**  
Gel, 1.2%/2.5%  
Each gram of clindamycin phosphate and benzoyl peroxide gel contains 10 mg (1.2%) clindamycin as phosphate, and 25 mg (2.5%) benzoyl peroxide in a white to off-white, opaque, smooth gel.

**4 CONTRAINDICATIONS**  
4.1 Hypersensitivity  
Clindamycin phosphate and benzoyl peroxide gel is contraindicated in those individuals who have shown hypersensitivity to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin. Anaphylaxis, as well as allergic reactions leading to hospitalization, has been reported in postmarketing use with clindamycin phosphate and benzoyl peroxide gel. (See Postmarketing Experience (6.2))  
4.2 Colitis/Enteritis  
Clindamycin phosphate and benzoyl peroxide gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis. (See Warnings and Precautions (5.1))

**5 WARNINGS AND PRECAUTIONS**  
5.1 Colitis  
Severe: 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. When significant diarrhea occurs, clindamycin phosphate and benzoyl peroxide gel should be discontinued. Severe colitis has occurred following oral and parenteral administration of clindamycin with an onset of up to several weeks following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine or paralytic agents may worsen severe colitis. Severe colitis may result in death.  
Mild: Patients should be advised to discontinue use of clindamycin phosphate and benzoyl peroxide gel if they experience watery or bloody stools, abdominal cramps, or may be associated with the passage of blood and mucus. Stool cultures for Clostridium difficile and stool assay for C. difficile toxin may be helpful diagnostically.  
5.2 Ultraviolet Light and Environmental Exposure  
Minimize sun exposure including use of tanning beds or sun lamps following drug application. (See Nonclinical Toxicology (13.1)).

**6 ADVERSE REACTIONS**  
6.1 Clinical Trials Experience  
Because clinical trials are conducted under prescribed conditions, adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice. Because clinical trials are also conducted under widely varying conditions, adverse reactions observed in the clinical trials of a drug cannot always be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.  
The following selected adverse reactions occurred in less than 0.2% of patients treated with clindamycin phosphate and benzoyl peroxide gel: application site pain (0.1%), application site irritation (0.1%), and application site irritation (0.1%).  
During clinical trials, subjects were assessed for local cutaneous signs and symptoms of erythema, scaling, itching, burning and stinging. Most local skin reactions increased and peaked around week 4 and continually decreased over time reaching near baseline levels by week 12. The percentage of subjects that had symptoms present before treatment, the maximum value recorded during treatment, and the percent with symptoms present at week 12 are shown in Table 1.  
Table 1: Local Skin Reactions - Percent of Subjects with Symptoms Present, Combined Results from the Two Phase 3 Trials (N = 772)

	Before Treatment (Week 0)			Maximum During Treatment			End of Treatment (Week 12)		
	Min*	Max*	Severe	Min*	Max*	Severe	Min*	Max*	Severe
Erythema	22	4	0	29	6	<1	15	2	0
Scaling	8	<1	0	19	3	0	6	1	0
Itching	10	2	0	15	2	0	6	<1	0
Burning	3	<1	0	8	2	0	2	<1	0
Stinging	2	<1	0	6	1	0	1	<1	0

\* Min = Minimum  
6.2 Postmarketing Experience  
Anaphylaxis, as well as allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin/benzoyl peroxide. 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**  
7.1 Erythromycin  
Clindamycin phosphate and benzoyl peroxide gel should not be used in combination with topical or oral erythromycin-containing products due to its clindamycin component. In vitro studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this in vivo antagonism is not known.  
7.2 Neuromuscular Blocking Agents  
Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, clindamycin phosphate and benzoyl peroxide gel should be used with caution in patients receiving such agents.

**8 USE IN SPECIFIC POPULATIONS**  
8.1 Pregnancy  
Pregnancy Category C  
There are no adequate and well-controlled studies in pregnant women treated with clindamycin phosphate and benzoyl peroxide gel. Clindamycin phosphate and benzoyl peroxide gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.  
Animal reproductive/toxicological toxicity studies have not been conducted with clindamycin phosphate and benzoyl peroxide gel or benzoyl peroxide. Developmental toxicity studies of clindamycin phosphate in rats and other related studies are reported in the full prescribing information (see Animal Toxicology and/or Pharmacology) based on mg/kg, respectively or subcutaneous doses of up to 200 mg/kg/day (D0 and D40) twice the amount of clindamycin in the highest recommended adult human dose based on mg/kg, respectively, revealed no evidence of teratogenicity.  
8.3 Nursing Mothers  
It is not known whether clindamycin is excreted in human milk after topical application of clindamycin phosphate and benzoyl peroxide gel. However, orally and parenterally administered clindamycin has been

## PATIENT INFORMATION

### Clinidamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5

**IMPORTANT:** For use on skin only (topical use). Do not get Clindamycin Phosphate and Benzoyl Peroxide Gel in your mouth, eyes, or vagina, or on your lips.

Read the Patient Information that comes with clindamycin phosphate and benzoyl peroxide 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 medical condition or your treatment.

#### What is Clindamycin Phosphate and Benzoyl Peroxide Gel?

Clindamycin phosphate and benzoyl peroxide gel is a prescription medicine used on the skin (topical) to treat acne vulgaris in people 12 years and older. Clindamycin phosphate and benzoyl peroxide gel contains clindamycin phosphate and benzoyl peroxide. It is not known if clindamycin phosphate and benzoyl peroxide gel is safe and effective for use longer than 12 weeks. It is not known if clindamycin phosphate and benzoyl peroxide gel is safe and effective in children under 12 years of age.

#### Who should not use Clindamycin Phosphate and Benzoyl Peroxide Gel?

Do not use Clindamycin Phosphate and Benzoyl Peroxide Gel if you have:  
• Crohn's disease  
• ulcerative colitis  
• had inflammation of the colon (colitis), or severe diarrhea with past antibiotic use  
Talk with your doctor if you are not sure if you have one of these conditions.

#### What should I tell my doctor before using Clindamycin Phosphate and Benzoyl Peroxide Gel?

Before using Clindamycin Phosphate and Benzoyl Peroxide Gel, tell your doctor about all of your medical conditions, including if you:  
• have any allergies.  
• have any other medical conditions.  
• are pregnant or planning to become pregnant. It is not known if clindamycin phosphate and benzoyl peroxide gel will harm your unborn baby.  
• are breastfeeding or plan to breast-feed. It is not known if clindamycin phosphate and benzoyl peroxide gel passes into your breast milk. One of the medicines in clindamycin phosphate and benzoyl peroxide gel contains clindamycin. Clindamycin when taken by mouth or by injection has been reported to appear in breast milk. You and your doctor should decide whether you will use clindamycin phosphate and benzoyl peroxide gel while breast-feeding.

#### Tell your doctor about all the medicines and skin products you use.

Especially tell your doctor if you will have surgery with general anesthesia. One of the medicines in clindamycin phosphate and benzoyl peroxide gel (clindamycin) can affect how certain medicines work when used in general anesthesia.  
• Clindamycin phosphate and benzoyl peroxide gel should not be used with products that contain erythromycin.  
• Other skin and topical acne products may increase the irritation of your skin when used with clindamycin phosphate and benzoyl peroxide gel.  
Know the medicines you take. Keep a list of them and show it to your

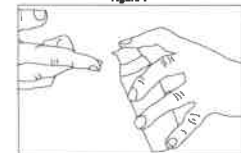
#### doctor and pharmacist when you get a new medicine.

#### How should I use Clindamycin Phosphate and Benzoyl Peroxide Gel?

- Use clindamycin phosphate and benzoyl peroxide gel exactly as prescribed.
- Your doctor will tell you how long to use clindamycin phosphate and benzoyl peroxide gel.
- Throw away (discard) any unused clindamycin phosphate and benzoyl peroxide gel.

#### Instructions for applying Clindamycin Phosphate and Benzoyl Peroxide Gel

- Apply clindamycin phosphate and benzoyl peroxide gel to your face one time each day as prescribed.
- Before you apply clindamycin phosphate and benzoyl peroxide gel, wash your face gently with a mild soap, rinse with warm water, and pat your skin dry.
- To apply clindamycin phosphate and benzoyl peroxide gel to your face, use the pump to dispense one pea-sized amount of clindamycin phosphate and benzoyl peroxide gel onto your fingertip. See Figure 1. One pea-sized amount of clindamycin phosphate and benzoyl peroxide gel should be enough to cover your entire face.



- Dot the one pea-sized amount of clindamycin phosphate and benzoyl peroxide gel onto six areas of your face (chin, left cheek, right cheek, nose, left forehead, right forehead). See Figure 2.



