PRODUCT MONOGRAPH

PrBENZACLIN®
Clindamycin, as phosphate, 1% and benzoyl peroxide 5% topical gel

Acne Vulgaris Therapy
ATC Code : D10AF

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PrBENZACLIN®

Clindamycin, as phosphate, 1% and benzoyl peroxide 5% topical gel

PART I HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form/Strength	All Non-medicinal Ingredients
Topical (dermal)	Topical Gel: 1% clindamycin, as phosphate and 5% benzoyl peroxide after reconstitution by the pharmacist.	Carbomer, Dioctyl Sodium Sulfosuccinate, Purified Water and Sodium Hydroxide.

INDICATIONS AND CLINICAL USE

BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) is indicated for:

- The topical treatment of moderate *acne vulgaris* characterized by comedones, inflammatory papules/pustules, with or without an occasional cyst or nodule (Grade II to III[1]).

BENZACLIN contains an antibacterial ingredient, clindamycin. To reduce the risk of development of drug-resistant bacteria and maintain the effectiveness of clindamycin, BENZACLIN should only be used for the authorized indication and clinical use.

BENZACLIN is not indicated for the treatment of cystic acne (Grade IV[1]).

CONTRAINDICATIONS

- Patients who have a history of hypersensitivity to preparations containing clindamycin, lincomycin or any other component of the preparation. For a complete listing of the ingredients in the formulation, see the **DOSAGE FORMS, COMPOSITION AND PACKAGING** section.
- Patients with a history of regional enteritis, ulcerative colitis, or a history of antibiotic-associated colitis (see **WARNINGS AND PRECAUTIONS**).

[1] Pillsbury DM, Heaton C. Manual of Dermatology 1980.

WARNINGS AND PRECAUTIONS

General

For external (dermatological) use only. Not for ophthalmic use.

Concomitant topical acne therapy is not recommended because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents. Exposure to sunlight or unnecessary UV light should be minimized.

Gastrointestinal

Orally and parenterally administered clindamycin have been associated with severe colitis, which may result in patient death. Use of the topical formulation of clindamycin can result in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.

Studies indicate that a toxin produced by clostridia is a 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. Endoscopic examination may reveal pseudomembranous colitis. Stool culture for *Clostridium difficile* and stool assay for *Clostridium difficile* toxin may be helpful diagnostically. **When significant diarrhea occurs, the drug should be discontinued. Large bowel endoscopy should be considered to establish a definitive diagnosis in cases of severe diarrhea.**

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with clindamycin.

Ophthalmologic/Mucosal/Skin

Avoid contact with eyes and mucous membranes. In the event of accidental contact with such sensitive surfaces (mucous membranes, eyes, abraded skin), rinse with large amounts of tepid tap water.

Special Populations

Pregnant Women
There are no well-controlled trials in pregnant women treated with BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%). It is not known whether BENZACLIN can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. BENZACLIN should not be given to a pregnant woman unless the benefits to the mother clearly outweigh the possible risks to the fetus.

Nursing Women
It is not known whether BENZACLIN is excreted in human milk after topical application. However, orally and parenterally administered clindamycin has been reported to appear in breast

milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatrics (<12 years of age)
The safety and effectiveness of this product in pediatric patients below the age of 12 have not been established.

Geriatrics (>65 years of age)
The safety and effectiveness of this product in geriatric patients above the age of 65 years have not been established.

Susceptibility/Resistance

Development of Drug-Resistant Bacteria
Prescribing BENZACLIN in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth
Prolonged use of BENZACLIN may result in overgrowth of non-susceptible organisms including fungi. If this should occur, therapy with BENZACLIN should be discontinued and appropriate measures taken.

P. acnes resistance to clindamycin has been documented. Resistance to clindamycin is often associated with resistance to erythromycin. If this should occur, therapy with BENZACLIN should be discontinued and alternative therapy should be initiated.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

The most frequent adverse reactions that may occur with BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) are mild to moderate adverse reactions of the skin; most commonly, dry skin.

Clinical Trial Adverse Reactions

Because clinical trials are conducted under very specific conditions, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates. Table 1 below presents a pooled summary of the most frequent (≥ 1%) adverse reactions reported during four randomized, double-blind, vehicle-controlled, multicentre trials conducted with BENZACLIN in patients with moderate acne vulgaris. A total of 420 male and female patients with

an average age of 19 years received BENZACLIN in these studies; 168 patients received vehicle. The average duration of treatment with BENZACLIN was 69 days.

Table 1 - Most Frequent Adverse Events (≥ 1%) Reported in the BENZACLIN or Vehicle Groups Considered to be Possibly, Probably or Definitely Related to Product Administration

Body System: Skin and Appendages	BENZACLIN n= 420	Vehicle n= 168
Very Common Adverse Reaction:		
Dry Skin	12%	6%
Common Adverse Reactions:		
Application site reaction	3%	<1%
Peeling	2%	-
Pruritus	2%	<1%
Erythema	1%	<1%

Sunburn was observed in 1% of the BENZACLIN group but considered related to the drug in less than 1% (2 patients). The use of a moisturizer in the studies may have reduced the incidence of dry skin.

Less Common Clinical Trial Adverse Drug Reactions (<1%)

Body as a Whole: Face edema, headache

Nervous System: Dizziness

Skin and Appendages: Rash, skin burning

Post-Market Adverse Drug Reactions

The most frequently reported post-market adverse events are related to the application site and are consistent with the type of events recorded in the controlled clinical trials. Typically, these application site reactions have included dry skin, erythema, burning sensation, rash, peeling and pruritis. Application site hypersensitivity (allergic reaction), colitis and diarrhea have also been reported.

DRUG INTERACTIONS

Drug-Drug Interactions

The interactions discussed in this section are based on either drug interaction case reports, or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Clindamycin, erythromycin, lincomycin and chloramphenicol containing products should not be used concurrently. *In vitro* studies have shown antagonism among these antimicrobials. *In vitro*

studies suggest that benzoyl peroxide contributes to the degradation of tretinoin especially when combined with exposure to UV light.

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Interactions with herbal products have not been established.

Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) should be applied twice daily, morning and evening, or as directed by a physician, to affected areas of the skin after it is gently washed with a mild non-medicated soap, rinsed with warm water and patted dry. Improvement has been seen as early as two weeks, although up to ten weeks of treatment may be required for best results.

Administration

Reconstitution
BENZACLIN is supplied to the pharmacist as two components: 1) a jar of benzoyl peroxide gel; 2) a vial containing clindamycin phosphate powder, both of which are to be admixed by the pharmacist and dispensed to the patient in the jar as 1% clindamycin and 5% benzoyl peroxide.

Table 2 - How Supplied and Mixing Instructions for the Pharmacist

Size (Net Weight)	Benzoyl Peroxide Gel	Total Active Clindamycin Phosphate Powder	Purified Water to Be Added to Vial
50 grams	41.4 g	0.6 g	10 mL

Prior to dispensing, tap the vial until powder flows freely. Add indicated amount of purified water to the vial (to the mark) and immediately shake to completely dissolve clindamycin. If needed, add additional purified water to bring level up to the mark. Add the solution in the vial to the gel and stir until homogenous in appearance (1 to 1 ½ minutes). BENZACLIN (as dispensed) can be stored between 15°C- 25°C for 3 months. Place a 3-month expiration date on the label immediately following mixing.

OVERDOSAGE

Acute overdosage with the topical use of BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) is unlikely. If BENZACLIN is applied excessively, marked dryness, peeling and redness might occur. The literature indicates that clindamycin could be absorbed topically (see **WARNINGS AND PRECAUTIONS**). In the event of accidental ingestion, treatment should be symptomatic.

ACTION AND CLINICAL PHARMACOLOGY

BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) contains 1% clindamycin (as phosphate) and 5% benzoyl peroxide. The use of a clindamycin and benzoyl peroxide combination product in acne is predicated upon the facts that both clindamycin and benzoyl peroxide are active against *Propionibacterium acnes* (*P. acnes*), and benzoyl peroxide is an oxidizing agent exhibiting keratolytic and desquamative activity (1, 2). Clindamycin phosphate is a water-soluble ester and semi-synthetic antibiotic which is derived from the parent antibiotic lincomycin (3). BENZACLIN penetrates the skin and has greater clinical and *P. acnes* reducing effects than either of its components. BENZACLIN inhibits clindamycin-resistant *P. acnes*. Topical clindamycin and benzoyl peroxide penetrate systemically to a minimal degree.

STORAGE AND STABILITY

Store BENZACLIN and its individual components between 15°C and 25°C (before and after reconstitution).

After reconstitution for dispensing to the patient, label BENZACLIN with a 3-month expiration date.

Do not freeze. Keep tightly closed. Keep out of the reach of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) is supplied as two components: a jar of benzoyl peroxide gel and a vial containing clindamycin phosphate powder. The pharmacist will dissolve the clindamycin phosphate powder in purified water, then add the solution to the jar of benzoyl peroxide gel and mix (see **DOSAGE AND ADMINISTRATION**).

As dispensed to the patient after reconstitution by the pharmacist, BENZACLIN contains 1% clindamycin (as clindamycin phosphate) and 5% benzoyl peroxide in an aqueous gel medium. It also contains the following nonmedicinal ingredients: Carbomer, Dioctyl Sodium Sulfosuccinate, Purified Water and Sodium Hydroxide.

BENZACLIN is dispensed in 50 g jar.

PART II: SCIENTIFIC INFORMATION

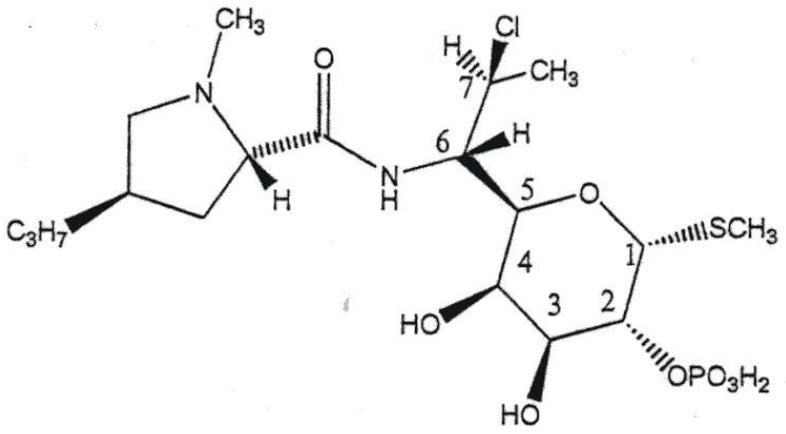
PHARMACEUTICAL INFORMATION

Drug Substance

Clindamycin Phosphate

Proper Name:	Clindamycin Phosphate
Chemical Name:	Methyl-7-chloro-6, 7, 8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo-alpha-D-galacto-octopyranoside-2-(dihydrogen phosphate).
Molecular formula:	The molecular formula for clindamycin phosphate is $C_{18}H_{34}ClN_2O_8PS$
Molecular mass:	The molecular weight is 504.97 g/mol.

Structural Formula:



Physicochemical Properties

Description:	Clindamycin is a white to off-white, hygroscopic, crystalline powder.

Drug Substance

Benzoyl Peroxide

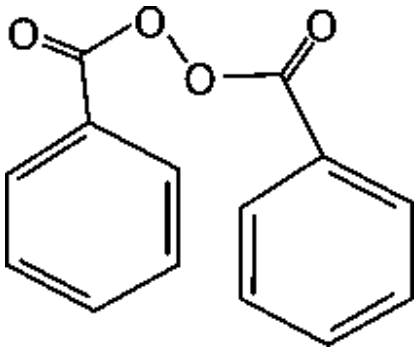
Proper name: Benzoyl Peroxide.

Chemical name: peroxide, dibenzoyl

Molecular formula: The molecular formula for benzoyl peroxide is $C_{14}H_{10}O_4$

Molecular mass: The molecular weight is 242.23 g/mol.

Structural formula:



Physicochemical properties

Description: Hydrous Benzoyl Peroxide is a white granular powder.

CLINICAL TRIALS

The effectiveness of BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%), versus clindamycin, benzoyl peroxide and vehicle was established in three independent and well controlled clinical studies involving 1259 patients. Among these studies 380, 379, 169 and 168 patients were randomized to receive BENZACLIN, 5% benzoyl peroxide gel, 1% clindamycin gel, or vehicle, respectively and 348, 327, 149, 144 completed 10 weeks. In all trials, eligible patients were between 13 and 30 years of age and had moderate acne. Additionally, at baseline, patients had to have a minimum of 10 to a maximum of 50 or 80 inflammatory lesions, and 10-100 comedones (baseline means of 23 and 35 respectively for the BENZACLIN groups). Treatments were applied twice daily for 10 weeks. Patients returned for clinic visits at weeks 2, 4, 6, 8, and 10 during which efficacy was evaluated. The efficacy measures were the change from baseline in number of inflammatory lesions, comedones and total lesions (combined inflammatory and comedones), and the physician and patient overall improvement ratings.

In these studies, BENZACLIN demonstrated significantly greater clinical improvements by 10 weeks than did vehicle or clindamycin alone against inflammatory and non-inflammatory lesions or than benzoyl peroxide alone against inflammatory lesions. The BENZACLIN groups also showed greater overall improvement than the benzoyl peroxide, clindamycin and vehicle groups according to the physician overall global improvement score in two studies and showed greater overall improvement than the clindamycin and vehicle groups in the third study. Improvements occurred as early as two weeks. The percent mean reduction in lesion counts for the BENZACLIN, the active constituents and the vehicle at week 10 are presented below.

Table 3 - Mean Percent Reduction in Lesion Counts for Treatment Groups and Vehicle

	BENZACLIN (n=348)	Benzoyl peroxide (n=327)	Clindamycin (n=149)	Vehicle (n=144)
Mean percent reduction in inflammatory lesions at Week 10				
Study 1	46%	32%	16%	- 3%*
Study 2	55%	48%	--	--
Study 3	63%	53%	45%	42%
Mean percent reduction in non-inflammatory lesions at Week 10				
Study 1	22%	22%	9%	- 1%*
Study 2	34%	31%	--	--
Study 3	54%	50%	39%	36%
Mean percent reduction in total lesions at Week 10				
Study 1	36%	28%	15%	- 0.2%*
Study 2	44%	37%	--	--
Study 3	58%	52%	42%	39%

*minus sign indicates increase

Two other clinical studies, conducted in acne patients and healthy volunteers, respectively, evaluated the topical antimicrobial efficacy of BENZACLIN versus 1% clindamycin gel alone.

The superior antimicrobial and clinical efficacy of twice daily treatment with BENZACLIN compared to clindamycin was seen in the 16-week study in acne patients. Significantly greater reductions in total *Propionibacterium acnes* (*P. acnes*) were generally obtained with BENZACLIN compared to clindamycin. Significantly fewer clindamycin-resistant *P. acnes* were observed in the

BENZACLIN group than in the clindamycin group at the end of the study. In the BENZACLIN group, counts of clindamycin -resistant *P. acnes* were lowered to 65% of baseline values at the end of 16 weeks, while in the clindamycin group, counts of clindamycin-resistant *P. acnes* were increased by >1600%. The superior clinical efficacy of BENZACLIN was demonstrated by significantly greater reductions in inflammatory lesions (47.9%) and comedones (44.5%) than were obtained with clindamycin (27.9% and 22.9%, respectively) at Week 16. The superiority of BENZACLIN was demonstrated against clindamycin-resistant *P. acnes* as well as coagulase negative staphylococci (CONS) resistant or sensitive to clindamycin.

In a two-week comparative study in healthy volunteers, BENZACLIN produced a reduction in *P. acnes*, which exceeded that of three clindamycin formulations by two orders of magnitude by the end of the first week of treatment. At the end of the study, BENZACLIN produced a 99.9% reduction (> 3 log) in the number of *P. acnes* organisms over the face and was significantly more effective than the clindamycin formulations of lotion, gel and solution whose log reductions ranged from 0.9 to 1.68 (See **MICROBIOLOGY** section).

DETAILED PHARMACOLOGY

Use of topical formulations of clindamycin can result in absorption of the antibiotic from the skin surface. Benzoyl peroxide has been shown to be absorbed by the skin where it is converted to benzoic acid (11). Less than 2% of the dose enters systemic circulation as benzoic acid. It is suggested that the lipophilic nature of benzoyl peroxide acts to concentrate the compound into the lipid-rich sebaceous follicle (2). Studies conducted with BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) demonstrated that the combination of clindamycin and benzoyl peroxide in the product formulation does not alter the dermal absorption of either compound.

Pharmacokinetic studies

An *in-vitro* percutaneous penetration study comparing BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%) and topical 1% clindamycin gel alone, demonstrated there was no difference in clindamycin penetration between the two drugs. Minimal penetration (less than 1%) occurred for both products. A second *in-vitro* skin penetration study of BENZACLIN demonstrated that the 1% clindamycin did not affect the penetration of benzoyl peroxide.

A single dose study in normal volunteers demonstrated that facial application of a 1g dose of BENZACLIN did not produce detectable (Lower Limit of Quantification was 2.5 ng/mL) plasma levels of clindamycin or other related compounds up to 24 hours later. Mean systemic bioavailability of topical clindamycin in BENZACLIN is suggested to be less than 1%.

Dermal Pharmacology Studies

Clinical studies have demonstrated that BENZACLIN did not have detectable phototoxic or photocontact allergic potential. The irritation and contact sensitization potential of BENZACLIN was found to be mild.

MICROBIOLOGY

BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%), is indicated for use in the topical treatment of moderate acne vulgaris, a condition in which *Propionibacterium acnes* (*P. acnes*) is implicated in the pathogenesis. Minimum inhibitory concentrations (MIC, (mcg/mL)) of clindamycin as well as benzoyl peroxide for *P. acnes* and staphylococci have been reported in the literature as follows:

	MIC (mcg/mL)		
	P. acnes	***S. aureus***	***S. epidermidis***
Clindamycin [4,5,6]	0.125 - 0.5	0.02	0.003
Benzoyl Peroxide [1,7]	64 - 800	NA	512

NA = not available

P. acnes resistance to clindamycin is common, as is cross-resistance to macrolides (6, 7, 8, 9). MICs for resistant strains of propionibacterium and staphylococci have been reported in the literature to reach 512 µg/mL. (5,8) No resistance to benzoyl peroxide has been reported. Combining benzoyl peroxide with a topical antibiotic has been demonstrated to inhibit clindamycin-resistant bacteria and prevent their emergence. (7, 10)

In clinical studies, the effects of the BENZACLIN combination of clindamycin and benzoyl peroxide and that of clindamycin alone were evaluated in clindamycin sensitive and clindamycin-resistant *P. acnes.*

In one two-week clinical study, involving human volunteers BENZACLIN reduced facial baseline *P. acnes* counts by 99.9% (>3 logs) whereas topical clindamycin solution, lotion and gel formulations reduced *P. acnes* by 88% to 95% (See **CLINICAL TRIALS** section).
In a second 16-week clinical study of BENZACLIN and clindamycin alone in the treatment of acne, clinical efficacy was significantly greater with BENZACLIN than with clindamycin alone. In addition, BENZACLIN produced a 10-fold greater reduction in *P. acnes* compared with clindamycin, and reduced clindamycin-resistant *P. acnes* counts at 16 weeks to 65% of baseline values. In the clindamycin group clindamycin-resistant *P. acnes* increased more than 1600% (>1.2 log) (10) (See **CLINICAL TRIALS** section).

TOXICOLOGY

There is extensive toxicology information in the scientific literature on clindamycin and benzoyl peroxide. (e.g. 12, 13, 14, 15, 16) The following information relates specifically to studies conducted with BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%).

Subchronic Toxicity

Two subchronic (3-month) topical toxicity studies showed only mild dermal irritation and mild infiltrative microscopic changes of the skin in New Zealand white rabbits and Sprague-Dawley albino rats. Both species were dosed at 20, 40, and 400 mg/kg/day of the product clindamycin 1% and benzoyl peroxide 5% gel, administered dermally (non-occluded) in 2 divided doses, 6 hours

apart per day for a period of at least 90 days. Control groups in both studies were treated with 5% benzoyl peroxide alone at the same dose volume as administered to the high dose clindamycin 1% and benzoyl peroxide 5% gel group. The untreated control groups were not administered any material but were merely observed. All animals survived the full duration of the studies and were free of systemic toxic effects. Mild dermal irritation and minimal to slight microscopic skin changes were seen for both clindamycin 1% and benzoyl peroxide 5% gel and 5% benzoyl peroxide alone. These changes are attributed to the benzoyl peroxide content of each product. Untreated animals exhibited no dermal irritation. No systemic toxicity was seen in any group.

Mutagenicity

Mutagenicity studies were not conducted with BENZACLIN (clindamycin, as phosphate, 1% and benzoyl peroxide 5%). Clindamycin phosphate was not mutagenic in *Salmonella typhimurium* or in a rat micronucleus test. Clindamycin phosphate sulfoxide, an oxidative degradation product of clindamycin phosphate and benzoyl peroxide, was not clastogenic in a mouse micronucleus test. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *Salmonella typhimurium* tests by some (17) but not all investigators (15, 16), and to cause sister chromatid exchanges in Chinese hamster ovary cells (12,18).

Carcinogenicity

In a controlled laboratory evaluation of photocarcinogenicity in albino hairless mice, median time to onset of skin tumors was decreased and the number of skin tumors was increased following 40 weeks of topical dosing with BENZACLIN accompanied with exposure to ultraviolet radiation. Although the significance of this study to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown (12).

Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced skin tumors in transgenic TG.AC mice in a study using 20 weeks of topical treatment (12). However, in 2-year dermal oncogenicity studies, there was no evidence of carcinogenic potential at doses up to 45 mg/day in Fischer 344 rats or doses up to 25 mg/day in B6C3F1 mice (19, 20).

Reproduction and Teratology

Animal reproductive/developmental toxicity studies have not been conducted with BENZACLIN. Developmental toxicity studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m^2 respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (100 and 50 times the amount of clindamycin in the highest recommended adult human dose based on mg/m^2, respectively) revealed no evidence of teratogenicity (21,13).

Doses of up to 1.7 mcmol benzoyl peroxide were dissolved in acetone and injected onto the inner shell membrane in the air chamber of three-day-old White Leghorn chicken eggs. There was a dose-

related increase in early embryonic deaths at all but the lowest dose level, with an LD_{50} estimated at 0.99 mcmol/egg. All doses of benzoyl peroxide increased the malformation rate, although no clear dose-response was evident (perhaps due to the increased embryonic death). The ED_{50} for mortality and malformations was calculated to be 0.27 mcmol/egg (22).

Studies have not been performed with BENZACLIN or benzoyl peroxide to evaluate the effect on fertility. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g BENZACLIN, based on mg/m^2) revealed no effects on fertility or mating ability (21, 13).

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IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PrBENZACLIN®
Clindamycin, as phosphate, 1% and benzoyl peroxide 5% topical gel

This leaflet is part III of a three-part "Product Monograph" published for BENZACLIN and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BENZACLIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
BENZACLIN has been prescribed by your doctor to treat your acne.

BENZACLIN is not indicated for the treatment of severe (cystic) acne.

BENZACLIN contains an antibacterial ingredient called clindamycin, and it should be used exactly as directed by your healthcare professional. Misuse or overuse of BENZACLIN could lead to the growth of bacteria that will not be killed by clindamycin. This means that BENZACLIN or other medicines that contain clindamycin may not work for you in the future. Do not share your medicine.

What it does:
Clindamycin phosphate and benzoyl peroxide have antibacterial properties. Benzoyl peroxide also is a peeling agent. Improvement has been seen as early as two weeks, although several months of treatment may be required for best results.

When it should not be used:
Do not use BENZACLIN if:

- You are allergic to clindamycin, lincomycin, benzoyl peroxide, or any component of this medication (See "What the medicinal ingredients are" and "What the nonmedicinal ingredients are").
- You have or have had ulcerative colitis, regional enteritis or antibiotic associated colitis.

What the medicinal ingredients are:
BENZACLIN is a mixture of two acne medications, clindamycin phosphate and benzoyl peroxide.

What the nonmedicinal ingredients are:
The non-medicinal ingredients are: Carbomer, Dioctyl Sodium Sulfosuccinate, Purified Water and Sodium Hydroxide.

What dosage forms it comes in:
Topical gel (clindamycin, as phosphate, 1% and benzoyl peroxide 5%).

WARNINGS AND PRECAUTIONS

- BENZACLIN is for external use only. Avoid contact with the eyes, nostrils, mouth, and all mucous membranes. If contact occurs, rinse well with water. If redness or soreness develops, contact your doctor.
- Do not use other topical acne preparations or other topical products, including cosmetics, on the affected area unless directed to do so by your physician. Many cosmetic products may also contain other peeling agents, which may interfere with the medication or worsen potential side effects.
- Exposure to sunlight should be minimized. To minimize exposure to sunlight, a hat or other clothing should be worn. Avoid unnecessary exposure to other sources of UV light (i.e., sun lamps, tanning beds).
- Tell your doctor if you are pregnant, breastfeeding or intend to become pregnant or breastfeed.
- BENZACLIN is available only on prescription. It has been prescribed by your doctor to treat your current condition. Do not give this medication to other people.
- Avoid contact with hair, fabrics, carpeting, or other materials, as benzoyl peroxide will cause bleaching.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are using any other medications, particularly clindamycin, erythromycin, lincomycin or chloramphenicol, as they may interfere with each other.

PROPER USE OF THIS MEDICATION

1. Prior to using BENZACLIN, wash affected areas gently with a mild non-medicated soap, then rinse with warm water and then gently pat dry.
2. Apply BENZACLIN to the whole area affected by acne, not just to the pimples themselves. Avoid contact with the eyes, nostrils, mouth, and all mucous membranes, as this product may be irritating.
3. Apply BENZACLIN in a thin layer twice a day, morning and evening, or as directed by your doctor. Wash hands after application. Do not apply more frequently than directed by your doctor. Moisturizer may be used to alleviate dry skin.
4. Although improvement has been seen as early as two weeks, several months of treatment may be required for best results. This medication should be used for the entire treatment period prescribed by your doctor even if your acne begins to improve as early as two weeks after you begin using BENZACLIN.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You may experience dry skin, itching, redness, irritation and peeling skin. If this persists or becomes bothersome, contact your doctor.

Stop use and immediately inform your doctor if:

- You have an allergic reaction (hypersensitivity) with symptoms such as rash, hives, swelling of the lips, face, eyelids or throat, or difficulty in breathing.
- You develop very rare side effects such as abdominal or stomach cramps, severe abdominal pain and bloating, severe watery diarrhea which may be bloody, nausea and vomiting.

HOW TO STORE IT

BENZACLIN may be stored between 15 °C and 25 °C for up to 3 months after mixing for dispensing.

An expiry date appears on the product label. You must discard any product you have not used by this date and obtain a fresh supply.

Do not freeze. Keep jar tightly closed.

Keep your medication in a safe place, out of the reach of children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or

Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Talk to your healthcare professional.

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); by contacting the sponsor: Bausch Health, Canada Inc., 2150 St-Elzéar Blvd. West, Laval, (Quebec) H7L 4A8; or by calling 1-800-361-4261.

This leaflet was prepared by:

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