

BenzePro™

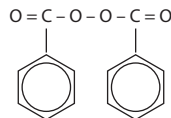
Creamy Wash

benzoyl peroxide

7.0%

Rx Only

DESCRIPTION: BenzePro™ Creamy Wash is intended for topical administration and contains Benzoyl Peroxide for use in the treatment of acne vulgaris. Benzoyl Peroxide is an oxidizing agent that possesses antibacterial properties and is classified as a keratolytic. Benzoyl Peroxide (C₁₄H₁₀O₄) is represented by the following chemical structure:



Each gram of BenzePro™ Creamy Wash contains 70 mg of Benzoyl Peroxide as micronized particles (via Curoxyl® 42) in an emulsion based formulation consisting of: aloe, carbomer 940, cetyl alcohol, disodium oleamido MEA-sulfosuccinate, disodium EDTA, glyceryl stearate/PEG-100 stearate, glycerin, green tea, laureth-12, magnesium aluminum silicate, propylene glycol, purified water, sodium coco-sulfate, sodium lauroamphoacetate, xanthan gum.

CLINICAL PHARMACOLOGY: The mechanism of action of Benzoyl Peroxide is not totally understood but its antibacterial activity against *Propionibacterium acnes* is thought to be a major mode of action. In addition, patients treated with Benzoyl Peroxide show a reduction in lipids and free fatty acids, and mild desquamation (drying and peeling activity) with simultaneous reduction in comedones and acne lesions. Little is known about the percutaneous penetration, metabolism, and excretion of Benzoyl Peroxide, although it has been shown that Benzoyl Peroxide absorbed by the skin is metabolized to benzoic acid and then excreted as benzoate in the urine. There is no evidence of systemic toxicity caused by Benzoyl Peroxide in humans.

INDICATIONS AND USAGE: BenzePro™ Creamy Wash is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS: BenzePro™ Creamy Wash is contraindicated in persons with a known hypersensitivity to any of its ingredients.

WARNINGS: Do not use if you:

- have very sensitive skin
- are sensitive to benzoyl peroxide

When using this product:

- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if:

- irritation becomes severe

PRECAUTIONS: For external use only. If severe irritation develops, discontinue use and institute appropriate therapy. After reaction clears, treatment may often be resumed with less frequent application. These preparations should not be used in or near the eyes or on mucous membranes.

INFORMATION FOR PATIENTS:

General: If accidental contact occurs with eyes, mouth, or mucous membranes, rinse with water.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data from several studies employing a strain of mice that is highly susceptible to developing cancer suggest that Benzoyl Peroxide acts as a tumor promoter. The clinical significance of these findings to humans is unknown. Benzoyl Peroxide has not been found to be mutagenic (Ames Test) and there are no published data indicating it impairs fertility.

Pregnancy: Teratogenic Effects: *Pregnancy Category C:* Animal reproduction studies have not been conducted with Benzoyl Peroxide. It is not known whether Benzoyl Peroxide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzoyl Peroxide should be used by a pregnant woman only if clearly needed. There are no available data on the effect of Benzoyl Peroxide on the later growth, development and functional maturation of the unborn child.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Benzoyl Peroxide is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Allergic contact dermatitis and dryness have been reported with topical Benzoyl Peroxide therapy.

OVERDOSAGE: If excessive scaling, erythema or edema occurs, the use of this preparation should be discontinued. To hasten resolution of the adverse effects, cool compresses may be used. After symptoms and signs subside, a reduced dosage schedule may be cautiously tried if the reaction is judged to be due to excessive use and not allergenicity.

DOSAGE AND ADMINISTRATION: BenzePro™ Creamy Wash: Apply to affected areas once or twice a day, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10-20 seconds, working into a full lather. Rinse thoroughly and pat dry. If excessive drying occurs, control by rinsing off cleanser sooner or using less often.

- If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

HOW SUPPLIED: BenzePro™ Creamy Wash is supplied in a 180 g bottle (NDC 42546-017-18).

Store at controlled room temperature 20°-25° C (68°-77° F); excursions permitted to 15°-30° C (59°-86° F).

Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:

PruGen Pharmaceuticals
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Scottsdale, AZ 85255



Rev.1.1