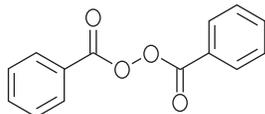


DESCRIPTION:

Each gram of BenzePrO™ Emollient Foam contains 53 mg of Benzoyl Peroxide as micronized particles (via Curoxyl® 42) in an aqueous based emollient foam vehicle containing BHT, C12-15 alkyl benzoate, cetostearyl alcohol, citric acid, dimethicone, disodium EDTA, emulsifying wax, glycerin, methylparaben, povidone, propylene glycol, propylparaben, purified water, sodium citrate, steareth-10, stearic acid, tolamine. Also contains: Propellant HFA-134A (1,1,1,2-tetrafluoroethane).

Benzoyl peroxide is an oxidizing agent that possesses antibacterial properties and is classified as a keratolytic. Benzoyl peroxide (C₁₄H₁₀O₄) is represented by the following structure:



CLINICAL PHARMACOLOGY:

The exact method of action of benzoyl peroxide in acne vulgaris is not known. Benzoyl peroxide is an antibacterial agent with demonstrated activity against *Propionibacterium acnes*. This action, combined with the mild keratolytic effect of benzoyl peroxide, is believed to be responsible for its usefulness in acne. Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid and excreted as benzoate in the urine.

INDICATIONS AND USAGE:

BenzePrO™ Emollient Foam is indicated for use in the topical treatment of mild to moderate acne vulgaris.

CONTRAINDICATIONS:

BenzePrO™ Emollient Foam should not be used in patients who have shown hypersensitivity to benzoyl peroxide or to any of the other ingredients in the product. Discontinue use if hypersensitivity is observed.

WARNINGS:

FOR EXTERNAL USE ONLY. Not For Ophthalmic Use. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Do not use this product 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, 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 lower concentration.

Stop use and ask a doctor:

- if irritation becomes severe.

Contents under pressure. Do not puncture or incinerate container. Do not expose to temperatures above 120°F (49°C).

PRECAUTIONS:

General:

If severe irritation develops, discontinue use and institute appropriate therapy.

Information for patients:

This medication is to be used as directed by a physician and should not be used to treat any condition other than that for which it was prescribed. Avoid contact with eyes, eyelids, lips, and mucous membranes. If accidental contact occurs, rinse with water. If excessive redness or irritation develops, discontinue use and consult your physician.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Based upon all available evidence, benzoyl peroxide is not considered to be a carcinogen. However, data from a study using mice known to be highly susceptible to cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of the findings is not known.

Pregnancy:

Category C animal reproduction studies have not been conducted with benzoyl peroxide. It is also 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.

Nursing Mothers:

It is not known whether this drug is excreted in the 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 below the age of 12 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.

DIRECTIONS:

Avoid contact with hair, fabrics or carpeting as benzoyl peroxide will cause bleaching or discoloration.

Prime can before initial use:

Shake can vigorously (until product moves inside can). Firmly strike bottom of can onto palm of other hand or a hard surface at least 3 times. Hold can upright over sink. Direct initial spray to a non-skin surface such as into cap of can. Press down on actuator for 1-3 seconds until foam begins to dispense. If foam does not dispense within 3 seconds, prime can again.

Before Each Use:

Shake vigorously and gently tap bottom of can onto palm of other hand or a solid surface at least 3 times.

During Use:

BenzePrO™ Emollient Foam can be used as either a leave-on or short contact application. Holding can upright, dispense BenzePrO™ Emollient Foam into palm of hand and apply to affected area once daily, or as directed by a physician. For facial acne, use a dollop the size of a marble. For acne on either the back or chest, use a dollop the size of a whole walnut. Rub in until completely absorbed. Wipe off any excess foam from actuator after use. Wash hands with soap and water after applying BenzePrO™ Emollient Foam.

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

Frequency of use should be adjusted to obtain the desired clinical response. Gentle cleansing of the affected areas prior to application of BenzePrO™ Emollient Foam may be beneficial.

HOW SUPPLIED:

BenzePrO™ Emollient Foam is supplied in 60g (NDC 42546-010-06) and 100g (NDC 42546-010-10) canisters. Will not dispense entire contents. Container is overfilled to guarantee dispensing at least the listed amount.

Store at room temperature: 59° - 77°F (15° - 25°C). Protect from freezing. Store upright.

Manufactured for:

PruGen Pharmaceuticals
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