



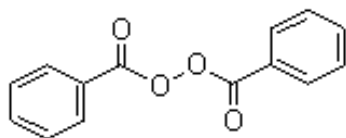
## FOR EXTERNAL USE ONLY

### Rx Only

### DESCRIPTION

Each gram of BenzE Foam™ Emollient Foam contains 5.3% benzoyl peroxide in an aqueous based emollient foam vehicle containing BHT, C12-15 alkyl benzoate, cetearyl alcohol, citric acid, dimethicone, disodium EDTA, emulsifying wax, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, steareth-10. 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 ( $C_{14}H_{10}O_4$ ) 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

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

### CONTRAINDICATIONS

BenzE Foam™ 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.**

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 and mucous membranes
- **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 this 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 and 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.

## DOSAGE AND ADMINISTRATION

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

**Prime Can Before Initial Use:** Gently push up on actuator with thumb until tab breaks. 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. Holding can upright over sink, direct initial spray to a non-skin surface. **DO NOT spray directly on the skin as the initial spray may expel cold, liquid propellant.** 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 can vigorously. Firmly strike bottom of can onto palm of other hand or a hard surface at least 3 times.

**During Use:** BenzEfoam™ can be used as either a leave-on or short-contact application. (See patient information.) Holding can upright, dispense BenzEfoam™ 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 BenzEfoam™. 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 BenzEfoam™ Emollient Foam may be beneficial.

## HOW SUPPLIED

BenzEfoam™ Emollient Foam is supplied in a 60g (NDC 16781-194-60) and 100g (NDC 16781-194-96) aluminum cans. **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 in USA For:



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## PATENT PENDING

P/N 2616-pf Rev. 1W

