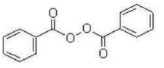
PRESCRIBING INFORMATION

BenzEFoam™ Ultra
Short Contact Foam
benzoyl peroxide **9.8%**

DESCRIPTION

Each gram of BenzEFoamUltra™ Short Contact Foam contains 9.8% 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

BenzEFoamUltra™ Short Contact Foam is indicated for use in the topical treatment of mild to moderate acne vulgaris.

CONTRAINDICATIONS

BenzEFoamUltra™ Short Contact 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.

When using this product, skin irritation and dryness is more likely to occur if:

- you leave BenzEFoamUltra™ Short Contact Foam on your skin longer than directed
- you use another topical acne medication at the same time

If irritation occurs:

- use BenzEFoamUltra™ Short Contact Foam less frequently
- use one topical acne medication at a time
- stop use and ask a doctor if irritation becomes severe

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

Contents under pressure. Do not puncture or incinerate container. Do not expose to temperature above 120ºF (49ºC).

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.

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. **Until primed, 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: Holding can upright, dispense BenzEFoamUltra™ into palm of hand. Cover the entire affected area with a thin layer 1 to 3 times daily. Rub in until completely absorbed. Rinse off after 2 minutes. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two to three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day. Wash hands with soap and water after use. 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:

BenzEFoamUltra™ Short Contact Foam is supplied in 100g (NDC 16781-201-96) aluminum cans. **Will not dispense entire contents. Container is overfilled to guarantee dispensing at least the listed amount.**

Store at room temperature: 59º - 77ºF (15º - 25ºC). Protect from freezing. Store upright.

MANUFACTURED IN USA FOR:

Onset Therapeutics
Cumberland, RI 02864
(888) 713-8154
www.onsettx.com

Onset THERAPEUTICS

Patent Pending

P/N 2620 Rev. 0 AD