

ENZOCLEAR FOAM- benzoyl peroxide aerosol, foam

Lacer Pharma, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

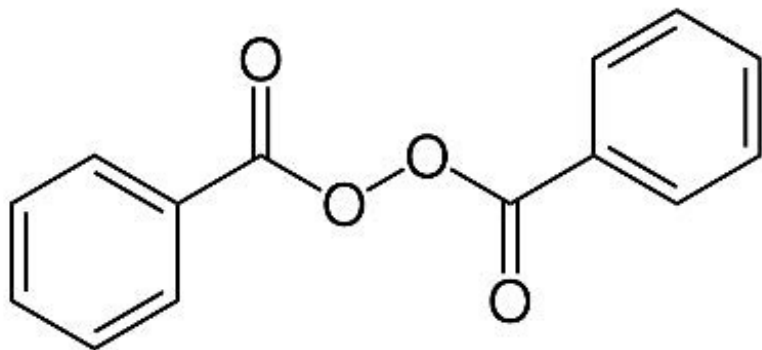
Enzoclear™ Foam

Rx Only

DESCRIPTION

Each gram of Enzoclear™ Foam contains 9.8% benzoyl peroxide in an aqueous based emollient foam vehicle containing BHT, C12-15 alkyl benzoate, cetostearyl alcohol, citric acid, dimethicone, disodium EDTA, emulsifying wax, glycerin, methylparaben, polyester-5, 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 (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 & USAGE

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

CONTRAINDICATIONS

Enzoclear™ 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 reach of children.

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

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

If irritation occurs:

- use Enzoclear™ 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 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 the 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 & ADMINISTRATION

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

Prime Can Before Initial Use: Shake can well. Firmly strike bottom of can onto palm of hand 3 times. Hold can upright and direct initial spray to a non-stick surface.

Until foam dispenses, DO NOT spray directly on the skin as the initial spray 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, repeat priming process.

During Use: WASH-OFF APPLICATION: Shake can well. Holding can upright, dispense Enzoclear™ Foam into palm of hand. Cover the entire affected area with a thin layer 1 to 3 times daily, or as directed by a physician. Rub in until completely absorbed. Rinse off after 2 minutes. Wipe off any excess foam from actuator after use. LEAVE-ON APPLICATION: Shake can well. Holding can upright, dispense Enzoclear™ Foam into palm of hand and apply to the 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.

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 once 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

Enzoclear™ Foam is supplied in 100g (NDC 73159-**001**-01) aluminum cans.

Will not dispense entire contents. Container is overfilled to guarantee at least the listed amount.

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

Protect from freezing.

Store upright.

Manufactured for:

Lacer Pharma, LLC
1636 Popps Ferry Road, Suite 219
Biloxi, MS 39532
Phone: (228) 872-9607

PATIENT INFORMATION

IMPORTANT: For use on skin only (topical use). When using this product, avoid unnecessary sun exposure and use a sunscreen. Avoid contact with hair and dyed fabrics, which may be bleached by this product. When using this product, skin irritation may occur.

Stop use and ask a doctor if irritation becomes severe.

Read the Patient Information that comes with Enzoclear™ Foam before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of speaking with your doctor about your medical condition or your treatment.

What is Enzoclear™ Foam?

Enzoclear™ Foam is a prescription medicine used on the skin (topical) to treat mild to moderate acne vulgaris.

Who should not use Enzoclear™ Foam?

Do not use Enzoclear™ Foam if you have very sensitive skin or are sensitive to benzoyl peroxide.

What should I tell my doctor before using Enzoclear™ Foam?

Before using Enzoclear™ Foam, tell your doctor about all of your medical conditions, including if you:

- Have any allergies
- Are pregnant or are planning to become pregnant. It is not known if Enzoclear™ Foam will harm your unborn baby.
- Are breastfeeding or plan to breast-feed. It is not known if Enzoclear™ Foam passes into your breast milk.

Tell your doctor about all the medicines and skin products you use. Other skin and topical acne products may increase the irritation of your skin when used with Enzoclear™ Foam. Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

Instructions for applying Enzoclear™ Foam

CAUTION: Enzoclear™ Foam may bleach hair or colored fabric

- **Prime Can Before Initial Use:** Shake can well. Firmly strike bottom of can onto palm 3 times. Hold can upright and direct initial spray to a non-skin surface. **Until foam dispenses, 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.
- **During Use:** WASH-OFF APPLICATION: Shake can well. Holding can upright, dispense Enzoclear™ Foam into palm of hand. Cover the entire affected area with a thin layer 1 to 3 times daily, or as directed by a physician. Rub in until completely absorbed. Rinse off after 2 minutes. Wipe off any excess foam from actuator after use. LEAVE-ON APPLICATION: Shake can well. Holding can upright, dispense Enzoclear™ Foam into palm of hand and apply to the 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. 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 occurs, stop use of both products and ask a doctor.
- **Will not dispense entire contents. Container is overfilled to guarantee dispensing at least the listed amount.**

What should I avoid while using Enzoclear™ Foam?

- Limit your time in sunlight. Avoid using tanning beds or sun lamps. If you have to be in sunlight, wear a wide-brimmed hat or other protective clothing, and a sunscreen with SPF 15 rating or higher. Your doctor can give you more information about why this is important.
- Do not wash the affected area more than 2 to 3 times a day. Washing or scrubbing your skin too often may make your acne worse.

What are the possible side effects with Enzoclear™ Foam?

Side effects with Enzoclear™ Foam include:

- **Skin irritation.** Skin irritation and dryness is more likely to occur if you leave Enzoclear™ Foam on your skin longer than directed or use another topical acne medication at the same time. Stop use and ask a doctor if irritation becomes severe.

This is not the only possible side effect with Enzoclear™ Foam. Call your doctor for medical advice about side effects. You may report side effects to Lacer Pharma, LLC at 1-833-990-0046.

How should I store Enzoclear™ Foam?

Store at room temperature 59°-77°F (15°-25°C). Do not expose to temperatures above 120°F (49°C). Protect from freezing. Store upright.

Keep Enzoclear™ Foam and all medicines out of the reach of children.

General Information about Enzoclear™ Foam

Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information leaflets. Do not use Enzoclear™ Foam for a condition for which it was not prescribed. Do not give Enzoclear™ Foam to other people, even if they have the same condition you have. This leaflet summarizes the most important information about Enzoclear™ Foam. If you would like more information, talk with your doctor. You can also ask your doctor or pharmacist for information about Enzoclear™ Foam that is written for healthcare professionals. For more information about Enzoclear™ Foam, call 1-833-990-0046.

What are the ingredients in Enzoclear™ Foam?

Active Ingredient: benzoyl peroxide 9.8%

Inactive Ingredient: BHT, C12-15 benzoate, cetostearyl alcohol, citric acid, dimethicone, disodium EDTA, emulsifying wax, glycerin, methylparaben, polyester-5, propylene glycol, propylparaben, purified water, sodium citrate, steareth-10. Also contains: Propellant HFA-134a (1,1,1,2-tetrafluoroethane)

Packaging

CARTON LABEL

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Keep out of the reach of children. Contents under pressure. Do not puncture or incinerate container. Do not expose to temperatures above 120°F (49°C).

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

Rx Only

Enzoclear™ Foam
oxide Foam 9.8%

LACER PHARMA

NDC #73159-001-01
Net Wt. 100g

Will not dispense entire contents. Container is overfilled to guarantee dispensing a minimum of 100 grams.

DIRECTIONS: See enclosed prescribing information and patient information.

Prime Can Before Initial Use: Shake can well. Firmly strike bottom of can onto palm of hand 3 times. Hold can upright and direct initial spray to a non-skin surface. Until foam dispenses, 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.

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from freezing. Store upright.



Enz
Benzoyl Pero

MANUFACTURED FOR:
LACER PHARMA
Lacer Pharma LLC
996 N. Halstead Road, Suite D
Ocean Springs, MS 39564
Tel. (228) 872-9607
www.lacerpharma.com

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Benzoyl Peroxide Foam 9.8%

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MANUFACTURED FOR:
LACER PHARMA
Lacer Pharma LLC
996 N. Halstead Road, Suite D
Ocean Springs, MS 39564-3107
Tel. (228) 872-9607
www.lacerpharma.com

ENZOCLEAR FOAM

benzoyl peroxide aerosol, foam

Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73159-001
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)			BENZOYL PEROXIDE	9.8 g in 1 g
Inactive Ingredients				
Ingredient Name				Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYESTER-5 (TG-38) (UNII: 2L9351NW8W)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
STEARETH-10 (UNII: FD0913P475)				
NORFLURANE (UNII: DH9E53K1Y8)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73159-001-01	100 g in 1 CAN; Type 0: Not a Combination Product	07/25/2019	04/10/2023
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			07/25/2019	04/10/2023

Labeler - Lacer Pharma, LLC (117072266)
Establishment

Name	Address	ID/FEI	Business Operations
Lacer Pharma, LLC		117072266	manufacture(73159-001)

Revised: 4/2023

Lacer Pharma, LLC