

Rx Only

ZODERM[®] CREAM

(Benzoyl Peroxide)

Rx Only

ZODERM[®] GEL

(Benzoyl Peroxide)

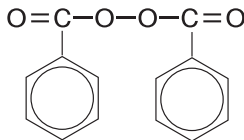
Rx Only

ZODERM[®] CLEANSER

(Benzoyl Peroxide)

DESCRIPTION:

ZODERM[®] 4.5% cream, ZODERM[®] 6.5% cream, ZODERM[®] 8.5% cream, ZODERM[®] 4.5% gel, ZODERM[®] 6.5% gel, ZODERM[®] 8.5% gel, ZODERM[®] 4.5% cleanser, ZODERM[®] 6.5% cleanser and ZODERM[®] 8.5% cleanser are intended for topical administration and contain 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 mL of ZODERM[®] 4.5% cream contains 45 mg of Benzoyl Peroxide. Each mL of ZODERM[®] 6.5% cream contains 65 mg of Benzoyl Peroxide. Each mL of ZODERM[®] 8.5% cream contains 85 mg of Benzoyl Peroxide. Each mL of ZODERM[®] cream is in an emulsion-based formulation consisting of: Purified Water, Urea (10%), Laureth-4, Octyldodecanol, Sodium Citrate, Glyceryl Stearate/PEG-100 Stearate, Cetearyl Alcohol and Ceteareth-20, Sodium Lauryl Sulfoacetate, Citric Acid, Cetyl Alcohol, Cyclomethicone, Carbomer and Disodium EDTA.

Each mL of ZODERM[®] 4.5% gel contains 45 mg of Benzoyl Peroxide. Each mL of ZODERM[®] 6.5% gel contains 65 mg of Benzoyl Peroxide. Each mL of ZODERM[®] 8.5% gel contains 85 mg of Benzoyl Peroxide. Each mL of ZODERM[®] gel is in an emulsion-based formulation consisting of: Purified Water, Urea (10%), Disodium EDTA, Carbomer, Triethanolamine, Poloxamer, Glycerin and Disodium Oleamido MEA-Sulfosuccinate.

Each mL of ZODERM[®] 4.5% cleanser contains 45 mg of Benzoyl Peroxide. Each mL of ZODERM[®] 6.5% cleanser contains 65 mg of Benzoyl Peroxide. Each mL of ZODERM[®] 8.5% cleanser contains 85 mg of Benzoyl Peroxide. Each mL of ZODERM[®] cleanser is in an emulsion-based formulation consisting of: Purified Water, Urea (10%), Sodium Lauryl Sulfoacetate, Glycerin, Propylene Glycol, Magnesium Aluminum Silicate, Disodium Oleamido MEA-Sulfosuccinate, Sodium Octoxynol-2 Ethane Sulfonate, Cetyl Alcohol, Laureth-12, Glyceryl Stearate/PEG-100 Stearate, Xanthan Gum, Citric Acid, Sodium Citrate, Carbomer and Disodium EDTA.

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:

ZODERM[®] cream, ZODERM[®] gel, and ZODERM[®] cleanser are indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS: These preparations are contraindicated in patients with a history of hypersensitivity to any of their components.

WARNINGS: When using this product, avoid unnecessary sun exposure and use a sunscreen.

PRECAUTIONS: General: 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: Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. Contact with any colored material (including hair and fabric) may result in bleaching or discoloration. If excessive irritation develops, discontinue use and consult your physician.

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.

DOSE AND ADMINISTRATION:

ZODERM[®] cream and ZODERM[®] gel: Apply once or twice daily to cover affected areas, or as directed by your dermatologist. Use after washing with a mild cleanser and water. If excessive drying occurs, it may be controlled by applying smaller amounts of product or using less often.

ZODERM[®] cleanser: Wash affected areas once or twice a day, or as directed by your dermatologist. Wet skin and liberally apply to areas to be cleaned, massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If excessive drying occurs, it may be controlled by rinsing off cleanser sooner or using less often.

HOW SUPPLIED:

ZODERM[®] 4.5% cream is supplied in 125 mL tubes, NDC 10337-740-21.
 ZODERM[®] 6.5% cream is supplied in 125 mL tubes, NDC 10337-748-21.
 ZODERM[®] 8.5% cream is supplied in 125 mL tubes, NDC 10337-741-21.
 ZODERM[®] 4.5% gel is supplied in 125 mL tubes, NDC 10337-742-21.
 ZODERM[®] 6.5% gel is supplied in 125 mL tubes, NDC 10337-749-21.
 ZODERM[®] 8.5% gel is supplied in 125 mL tubes, NDC 10337-743-21.
 ZODERM[®] 4.5% cleanser is supplied in 400 mL bottles, NDC 10337-744-51.
 ZODERM[®] 6.5% cleanser is supplied in 400 mL bottles, NDC 10337-751-51.
 ZODERM[®] 8.5% cleanser is supplied in 400 mL bottles, NDC 10337-745-51.

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

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

Patent Pending

Manufactured for:

DERMarts[®] DIVISION

DOAK DERMATOLOGICS
 A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

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