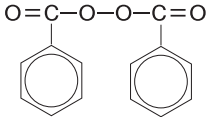


fougera®

R only

Benzoyl Peroxide Cleanser 4.5%, 6.5%, 8.5%

DESCRIPTION: Benzoyl Peroxide Cleanser 4.5%, 6.5% and 8.5% is intended for topical administration and contains 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 ($C_{14}H_{10}O_4$) is represented by the following chemical structure:



Each mL of Benzoyl Peroxide Cleanser 4.5% contains 45 mg of benzoyl peroxide. Each mL of Benzoyl Peroxide Cleanser 6.5% contains 65 mg of benzoyl peroxide. Each mL of Benzoyl Peroxide Cleanser 8.5% contains 85 mg of benzoyl peroxide. Each mL of Benzoyl Peroxide Cleanser is in an emulsion-based formulation consisting of the following inactive ingredients: carbomer, cetyl alcohol, citric acid, disodium EDTA, disodium oleamide MEA-sulfosuccinate, glycerin, glyceryl stearate/PEG-100 stearate, laureth-12, magnesium aluminum silicate, propylene glycol, purified water, sodium citrate, sodium lauryl sulfoacetate, sodium octoxynol-2 ethane sulfonate, urea (10%), and xanthan gum.

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: Benzoyl Peroxide Cleanser is 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 these products, 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. If excessive irritation develops, discontinue use and consult your physician. Contact with any colored material (including hair and fabric) may result in bleaching or discoloration.

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 that 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 these preparations 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: Wash affected areas once or twice daily, or as directed by your dermatologist. Wet skin and liberally apply to areas to be cleansed, 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:
Benzoyl Peroxide Cleanser 4.5% is supplied in 400 mL bottles, NDC 0168-0473-40.
Benzoyl Peroxide Cleanser 6.5% is supplied in 400 mL bottles, NDC 0168-0474-40.
Benzoyl Peroxide Cleanser 8.5% is supplied in 400 mL bottles, NDC 0168-0475-40.

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

Keep bottle tightly closed.

For Topical Use Only. Not for Ophthalmic, Oral or Vaginal use.

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

Manufactured for:
E. FOUGERA & CO.
A division of Nycomed US Inc.
Melville, New York 11747

Manufactured by: Groupe PARIMA, Inc.
Montreal, QC H4S 1X6 CANADA

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