

fougera®

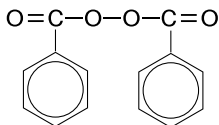
BENZOYL PEROXIDE 5.75% WASH

Benzoyl Peroxide in
a Urea Vehicle

Ronly

DESCRIPTION:

Benzoyl Peroxide 5.75% Wash 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 (C₁₄H₁₀O₂) is represented by the following chemical structure:



Each mL of Benzoyl Peroxide 5.75% Wash contains 57.5 mg of benzoyl peroxide in an emulsion-based formulation consisting of: purified water, urea (10%), sodium lauryl sulfoacetate, glycerin, propylene glycol, magnesium aluminum silicate, disodium oleamide 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:

Benzoyl Peroxide 5.75% Wash is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS: This preparation is contraindicated in patients with a history of hypersensitivity to any of its 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.

DOSAGE AND ADMINISTRATION:

Benzoyl Peroxide 5.75% Wash: Wash affected areas once or twice a day, 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 hydrating wash sooner or using less often.

HOW SUPPLIED:

Benzoyl Peroxide 5.75% Wash is supplied in 473 mL bottles, NDC 0168-0758-47.

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

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

Patent Pending

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

IL373A
R8/08