water base gel

Benzac® AC 5 & 10
(benzoyl peroxide gel)

Benzac® AC Wash 5 & 10
(benzoyl peroxide)

Rx only

DESCRIPTION: Benzac® AC 5 and 10 (benzoyl peroxide gel) and Benzac® AC Wash 5 and 10 (benzoyl peroxide) are topical, water-base, benzoyl peroxide containing preparations for use in the treatment of acne vulgaris. Benzoyl peroxide is an oxidizing agent which possesses antibacterial properties and is classified as a keratolytic. Benzoyl peroxide (C₁₇H₁₁O₄) is represented by the following chemical structure:

\[ \text{O} \text{C=O} \text{O-C=O} \text{O} \]

Benzac® AC 5 and Benzac® AC 10 contain, respectively, benzoyl peroxide 5% and 10% as the active ingredient in a gel base containing acrylates copolymer, carbomer 940, docusate sodium, edetate disodium, glycerin, polyoxamer 182, propylene glycol, purified water, silicon dioxide, and sodium hydroxide. May contain citric acid to adjust pH.

Benzac® AC Wash 5 and Benzac® AC Wash 10 contain, respectively, benzoyl peroxide 5% and 10% as the active ingredient in a vehicle consisting of acrylates copolymer, carbomer 940, glycerin, purified water, sodium C14-16 olefin sulfonate, and sodium hydroxide. May contain citric acid to adjust pH.

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 a 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: Benzac® AC 5 and 10 and Benzac® AC Wash 5 and 10 are indicated for topical treatment of acne vulgaris.

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

PRECAUTIONS: General: For external use only. If severe irritation develops, discontinue use and institute appropriate therapy. After the 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. Avoid contact with hair, fabric or carpet. Benzoyl peroxide will cause bleaching. When using this product, avoid unnecessary sun exposure and use a sunscreen. 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 are 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 latter 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 occur, 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:
Benzac® AC 5 or 10 should be applied once or twice daily to cover affected areas after washing with a mild cleanser and water.

Benzac® AC Wash 5 or 10. Wash once or twice daily, avoiding contact with the eyes and mucous membranes. Wet the area of application. Apply Benzac® AC Wash 5 or 10 to the hands and wash the affected areas. Rinse with water and pat dry.

HOW SUPPLIED:
Benzac® AC 5 Water Base Gel
60 g tubes – NDC 0299-3625-60
Benzac® AC 10 Water Base Gel
60 g tubes – NDC 0299-3630-60
Benzac® AC Wash 5
8 oz. plastic bottles – NDC 0299-3640-08
Benzac® AC Wash 10
8 oz. plastic bottles – NDC 0299-3645-08
Storage: Store Benzac® AC and Benzac® AC Wash at controlled room temperature 68°F to 77°F (20°C to 25°C).

Marketed by:
GALDERMA LABORATORIES, L.P.
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