Benzyol Peroxide Topical Wash 5% and 10% are topical, gel-based, benzoyl peroxide containing preparations for use in the treatment of acne vulgaris. Benzyol 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:

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\text{Benzoyl Peroxide Topical Wash 5% and 10% contain benzoyl peroxide USP as the active ingredient.}
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INACTIVE INGREDIENTS:
carbomer interpolymer type A NF, cetyl alcohol NF, disodium oleamido MEA-sulfosuccinate, edetate disodium, gelsulfuric acid, hydroxypropylmethyl cellulose, lauryl alcohol, MEA-sulfosuccinate, magnesium aluminum silicate NF, propylene glycol USP, purified water USP, sodium coco-sulfate, sodium lauroamphoacetate, xanthan gum NF.

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. 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 Topical Wash 5% and 10% 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.

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 not accidentally contact occurs, treat with water. Carbamyl acetate and organic cotton should not be used as applicators. If excessive irritation occurs, 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 BCC and SCC indicate that benzoyl peroxide is not genotoxic and is not a clastogen or aneugent.
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 function of the offspring.

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. Other supportive and symptomatic measures should be as directed by the practitioner. In cases of undue sensitivity, the reaction may be due to excessive use and not allergenicity.

DOSAGE AND ADMINISTRATION: Wash affected areas once or twice daily, or as directed by your dermatologist. Avoid contact with eyes or mucous membranes. 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 drying occurs, it may be controlled by rinsing wash of sooner or using less often.

HOW SUPPLIED: Benzoyl Peroxide Topical Wash 5% – 5oz. bottles - NDC 67405-425-05
Benzoyl Peroxide Topical Wash 5% – 8 oz. bottles - NDC 67405-425-08
Benzoyl Peroxide Topical Wash 10% – 5oz. bottles - NDC 67405-430-05
Benzoyl Peroxide Topical Wash 10% – 8oz. bottles - NDC 67405-430-08