

Benzoyl Peroxide 5 Wash

(Benzoyl Peroxide 5% Wash)

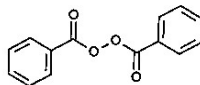
Regular Strength Acne Treatment

DESCRIPTION

Benzoyl Peroxide 5 Wash is a topical preparation containing 5% benzoyl peroxide as the active ingredient in a lathering base containing: purified water, ammonium lauryl sulfate, disodium cocoamphodiacetate, sodium chloride, carbomer, glycerin, propylene glycol, DM DM hydantoin, sodium hydroxide, methylparaben, and propylparaben.

The Chemical structure for the active ingredient is:

Benzoyl peroxide
 $C_{14}H_{10}O_4$ (anhydrous) 242.23



CLINICAL PHARMACOLOGY

The exact method of action of benzoyl peroxide in acne vulgaris is not known. Benzoyl peroxide is an antibacterial agent with demonstrated activity against *Propionibacterium acnes*. This action combined with the mild keratolytic effect of benzoyl peroxide is believed to be responsible for its usefulness in acne.

Little is known about the percutaneous penetration, metabolism and excretion of benzoyl peroxide. Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid and 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 Wash is indicated for the topical treatment of mild to moderate acne vulgaris. Benzoyl Peroxide 5 Wash may be used with other acne treatments including retinoic acid products, antibiotics and sulfur/salicylic acid containing preparations.

CONTRAINDICATIONS

Benzoyl Peroxide 5 Wash should not be used in patients who have shown hypersensitivity to benzoyl peroxide or any other ingredients in this product.

WARNINGS

FOR EXTERNAL USE ONLY. KEEP OUT OF REACH OF CHILDREN. Avoid contact with eyes, eyelids, lips and mucous membranes. If inadvertent contact occurs, rinse area thoroughly with water. Contact with colored material, including fabric and hair, may result in discoloration. When using Benzoyl Peroxide 5 Wash, avoid unnecessary sun exposure and use a sunscreen. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

PRECAUTIONS

Information for Patients

- ♦ Avoid contact with eyes, eyelids, lips and mucous membranes.
- ♦ May discolor hair and fabrics.
- ♦ Avoid unnecessary sun exposure and use a sunscreen.
- ♦ Use of oil-free make-up recommended.
- ♦ If severe irritation develops, discontinue use and consult your physician.

Carcinogenesis, Mutagenesis and Impairment of Fertility

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 not known. Benzoyl peroxide has not been found to be mutagenic (Ames test) and there are no published data indicating that it impairs fertility.

Pregnancy: Category C

Animal reproductive studies have not been conducted with benzoyl peroxide. It is also 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 below the age of 12 have not been established.

ADVERSE REACTIONS

Allergic contact dermatitis and dryness have been reported with topical benzoyl peroxide therapy. If excessive scaling, erythema or edema occurs, the use of Benzoyl Peroxide 5 Wash should be discontinued and appropriate therapy instituted. To hasten resolution of adverse effects, cool compresses may be used. After reaction clears, a reduced dosage schedule may often be resumed if the reaction is judged not to be due to allergenicity.

DOSAGE AND ADMINISTRATION

Shake well before using. It is recommended that therapy be initiated with Benzoyl Peroxide 5% Wash, washing the affected areas once a day during the first week, and twice a day thereafter as tolerated. Wet skin areas to be treated; apply Benzoyl Peroxide Wash, work to a full lather, rinse thoroughly and pat dry. Frequency of use should be adjusted to obtain the desired clinical response. Close cap tightly after use.

HOW SUPPLIED

Benzoyl Peroxide 5 Wash Net Wt 8 oz (227 g) NDC 68752-405-08

Store at controlled room temperature 59° - 85°F (15° - 30°C).

Rx Only.

Manufactured for TriMarc Laboratories.
Telephone 405.942.3289



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