

R_x Only

BENZASHAVE[®] 5% & 10%

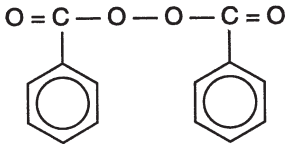
Medicated Shaving Cream

(benzoyl peroxide 5%)

(benzoyl peroxide 10%)

DESCRIPTION:

BenzaShave[®] 5% and BenzaShave[®] 10% (benzoyl peroxide 5% and 10%) are topical shaving cream preparations for use in the treatment of pseudofolliculitis (*p. barbae*, ingrown hairs, razor bumps) and acne vulgaris associated with shaving. Benzoyl peroxide is an oxidizing agent which possesses antibacterial properties and is classified as a keratolytic agent. Benzoyl peroxide (C₁₄H₁₀O₄) is represented by the following chemical structure.



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INGREDIENTS:

BenzaShave[®] 5%

Each gram of **BenzaShave[®]** (benzoyl peroxide 5%) contains: benzoyl peroxide 50 mg, purified water, edetate disodium, propylparaben, methylparaben, carbomer interpolymers A, sodium cocosulfate, sodium lauroamphoacetate, glycerin, stearic acid, myristic acid, dimethicone copolyol, mineral oil and coconut acid.

BenzaShave[®] 10%

Each gram of **BenzaShave[®]** (benzoyl peroxide 10%) contains: benzoyl peroxide 100 mg, purified

water, edetate disodium, propylparaben, methylparaben, carbomer interpolymers A, sodium cocosulfate, sodium lauroamphoacetate, glycerin, stearic acid, myristic acid, dimethicone copolyol, mineral oil and coconut acid.

CLINICAL PHARMACOLOGY:

The mechanism of action of benzoyl peroxide has not been determined but may be related to its antibacterial activity against *Propionibacterium acnes* and its ability to cause drying and peeling. Benzoyl peroxide reduces the concentration of free fatty acids in the sebum. Little is known about the percutaneous penetration, metabolism and excretion of benzoyl peroxide, although it is likely that benzoic acid is a major metabolite. There is no evidence of systemic toxicity caused by benzoyl peroxide in humans.

INDICATIONS AND USAGE:

A medicated shaving cream containing 5% or 10% benzoyl peroxide that effectively intervenes to aid in the treatment of pseudofolliculitis (*p. barbae*, ingrown hairs, razor bumps) and acne vulgaris associated with shaving. This formula primes and lifts hair follicles, promoting a clean, close shave.

CONTRAINDICATIONS:

These products are contraindicated in patients with a history of hypersensitivity to benzoyl peroxide or to any of the other ingredients of the preparations.

PRECAUTIONS:

General: For external use only. This preparation should not be used in or near the eyes or on mucous membranes. If severe irritation develops, discontinue use and institute appropriate therapy. After the reaction clears, treatment may often be resumed with less frequent application.

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 a physician. May bleach hair and colored fabric.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data from several studies using mice known to be highly susceptible to cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of these findings to humans is unknown.

Pregnancy: Pregnancy Category C: Animal reproduction 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 data available on the effect of benzoyl peroxide on the 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 pediatric patients have not been established.

ADVERSE REACTIONS: Allergic contact dermatitis has been reported with topical benzoyl peroxide therapy.

DOSAGE AND ADMINISTRATION:

Wet area to be shaved. Apply a small amount of **BenzaShave**[®] with fingertips. Gently rub over entire area and shave.

HOW SUPPLIED:

BenzaShave[®] (benzoyl peroxide 5%), 4 oz (113.4 g) tube, NDC 10337-805-41.

BenzaShave[®] (benzoyl peroxide 10%), 4 oz (113.4 g) tube, NDC 10337-806-41.

KEEP OUT OF REACH OF CHILDREN.

Store at Controlled Room Temperature 15°-25°C (59°-77°F).

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

For control number and expiration date, see crimp of tube.

Manufactured for:

DERMarts[®] DIVISION



DOAK DERMATOLOGICS

A SUBSIDIARY OF BRADLEY PHARMACEUTICALS, INC.

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