

TRIAZ (benzoyl peroxide)

Rx Only

DESCRIPTION: TRIAZ® (benzoyl peroxide) 3%, 6%, and 9% Gels, TRIAZ® (benzoyl peroxide) 3%, 6%, and 9% Cleansers and TRIAZ® (benzoyl peroxide) 3%, 6%, and 9% Pads are topical, gel-based, benzoyl peroxide containing preparations 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 (C₁₄H₁₀O₄) is represented by the following chemical structure:



TRIAZ 3% Gel contains Benzoyl Peroxide USP 3% as the active ingredient in a gel-based formulation consisting of: Purified Water USP, C12-15 Alkyl Benzoate, Glycerin USP, Cetearyl Alcohol, Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7, Glyceryl Stearate (and) PEG-100 Stearate, Steareth-2, Steareth-20, Dimethicone, Glycolic Acid, Zinc Lactate, Lactic Acid USP, Edetate Disodium USP, Sodium Hydroxide NF.

TRIAZ 6% and 9% Gels contain, respectively, Benzoyl Peroxide USP 6% and 9% as the active ingredient in a gel-based formulation consisting of: Purified Water USP, C12-15 Alkyl Benzoate, Glycerin USP, Cetearyl Alcohol, Glycolic Acid, Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7, Glyceryl Stearate (and) PEG-100 Stearate, Steareth-2, Steareth-20, Sodium Hydroxide NF, Dimethicone, Zinc Lactate, Edetate Disodium USP.

TRIAZ 3% Cleanser contains Benzoyl Peroxide USP 3% as the active ingredient in a vehicle consisting of: Glycerin USP, Petrolatum USP, C12-15 Alkyl Benzoate, Sodium Cocoyl Isethionate, Special Petrolatum Fraction, Sodium C14-16 Olefin Sulfonate, Zinc Lactate, Carbomer, Potassium Metaphosphate NF, Titanium Dioxide USP, Trolamine NF, Glycolic Acid, Lavender Extract, Menthol USP.

TRIAZ 6% and 9% Cleansers contain, respectively, Benzoyl Peroxide USP 6% and 9% as the active ingredient in a vehicle consisting of: Glycerin USP, Petrolatum USP, C12-15 Alkyl Benzoate, Sodium Cocoyl Isethionate, Special Petrolatum Fraction, Sodium C14-16 Olefin Sulfonate, Zinc Lactate, Carbomer, Potassium Metaphosphate NF, Titanium Dioxide USP, Trolamine NF, Glycolic Acid, Lavender Extract, Menthol USP.

TRIAZ 3%, 6%, and 9% Pads contain, respectively, Benzoyl Peroxide 3%, 6%, and 9% as the active ingredient in a gel-based formulation consisting of: Purified Water USP, C12-15 Alkyl Benzoate, Glycerin USP, Cetearyl Alcohol, Steareth-2, Polysorbate 20 NF, Corn Starch Modified, Dimethicone, Glyceryl Stearate (and) PEG-100 Stearate, Steareth-20, Edetate Disodium USP, Glycolic Acid, Carbomer, Sodium Hydroxide NF, Zinc Lactate.

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: TRIAZ 3%, 6%, and 9% Gels, TRIAZ 3%, 6%, and 9% Cleansers and TRIAZ 3%, 6%, and 9% Pads 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.

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 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 effect 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 these preparations 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:

TRIAZ Gels: Apply once or twice daily to cover affected areas, or as directed by your dermatologist. Use after washing with a mild cleanser, such as one of the TRIAZ Cleansers, and water.

TRIAZ Cleansers: 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 cleanser off sooner or using less often.

TRIAZ Pads: Apply once or twice daily to cover affected areas, or as directed by your dermatologist. Use after washing with a mild cleanser, such as one of the TRIAZ Cleansers, and water.

HOW SUPPLIED:

	SIZE	NDC NUMBER
TRIAZ 3% Gel	1.5 oz. (42.5 g) tube	NDC 99207-209-01
TRIAZ 6% Gel	1.5 oz. (42.5 g) tube	NDC 99207-051-01
TRIAZ 9% Gel	1.5 oz. (42.5 g) tube	NDC 99207-207-01
TRIAZ 3% Cleanser	6 oz. (170.3 g) tube	NDC 99207-206-12
TRIAZ 3% Cleanser	12 oz. (340.2 g) bottle	NDC 99207-206-09
TRIAZ 6% Cleanser	6 oz. (170.3 g) tube	NDC 99207-116-12
TRIAZ 6% Cleanser	12 oz. (340.2 g) bottle	NDC 99207-116-09
TRIAZ 9% Cleanser	6 oz. (170.3 g) tube	NDC 99207-208-12
TRIAZ 9% Cleanser	12 oz. (340.2 g) bottle	NDC 99207-208-09
TRIAZ 3% Pads	1.0 g. Individual foil-wrapped pads, 30 per box	NDC 99207-221-30
TRIAZ 3% Pads	1.0 g. Individual foil-wrapped pads, 60 per box	NDC 99207-221-60
TRIAZ 6% Pads	1.0 g. Individual foil-wrapped pads, 30 per box	NDC 99207-222-30
TRIAZ 6% Pads	1.0 g. Individual foil-wrapped pads, 60 per box	NDC 99207-222-60
TRIAZ 9% Pads	1.0 g. Individual foil-wrapped pads, 30 per box	NDC 99207-223-30
TRIAZ 9% Pads	1.0 g. Individual foil-wrapped pads, 60 per box	NDC 99207-223-60

Store at 15° - 25°C (59° - 77°F).

TRIAZ Cleansers are covered by U.S. Patents: 5,648,389; 5,409,706; and 5,632,996. TRIAZ Gels are covered by U.S. Patent 5,648,389.

TRIAZ Pads are covered by U.S. Patents: 5,632,996; 5,648,389.

TRIAZ Gels and TRIAZ Cleansers manufactured for:

MEDICIS, The Dermatology Company,® Scottsdale, AZ 85258

by: Contract Pharmaceuticals Limited, Mississauga, Ontario L5N 6L6 CANADA

Made in Canada

TRIAZ Pads manufactured for:

MEDICIS, The Dermatology Company,® Scottsdale, AZ 85258

by: Tapemark, West St. Paul, MN 55118

Made in U.S.

www.Triaz.com