

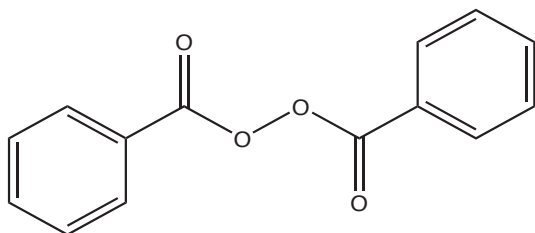
BPO 4% Gel
(benzoyl peroxide 4%)

BPO 8% Gel
(benzoyl peroxide 8%)

AQUEOUS BASE ACNE GEL FOR TOPICAL USE

DESCRIPTION

BPO 4% Gel and BPO 8% Gel are topical preparations containing benzoyl peroxide 4% and 8%, respectively, as the active ingredient in a gel vehicle containing aloe barbadensis leaf juice, benzyl alcohol, cetareth-20, cetyl alcohol, dimethyl isosorbide, purified water, simethicone and stearyl alcohol. The structural formula of benzoyl peroxide is:



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. Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid and excreted as benzoate in the urine.

INDICATIONS AND USAGE

BPO 4% Gel and BPO 8% Gel are indicated for use in the topical treatment of mild to moderate acne vulgaris. BPO 4% Gel or BPO 8% Gel may be used as an addition in acne treatment regimens including antibiotics, retinoic acid products and sulfur/salicylic acid containing preparations.

CONTRAINDICATIONS

BPO 4% Gel and BPO 8% Gel should not be used in patients who have shown hypersensitivity to benzoyl peroxide or to any of the other ingredients in the product.

PRECAUTIONS

General — For external use only. Avoid contact with eyes and mucous membranes. **AVOID CONTACT WITH HAIR, FABRICS OR CARPETING AS BENZOYL PEROXIDE WILL CAUSE BLEACHING.**

Carcinogenesis, Mutagenesis, Impairment of Fertility —

Based upon all available evidence, benzoyl peroxide is not considered to be a carcinogen. However, data from a study using mice known to be highly susceptible to cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of the findings is not known.

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 if it can affect reproduction capacity. Benzoyl peroxide should be used by a pregnant woman only if clearly needed.

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.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

ADVERSE REACTIONS

Contact sensitization reactions are associated with the use of topical benzoyl peroxide products and may be expected to occur in 10 to 25 of 1000 patients. The most frequent adverse reactions associated with benzoyl peroxide use are excessive erythema and peeling which may be expected to occur in 5 of 100 patients. Excessive erythema and peeling most frequently appear during the initial phase of drug use and may normally be controlled by reducing frequency of use.

DOSAGE AND ADMINISTRATION

Therapy may be initiated with either BPO 4% Gel or BPO 8% Gel. The medication should be applied once or twice daily to affected areas. Frequency of use should be adjusted to obtain the preferred clinical response. Gentle cleansing of the affected areas prior to application of BPO 4% Gel or BPO 8% Gel may be beneficial. Clinically visible improvement will normally occur by the third week of therapy. Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continuing use of the drug is normally required to maintain a satisfactory clinical response.

HOW SUPPLIED

BPO 4% Gel is supplied in 42.5 g (1.5 oz) tubes NDC 42192-162-15. BPO 8% Gel is supplied in 42.5 g (1.5 oz) tubes NDC 42192-163-15. Store at controlled room temperature 15°-30°C (59°-86°F).

Manufactured for:
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