

BENZOX AC GEL PRESCRIBING INFORMATION

Benzoyl Peroxide 2.5%/5% Gel

COMPOSITION

Each g of Benzox AC Gel 2.5% contains:	
Benzoyl Peroxide	25 mg
Each g of Benzox AC Gel 5% contains:	
Benzoyl Peroxide	50 mg
In a unique gel base of Acrylates Co-polymer with Glycerine	

DESCRIPTION

Benzox AC Gel 2.5% and **5%** are topical aqueous-base preparations containing benzoyl peroxide as the active ingredient. Benzoyl peroxide is an oxidizing agent that possesses antibacterial properties and is classified as a keratolytic agent.

CLINICAL PHARMACOLOGY

Benzoyl peroxide is an antibacterial agent with demonstrated activity against *Propionibacterium acnes*. The exact mode of action of benzoyl peroxide in acne vulgaris is not known. It is believed to act by slowly releasing active oxygen.

Benzoyl peroxide improves both inflammatory and noninflammatory lesions of acne. It is suggested that the lipophilic nature of benzoyl peroxide acts to concentrate the compound into the lipid-rich sebaceous follicles.

The medication also has some keratolytic effect, which produces comedolysis, as well as drying and desquamative actions that contribute to its efficacy in acne.

Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid. About 5% of the metabolized medication is systemically absorbed and eliminated as benzoate in the urine. There is no evidence of systemic toxicity caused by Benzoyl Peroxide in humans.

Acrylates Co-polymer beads absorb surface lipids and **Glycerin** moisturizes dry skin thereby reducing irritation and improving patient compliance.

INDICATIONS

Benzox AC Gel 2.5% and **5%** are indicated for the topical treatment of mild to moderate non-inflammatory and inflammatory acne vulgaris. In more severe acne, benzoyl peroxide may be indicated as an adjunct to therapeutic regimens for acne including oral and topical antibiotics, retinoic acid preparations, and sulfur/salicylic acid-containing preparations.

CONTRAINDICATIONS

Benzox AC Gel should not be used in patients who are hypersensitive to benzoyl peroxide, sulphur or to any of the other ingredients in this formula.

WARNINGS

When using this product, avoid unnecessary sun exposure and use a sunscreen.

PRECAUTIONS

General — **Benzox AC Gel 2.5%** and **5%** are 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. 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 these findings is not known.

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

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 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

Contact sensitization reactions are associated with the use of topical benzoyl peroxide products and may be expected to occur in 10-25 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

It is recommended that therapy be initiated with **Benzox AC Gel 2.5%**, applying the medication to the affected areas once a day during the first week, and twice a day thereafter as tolerated. Frequency of use should be adjusted to obtain the desired clinical response. Therapy with **Benzox AC Gel 5%** may be initiated in patients who demonstrate accommodation to **Benzox AC Gel 2.5%**.

Gentle cleansing of the affected areas prior to application of **Benzox AC Gel 2.5%**, or **5%** may be beneficial.

Clinically visible improvements 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.

PRESENTATION

Benzox AC 2.5% and 5% Gel is available in a tube of 20 g.

STORAGE

Store preferably between 15°C and 30°C.

Keep this medication out of reach of children.