BENZAC® AC

BENZOYL PEROXIDE

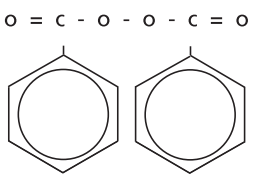
Water Base Gel

For external use only

PRODUCT INFORMATION

DESCRIPTION

BENZAC® AC 2.5, 5 & 10 (benzoyl peroxide gels) are topical, water-base, benzoyl peroxide containing preparations for use in the treatment of acne vulgaris. Benzoyl peroxide is an oxidizing agent which possesses antibacterial properties and is classified as a keratolytic. Benzoyl peroxide ($C_{14}H_{10}O_4$) is represented by the following chemical structure:



BENZAC® AC 2.5, BENZAC® AC 5 and BENZAC® AC 10 contain, respectively, benzoyl peroxide 2.5%, 5% and 10% as the active ingredient in a gel base containing sodium docusate, disodium edetate, carbomer 940, silicon dioxide, propylene glycol, poloxamer 182, sodium hydroxide and purified water. May contain citric acid to adjust pH.

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 a simultaneous reduction in comedones and acne lesions.
The percutaneous penetration of benzoyl peroxide in rat, rabbit, monkey and man is low. The majority of the penetrated benzoyl peroxide is converted into benzoic acid which after absorption in the systemic circulation is rapidly eliminated by the kidney. There is no evidence of any tissue accumulation. There is no evidence that cutaneous application of the proposed clinical doses of Benzac preparations should be associated with any systemic adverse reaction in humans.

INDICATIONS

BENZAC® AC 2.5, 5 & 10 are indicated for the topical treatment of acne vulgaris.

CONTRA-INDICATIONS

These preparations are contra-indicated in patients with history of hyper-sensitivity to any of their components.

PRECAUTIONS

General: For external use only.
A mild burning sensation will probably be felt on first application and some reddening and peeling of the skin will occur within a few days. During the first weeks of treatment a sudden increase in peeling will occur in most patients. This is not harmful and will normally subside within a day or two if treatment is temporarily discontinued. If severe irritation occurs, patients should be directed to use the medication less frequently, to temporarily discontinue use or to discontinue use altogether.
Benzoyl peroxide may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.

Information for Patients:
Avoid contact with eyes, eyelids, mouth, nostrils or mucous membranes. If accidental contact occurs, rinse thoroughly 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. May contain benzoic acid as a degradation product of benzoyl peroxide.
Repeated exposure to sunlight or UV radiation should be avoided.
Due to the risk of sensitisation, benzoyl peroxide gel or lotion should not be applied on damaged skin.

Pregnancy, fertility and nursing mothers:
There is no safety concern relating to the effects of cutaneously applied benzoyl peroxide on reproductive function, fertility, teratogenicity, embryotoxicity, or peri- and post- natal development from animal data.

In widespread clinical use for the cutaneous treatment of acne vulgaris, at concentrations up to 10% w/w for several decades, benzoyl peroxide has never been associated with such effects in humans. Benzoyl peroxide should only be used by a pregnant woman if clearly needed. It is not known whether this drug is excreted in animal or human milk. Because many drugs are excreted in human milk, caution should be exercised when benzoyl peroxide is administered to a nursing woman and the preparation should not be applied on the chest to avoid accidental transfer to the infant.

Pediatric Use: Safety and effectiveness in children have not been established.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

There are no known interaction with other medications which might be used cutaneously and concurrently with benzoyl peroxide gel or lotion; however, drugs with desquamative, irritant and drying effects should not be used concurrently with benzoyl peroxide gel or lotion.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Based on the pharmacodynamics profile and extensive clinical experience, performance related to driving and using machines should not be affected during treatment with benzoyl peroxide.

ADVERSE REACTIONS

The adverse reactions resulting from clinical trials are all skin disorders. They are reversible when treatment is reduced in frequency or discontinued.

The following categories are used to indicate the frequency of occurrence of adverse effects:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Unknown (Frequency not assessable based on the available data).

They are presented in the table below:

Skin and subcutaneous tissue disorders	Very common (≥1/10)	Dry skin, Erythema, Skin exfoliation (peeling), Skin Burning
	Common (≥1/100 to < 1/10)	Pruritus, Pain of skin (pain, stinging), Skin irritation (irritant contact dermatitis)
	Uncommon (≥1/1000 to <1/100)	Allergic contact dermatitis

Swelling face and allergic reactions, including application site hypersensitivity and anaphylaxis (unknown frequency) have been reported during post-marketing surveillance.

OVERDOSAGE

Benzoyl peroxide gels are preparations indicated for topical treatment only. If the medication is applied excessively, no more rapid or better results will be obtained and severe irritation might develop. In this event, treatment must be discontinued and appropriate symptomatic therapy should be instituted.

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

Before each application, the skin should be cleaned and dried carefully. It is recommended to initiate the treatment with benzoyl peroxide 2.5 or 5% gel. BENZAC® AC 2.5, 5 & 10 should be applied once or twice daily in a thin layer to cover affected areas.

Persons with sensitive skin should be directed to apply the gel once daily before going to bed.

In case adequate results are not achieved with 5% gel, the treatment with benzoyl peroxide 10% gel may be started.

HOW SUPPLIED

BENZAC® AC 2.5, 5 & 10 are available in 5g, 15g, 30g, 40g and 60g tubes (not all strengths / sizes are marketed).

STORAGE

Do not store BENZAC® AC 2.5, 5 & 10 above 25°C.

Keep out of reach of children.

Manufactured by:
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