Leaflet is continuously updated and as a result some information may not be current.

Benzoyl Peroxide Gel IP

Benzac®AC 2.5% & 5%

GEL

FOR EXTERNAL USE ONLY

PRODUCT INFORMATION

DESCRIPTION

BENZAC®AC 2.5% & 5% Gel (benzoyl peroxide gels) are topical, aqueous-base with glycerol and acrylates-copolymer, 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.

BENZAC®AC 2.5% & 5% Gel contain, Benzoyl Peroxide 2.5% and 5% w/w, respectively as the active ingredient in a aqueous gel base.

Composition

Benzoyl Peroxide Gel IP 2.5%

Hydrous Benzoyl Peroxide IP
equivalent to Anhydrous Benzoyl Peroxide .....2.5% w/w
Aqueous gel base.....q.s
with Glycerol and Acrylates co-polymer

Benzoyl Peroxide Gel IP 5%

Hydrous Benzoyl Peroxide IP
equivalent to Anhydrous Benzoyl Peroxide .....5% w/w
Aqueous gel base.....q.s
with Glycerol and Acrylates co-polymer

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% Gel are indicated for the topical treatment of acne vulgaris.

POSOLOGY AND METHOD OF 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. The gel is applied on a thin layer to cover the affected areas, once or twice daily. Person with sensitive skin should be directed to apply the gel once daily before going to bed.

CONTRA-INDICATIONS

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

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

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, mouth, angles of the nose or mucous membranes. If accidental contact occurs, rinse thoroughly with water. Due to the risk of sensitisation, benzoyl peroxide gel should not be applied on damaged skin. 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.

Pregrancy, fertility and nursing mothers:

There is no safety concern relating to the effects of cutaneously applied benzoyl peroxide on reproductive function, fertility, eratogenicity, 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 be used by a pregnant woman only if clearly needed. 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 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 interactions with other medications which might be used cutaneously and concurrently with benzoyl peroxide gel; however, drugs with desquamative, irritant and drying effects should not be used concurrently with benzoyl peroxide gel.

Effects on Ability to Drive and Use Machines
Based on the pharmacodynamic 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 (e.g excessive scaling, erythema or edema) might develop. In this event, treatment must be discontinued and appropriate symptomatic therapy in compresses 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. BENZAC AC 2.5% and 5% 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.

STORAGE
Store BENZAC®AC 2.5% & 5% Gel at temperature not exceeding 25°C. Do not freeze.
Keep out of reach of children.

HOW SUPPLIED
BENZAC®AC 2.5 % and BENZAC®AC 5% is supplied in pack of 20 g, 30 g tube.

Manufactured by:
Encube Ethicals Pvt Ltd
Plot No C, Madkaim Ind. Estate, Madkaim
Post Mardol, Ponda, Goa-403 404.

Marketed by
Galderma India Private Limited
(Formerly known as Nestlé Skin Health India Private Limited)
8th Floor, D Wing, Unit No. 801 & 802, Lotus Corporate Park,
Off. Western Express Highway, Goregaon East, Mumbai,
Maharashtra, India, 400063.

GALDERMA

Benzac is a registered trademark.

Reference: Core Data Sheet - Benzoyl Peroxide - Version 6.0

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