New Zealand Datasheet

1 PRODUCT NAME
BENZAC® AC Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Benzoyl peroxide 25 mg/g, 50mg/g and 100 mg/g

3 PHARMACEUTICAL FORM
BENZAC AC Gel contains benzoyl peroxide 25mg/g or 50mg/g or 100mg/g in a white to off-white smooth gel

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
As an aid in the treatment of mild to moderate acne vulgaris

4.2 Dosage and method of administration
Wash and dry affected areas. Apply the gel in a thin layer to cover the affected areas once daily, leaving on the skin for 2 hours then wash off with water. After three days if no discomfort is felt, apply in the evening and allow to remain all night. After a further three days, if there is no discomfort and the acne is resisting treatment, apply twice a day, once in the morning. Leave on all day then wash the affected area and apply again in the evening. Leave on all night.

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

Normal use may cause a mild burning feeling at first followed by some redness with some peeling during the first few days.

BENZAC AC Gel is available in three strengths, 2.5%, 5% and 10%. Unless otherwise directed begin acne therapy with the weakest strength. This suggestion applies especially to people with sensitive skins.

4.3 Contraindications
BENZAC AC Gel is contraindicated in patients with a history of hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use
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.

BENZAC AC Gels should not be used on or near the eyes, mouth, angles of the nose or on mucous membranes. If accidental contact occurs rinse thoroughly with water.

Avoid excessive exposure to sunlight or other sources of ultraviolet light. Do not use at high altitudes or near snow covered ground.

Be careful not to use cosmetic products containing alcohol, abrasives or medicated soaps. These may cause an extra irritant or drying effect.

Contact with any coloured material (including hair or fabric) may result in bleaching or discolouration.

Due to the risk of sensitization, benzoyl peroxide gel should not be applied on damaged skin.

4.5 Interaction with other medicines and other forms of interaction

There are no known interactions with other medications which might be used cutaneously and concurrently with BENZAC AC Gel, however drugs with desquamative, irritant and drying effects should not be used concurrently.

4.6 Fertility, Pregnancy and lactation

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. Although safe for use during pregnancy BENZAC AC Gel should only be used by a pregnant woman if clearly needed.

It is not known whether benzoyl peroxide is excreted in human milk. Caution should be exercised when BENZAC AC Gel is administered to a breastfeeding woman and the preparation should not be applied on the chest to avoid accidental exposure of the infant.

4.7 Effects on ability to drive and use machines

BENZAC AC Gel has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

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 sensation
	Common (≥1/100 to <1/10)	Pruritus Pain of skin (pain, stinging) Skin irritation (irritant contact dermatitis)
	Uncommon (≥ 1/1,000 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-acne preparations for topical use, ATC Code: D10AE01

Benzoyl peroxide has been shown to have potent broad spectrum antimicrobial activity, particularly against *Proprionibacterium acnes* which is normally present in affected hair follicles. In addition benzoyl peroxide has demonstrated exfoliative and comedolytic activities both of which are beneficial in the treatment of acne. The addition of acrylates copolymer provides control of excess sebum production and glycerin is included for its humectant properties.

5.2 Pharmacokinetic properties

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 into 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 AC Gel should be associated with any systemic adverse reactions in humans.

5.3 Preclinical safety data

In animal studies by the cutaneous route, benzoyl peroxide is associated with a minimal to moderate skin irritation potential including erythema and oedema. Phototoxic and photoallergic reactions have been reported for benzoyl peroxide therapy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Docusate sodium, disodium edetate, poloxamer 182, carbomer 940, propylene glycol, acrylates copolymer, glycerol, purified water, citric acid and/or sodium hydroxide.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

50g plastic tube contained in a carton for each strength.

6.6 Special precautions for disposal

Not applicable.

7 MEDICINE SCHEDULE

BENZAC AC Gel 2.5% and 5% are General Sales Medicines, BENZAC AC Gel 10% is a Pharmacy Only Medicine.

8 SPONSOR

Sponsor and distributor in New Zealand
Healthcare Logistics
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Auckland
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9 DATE OF FIRST APPROVAL

6 June 1996

10 DATE OF REVISION OF THE TEXT

19 November 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8.0	Correction of sponsor details