Applicant:	**GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD.**
Proprietary name:	**BENZAC® AC 5 GEL**
Registration Number	**X/13.12/133**

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE

BENZAC® AC 5 % w/w GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

BENZAC® AC 5 GEL contains: 5 g benzoyl peroxide per 100 g in an aqueous gel base.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to slightly off-white, smooth and homogenous gel, without foreign particles with a characteristic odour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BENZAC® AC 5 GEL is indicated for the topical treatment of *acne vulgaris*.

4.2 Posology and method of administration

Posology

Before each application, the skin should be cleaned and dried.

BENZAC® AC 5 GEL should be applied once or twice daily to cover affected areas after washing with a mild cleanser and water.

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

Paediatric Population: No data available.

4.3 Contra-indications:

Hypersensitivity to the active or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

BENZAC® AC 5 GEL contains:

- Propylene glycol that can be irritating to the skin.

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.

BENZAC® AC 5 GEL may cause swelling and blistering of the skin, if any of these symptoms occur, medication should be discontinued.

Avoid contact with the eyes, eyelids, mouth, angles of the nose and mucous membranes. If accidental contact occurs, rinse thoroughly with water. Contact with any materials (e.g. hair or fabric) may result in bleaching or discolouration.

Caution should be exercised when applying BENZAC® AC 5 GEL to the neck and other sensitive areas.

Repeated exposure to sunlight or UV radiation should be avoided.

Due to the risk of sensitisation, BENZAC® AC 5 GEL should not be applied on damaged skin.

4.5 INTERACTIONS 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 5 GEL; however, medicines with desquamative, irritant and drying effects should not be used concurrently with BENZAC® AC 5 GEL.

Concurrent use with PABA-containing sunscreens may result in transient discolouration of the skin. If excessive irritation develops, a medical practitioner should be consulted.

4.6 Fertility, pregnancy and lactation:

Pregnancy

Safety in pregnancy has not been established.

Lactation

Safety in lactation has not been established.

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.

4.7 Effects on ability to drive and the use of machines

BENZAC® AC 5 GEL has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Allergic contact dermatitis and dryness have been reported with BENZAC® AC 5 GEL therapy. If severe irritation develops, discontinue use and consult a doctor. After the reaction clears, treatment may often be resumed with less frequent application.

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

Table 1: Adverse reactions reported in clinical trials:

System Organ Class	Incidence	Preferred Terms
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.

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 providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Refer to section 4.8 and section 4.4

BENZAC® AC 5 GEL is indicated for topical treatment only. If BENZAC® AC 5 GEL 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.

If excessive scaling, erythema or oedema occurs, the use of this preparation must be discontinued. To hasten resolution of the adverse effects, cool compresses may be used. Further treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 13.12 Acne preparations.

Benzoyl peroxide has *in vitro* bactericidal activity as well as keratolytic properties and reduces the concentration of free fatty acids in the sebum.

5.2 Pharmacokinetic properties

Not applicable. BENZAC® AC 5 GEL is a topical preparation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Docusate sodium

Disodium edetate

Poloxamer 182

Carbomer 940

Propylene glycol

Acrylates copolymer

Glycerol

Colloidal Anhydrous Silica

Purified water

Sodium hydroxide to adjust the pH.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

FOR EXTERNAL USE ONLY.

6.5 Nature and contents of container

Plastic tubes containing 15 gram, 20 gram or 40 gram.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Galderma Laboratories South Africa (Pty) Ltd

Nicol Main Office Park,

First Floor, Block C,

FutureSpace,

2 Bruton Road,

Bryanston,

2191.

8. REGISTRATION NUMBERS:

X/13.12/133

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9. DATE OF FIRST AUTHORISATION

10 February 1993

10. DATE OF REVISION OF THE TEXT

02 May 2022