Applicant:	**GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD**
Proprietary name:	**BENZAC®AC 5 WASH**
Dosage form and strength:	**Wash (5g per 100 g benzoyl peroxide)**
Registration Number	**30/13.12/0044**

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE

BENZAC® AC 5 % w/w WASH

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to off-white smooth gel with a faint odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Apply **BENZAC® AC 5 WASH** to the affected areas, whilst avoiding contact with the eyes and mucous membranes. Rub in gently with fingertips and leave in contact with skin for 30 seconds before rinsing off with water. Pat dry. Use once or twice daily.

For topical administration only.

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

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 WASH 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 WASH** 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 WASH** should not be applied on damaged skin.

Paediatric population

Safety of use during childhood has not been established.

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

Concurrent use with para-aminobenzoic acid containing sunscreens may result in transient discolouration of the skin. If excessive irritation develops, discontinue use and consult a doctor.

4.6 Fertility, pregnancy and lactation:

Pregnancy

Safety in pregnancy has not been established.

Lactation

Safety in lactation has not been established.

BENZAC® AC 5 WASH 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 WASH 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 WASH** 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 WASH is indicated for topical treatment only. If **BENZAC® AC 5 WASH** is applied excessively, 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Acrylates copolymer

Glycerol

Carbomer 940

Sodium C14-C16 Olefin Sulfonate

Sodium Hydroxide (for pH adjustment)

Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

18 months

6.4 Special precautions for storage

Store at or below 25 °C.

FOR EXTERNAL USE ONLY.

6.5 Nature and contents of container

Plastic tubes containing 100 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

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Block C, First Floor,

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8. REGISTRATION NUMBERS:

30/13.12/0044

9. DATE OF FIRST AUTHORISATION

08 March 1999

10. DATE OF REVISION OF THE TEXT

02 May 2022

Namibia Reg. No.: 04/13.12/0714

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