SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Benzac 5%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl peroxide 5 %w/w

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical Gel

White to off-white, gel

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of acne vulgaris.

4.2 Posology and method of administration

For external use only.

Adults and children:

Before each application, the skin should be cleaned and dried. Apply in a thin layer once or twice daily or as directed to the affected areas. Persons with sensitive skin should be directed to apply the gel once daily before going to bed. The extent of any drying or peeling may be adjusted by modifying the dosage schedule.

Benzac 5 % should preferably be used in the following cases:

- for emerging acne in teenagers,
- In subjects with sensitive skin, notably children and blond-haired or red-haired subjects,
- at the start of treatment, during a trial period, to ensure that the product is well tolerated,
- for maintenance treatment of acne scars.

1 application every 2-3 days as maintenance treatment for Benzac 5 %.

Apply Benzac by massaging gently with the fingertips until fully absorbed.
Wash hands after use.
Keep away from heat and flame.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

For external use only.

Benzac may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.

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.

Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation.

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy may occur, which sometimes may be severe, especially with the use of peeling, desquamating, or abrasive agents.

Benzoyl peroxide gel should not come into contact with the eyes, mouth, angles of the nose or mucous membranes. If the preparation enters the eye, wash thoroughly with water. Caution should be exercised when applying the drug to the neck and other sensitive areas.

As Benzac may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight or UV radiation should be avoided or minimised. When strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing.

Contact with any coloured material including hair and dyed fabrics may result in bleaching or discoloration.

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed; however, drugs with desquamative, irritant and drying effects should not be used concurrently with benzoyl peroxide gel*.*

4.6 Fertility, pregnancy and lactation

Pregnancy
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. Benzac should only be used by a pregnant woman if clearly needed.

Breast-feeding
It is unknown whether benzoyl peroxide/metabolites are excreted in human milk. A risk to the new-borns/infants cannot be excluded. 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 use machines

Benzac 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 (not know frequency) have been reported during post-marketing surveillance.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

4.9 Overdose

Benzoyl peroxide gel is a preparation 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-acne preparations for topical use,
ATC Code: D10AE01
Benzoyl peroxide is an established and effective keratolytic agent with antibacterial properties. It has been shown to be effective in reducing the local population of Propionibacterium acnes leading to a reduction in the production of irritant fatty acids in the sebaceous glands.

5.2 Pharmacokinetic properties

Not applicable. Benzac is a topical preparation.

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

Glycerol, Propylene glycol, Acrylates copolymers, Carbomer 940, Poloxamer 182, Disodium edetate, Dioctyl sodium sulfosuccinate, Silica colloidal anhydrous, Sodium hydroxide, Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.
After first opening, the gel should be used within 3 months.

6.5 Nature and contents of container

60 g tube.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MANUFACTURER

Laboratories Galderma, France

8. REGISTRATION HOLDER:

Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.

Registration number:
Benzac 5%: 1033027997

Revised in November 2020