# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**Benzac 5%**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl peroxide 5% w/w

Excipients with known effects:
One gram of gel contains 40 mg of propylene glycol.
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Gel

White to off-white gel in a tube.

## 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 adolescents aged 12 years and over:

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 ( see section 4.4) .

### 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.

This product is not suitable for individuals with severe acne (characterised by large numbers of inflamed spots on the face or the presence of nodules and cysts), moderate acne (characterised by papules and pustules) or previous scarring from acne, who should seek treatment advice from a doctor.

Individuals with extensive acne lesions affecting other areas (e.g. the chest shoulders and back), which they want to treat, should consult their pharmacist or doctor. These lesions are often more difficult to treat and topical treatments may not be appropriate if they are widespread.

Individuals with mild acne that are particularly concerned by their condition should consult their doctor.

**Benzac 5%** 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. Adjunctive use of moisturizers can help to limit the potential for skin irritation.

If severe irritation occurs, individuals should temporarily discontinue use until the irritation subsides. If treatment is restarted, the product should be applied less frequently (i.e. once a day instead of twice daily or alternate days instead of once a day). If severe irritation occurs again after treatment is restarted,

discontinue use altogether.

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

In the event of scarring following initial treatment with Benzac 5% Gel, treatment should be discontinued and advice should be sought from a doctor

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. **Benzac 5%** should not be applied to the neck and other sensitive areas (around the eyes and mouth, angles of the nose and mucous membranes).

As **Benzac 5%** may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight or UV radiation should be avoided. When strong sunlight cannot be avoided, individuals should use a sunscreen product and wear protective clothing.

Contact with any coloured material including hair and dyed fabrics may result in bleaching or discoloration.
Individuals should wash hands after use.

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

**Benzac 5%** should not be used in conjunction with other benzoyl peroxide preparations, nor with any other topical or systemic treatment(s) for acne except under medical supervision.

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.

Individuals should cease use and seek medical advice if their condition deteriorates despite therapy, or in cases of a lack of response after use for 12 weeks.

This medicine contains 40 mg of propylene glycol in each gram, which is equivalent to 4.0 % w/w. It may cause skin irritation.

## 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 5%** should only be used by a pregnant woman under medical supervisionif 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. **Benzac 5%**
should only be used by a nursing woman under medical supervision.

## 4.7 Effects on ability to drive and use machines

**Benzac 5%** 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<br>Erythema<br>Skin exfoliation (peeling)<br>Skin burning sensation |
| | Common (≥1/100 to <1/10) | Pruritus<br>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, including the use of moisturizers, 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 Cutibacterium acnes leading to a reduction in the production of irritant fatty acids in the sebaceous glands.

### 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 for any tissue accumulation.

### 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, sodium docusate, 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.

Keep away from heat and flame

### 6.5 Nature and contents of container

White low density polyethylene tubes.

Pack size: 60g

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. MANUFACTURER:

LABORATORIES GALDERMA, Z.I. MONTDESIR 74540 ALBY SUR CHERAN, FRANCE.

## 8. REGISTRATION HOLDER:

A.M.I. MEDICAL TECHNOLOGIES LIMITED, ISRAEL - HANAGAR 22, HOD HASHARON, 4501317, ISRAEL.

**Registration number:**
103-30-27997-00

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