

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(MEDICINAL PRODUCTS) - 1986

The medicine is dispensed without a doctor's prescription

BENZAC 5%

Gel

The active ingredient:

Benzoyl peroxide 5% (w/w)

For a list of the inactive ingredients and allergens in the medicine see section 6 'Additional information'. See also section 2 'Important information about some of the ingredients of the medicine'.

Carefully read the entire leaflet before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or to the pharmacist.

The gel is not intended for children under 12 years of age.

You should use the medicine in accordance with the instructions in the Dosage section of this leaflet. Consult a pharmacist if you need further information.

Refer to the doctor if the symptoms worsen or do not improve within 12 weeks (see section 2 'Special warnings about using the medicine').

1. WHAT IS THE MEDICINE INTENDED FOR?

For the topical treatment of acne vulgaris.

Therapeutic group: Topical preparations for acne treatment- peroxides.

Benzac 5% contains the active ingredient benzoyl peroxide which kills bacteria known as *Cutibacterium acnes*, one of the main causes of acne.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (for the list of additional ingredients, see section 6 'Additional information'). An allergic reaction may include a rash or itching.
- You have any inflamed spots or larger lumps, you may have more severe acne. You should refer to a doctor or pharmacist for advice about the treatment.
- You have scars from past acne spots, usually appear as a shallow dent or deeper pit in the skin, you should see a doctor or pharmacist for advice about the treatment.
- You have acne on your shoulders, back or chest. You should see a doctor or pharmacist for advice about the treatment. Acne treatment in these areas might be complicated.

Special warnings about using the medicine

- If you are not certain that you suffer from acne, refer to a doctor or pharmacist before using Benzac 5%.
- If you are worried or troubled about your acne, even if it is mild, you should consult a doctor or pharmacist. Acne may be associated with increased risk of depression, anxiety, poor self-image and poor self-esteem. If you experience any of these physiological effects, refer to a doctor for professional advice.
- Avoid contact of the gel with the eyes (including the eyelids), mouth, nostrils or other mucous membranes. If accidentally there is contact between the gel and these areas, immediately rinse the area thoroughly with water.
- Do not use Benzac 5% on damaged, inflamed skin or on open wounds.
- Use of the medicine may cause swelling and blistering of the skin. If any of these symptoms occur, the use of the medicine should be discontinued and you should refer to a doctor or pharmacist.
- The gel has bleaching ability, therefore, avoid contact of the gel with the hair, or with coloured fabrics, including clothing, towels and bed linens. Make sure to thoroughly wash your hands after use.
- Avoid applying the gel on the neck or other sensitive areas of the skin (e.g. around the eyes).
- Since the medicine may cause increased sensitivity to sunlight, avoid excessive exposure to sunlight as much as possible. Do not expose yourself to UV radiation from other sources (e.g., tanning beds). If you must be exposed to the sun, be sure to have proper protection (long clothing, hat, sunscreen, etc.) and use the medicine in the evening.
- The use of this gel may cause skin effects, such as: redness, peeling, burning or local irritation, in particular at the beginning of the treatment. If the symptoms are unbearable or serious, treatment should be stopped. See also section 3 'How should you use the medicine' and section 4 'Side effects'.

- You should refer to a doctor in case the symptoms worsen or do not improve within 12 weeks. Some acne forms may leave scars as a result of unsuitable treatment. The doctor or the pharmacist may recommend a suitable alternative treatment.

Children and Adolescents

The gel is not intended for children under 12 years of age.

Drug Interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- During the course of treatment with **Benzac 5%**, do not use any medicine or cosmetic product that may irritate, peel or dry the skin.
- Preparations containing the active ingredient benzoyl peroxide or other products for acne treatment should not be used during treatment with **Benzac 5%**, unless a doctor has instructed you to do so, since concomitant treatment with these preparations and Benzac 5% may cause redness and skin pain.

Pregnancy and breastfeeding

- Do not use the medicine if you are pregnant, planning a pregnancy, think you are pregnant, or are breastfeeding, unless the doctor has instructed you to do so.
- If the doctor instructs you to use Benzac 5% while you are breastfeeding, do not apply the gel to the chest, to prevent exposure of the baby to the medicine.
- Consult the doctor or pharmacist before using any medicine.

Driving and using machines

The medicine has no or negligible effect on the ability to drive or operate machines.

Important information about some of the ingredients of the medicine

The gel contains propylene glycol which may cause skin irritation.

3. HOW SHOULD YOU USE THE MEDICINE?

Use the medicine as detailed in the leaflet. Check with the doctor or pharmacist if you are not sure about the dosage and how to use the medicine.

Attention! Do not swallow! The gel is intended for external use only.

The usual dosage and method of use are:

- Before applying the gel, clean the skin in the designated area with a gentle soap and water, and gently pat it dry.
- Apply a thin layer of **Benzac 5%** once or twice a day to the affected areas.
- If you have sensitive skin, it is recommended to use once a day at bedtime.
- In case drying and/or skin peeling develops - reduce the frequency of gel application (e.g., to once a day or once every two days) until your skin adjusts to the medicine. If the skin effects do not resolve, refer to a doctor.

Do not exceed the recommended dose.

- Make sure to wash your hands after usage.

The duration of the treatment depends on improvement of the acne. After using **Benzac 5%** for one month, it is recommended to consult a doctor or pharmacist to evaluate the condition.

If there is no improvement in your condition, or if the condition has worsened, refer to the doctor.

If you accidentally used a higher dosage or if the gel was accidentally swallowed:

- If you accidentally used a higher dosage, your skin may become irritated, therefore, wash the area and remove as much of the gel as possible. If the skin is very irritated, stop treatment and refer to the doctor. After the condition has resolved, treatment can be resumed, as instructed.
- If the gel was accidentally swallowed or if a child accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forget to use this medicine at the designated time, use the medicine as usual as soon as you remember, according to the instructions for use.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of the gel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to a doctor immediately if the following side effects occur:

- Severe allergic reaction, anaphylactic reaction. Signs of severe allergic reaction may include, among others: breathing difficulties, fainting (shock), swelling of the neck, eyes, face, mouth, lips or tongue (angioedema), raised and itchy rash (urticaria).
- Severe skin irritation, redness, itching or peeling.
- Skin swelling and/or blisters.
- Scarring following first treatment with the gel.

Additional side effects:

Very common side effects (occur in more than 1 user in 10):

Skin effects: dryness, redness, peeling, burning sensation.

Common side effects (occur in 1-10 in 100 users):

Skin effects: itching (pruritus), pain, tingling, irritation (irritant contact dermatitis).

Uncommon side effects (occur in 1-10 in 1,000):

Allergic contact dermatitis (redness, inflammation, bumps, or dry and cracked rash or a burn-like rash on the skin at the site of exposure to the gel).

The side effects are usually reversible if the treatment is reduced in frequency or discontinued.

If a side effect occurs, if one of the side effects worsens, or if you suffer from side effect not listed in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report adverse effects and problems associated with medications and drugs” found on the Ministry of Health home page (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store below 25°C.
- After first opening of the tube, the gel can be used for 3 months, but no later than the expiry date stamped on the package.
- Keep away from sources of heat and fire.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the gel also contains:

Glycerol, propylene glycol, acrylates copolymers, carbomer 940, poloxamer 182, disodium edetate, sodium docusate, silica colloidal anhydrous, sodium hydroxide, purified water.

The gel contains 40 mg/g propylene glycol, equivalent to 4.0% w/w.

What does the medicine look like and what are the contents of the package?

White to off-white gel packed in a tube.

The tube contains 60 grams.

The Manufacturer: Laboratoires Galderma, Z.I. Montdesir 74540 Alby-sur-cheran, France.

Registration holder: A.M.I Medical Technologies Limited, Hanagar 22. Hod-Hasharon 4501317, Israel.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 103-30-27997-00

Revised in November 2023 according to MOH guidelines.

BENZ GEL PL SH 131223 GSL