

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed without a doctor's prescription

BENZAC 5% (W/W) Gel

The active ingredient and its concentration:

Benzoyl peroxide 5%

For information regarding inactive ingredients and allergens, see section 6.

See also 'Important information about some of the ingredients of the medicine' in section 2.

Read the entire leaflet carefully before using the medicine.

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

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

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 are not improving.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the topical treatment of acne vulgaris.

Therapeutic group: Topical preparations for acne treatment – peroxides.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

You are sensitive (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). An allergic reaction may be manifested by, for example, rash or itching.

Special warnings regarding use of the medicine:

- Avoid contact of the gel and the eyes (including the eyelids), mouth, nostrils or other mucous membranes. If contact is accidentally made between the gel and these areas, immediately rinse the area thoroughly with warm water.
- Do not use the gel on damaged or inflamed skin or on open wounds.
- The use of the medicine may cause swelling and blistering of the skin. If these symptoms occur, the use of the medicine should be discontinued.
- The gel has a bleaching quality, therefore, avoid contact of the gel with the hair, or with colored fabrics (e.g., clothing, towels, bed linens). Make sure to wash your hands thoroughly after use.
- Caution should be used when applying the gel on the neck or other sensitive areas.
- Since the medicine may cause increased sensitivity to sunlight, avoid, as much as possible, exposure to sunlight or 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'.

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.

Tell the doctor or the pharmacist especially in the following situations:

- During the course of treatment with Benzac, avoid use of any medicine or cosmetic product that may irritate, peel or dry the skin.
- Other skin preparations for treatment of acne: do not use during treatment with Benzac, unless a doctor has instructed you to do so, since concomitant treatment with these preparations and Benzac may cause skin redness and pain.

Pregnancy and breastfeeding:

- Do not use the medicine if you are pregnant, think you are pregnant, or are breastfeeding unless the doctor has approved use of the medicine.
- Avoid use of the medicine if you are breastfeeding unless the doctor has instructed you to do so. If the doctor instructs you to use it while you are breastfeeding, do not apply the gel to the chest, to avoid exposure of the baby to the medicine.

Consult the doctor or pharmacist before using any medicine.

Use in children:

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

Important information about some of the ingredients of the medicine:

The gel contains 40 mg propylene glycol (E1520) per gram, which is equivalent to 4.0% w/w. This ingredient 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 uncertain about the dosage and how to use the medicine.

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

The standard dosage and instructions for use are usually:

- 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 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 of drying and/or peeling which may occur to your skin, reduce the frequency of application of the gel (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.

The duration of the treatment depends on the improvement of the acne. After using Benzac 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 there is any deterioration, 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 off the area and remove as much of the gel as possible. If the skin is very irritated, stop treatment and refer to the doctor. When 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 forgot 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 or use 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.

If the following side effects occur, stop the treatment and contact the doctor immediately:

- Severe allergic reaction (including anaphylactic reaction, angioedema or shock) or any signs of sensitivity that may include, among others: breathing difficulties, fainting, swelling of the neck, eyes, face, mouth, lips or tongue; urticaria (type of raised and itchy rash).
- Severe skin irritation, redness, itching or peeling.
- Swelling and/or blistering of the skin.

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, pain, irritation, irritant contact dermatitis.

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

Allergic contact dermatitis.

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

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (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) that appears 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 medicine's tube, the gel can be used for 3 months, but no later than the expiry date stamped on the package.
- Keep the closed tube away from direct heat.
- 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. FURTHER INFORMATION

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

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

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.

Manufacturer: Galderma Laboratories Ltd., Montdesir Industrial Zone 74540, Alby-sur-Chéran, France.

Registration Holder: A.M.I Medical Technologies Ltd., 22 Hanagar St., Hod Hasharon, 4501317, Israel.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: Benzac 5%: 103-30-27997-00

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