

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold without a doctor's prescription

Benzac 5% Gel

Active ingredient:

Benzac 5%: 5% Benzoyl Peroxide

For the list of the additional ingredients, see section 6.

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

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

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

Use this medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information. Refer to your doctor if the symptoms get worse or do not improve.

1. What is the medicine intended for?

The medicine is intended for treatment of acne.

Therapeutic group: peroxides

2. Before using the medicine

Do not use the medicine if:

Do not use if you are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6). An allergic reaction may be manifested for instance in a rash or itching.

Special warnings regarding the use of this medicine:

- Do not use the gel on damaged, inflamed skin or on open wounds.
 - Do not use the gel if the skin is particularly sensitive, for instance if you suffer from sensitivity, irritation or peeling, remaining from a previous skin treatment, or if you suffer from burns (until the skin heals).
 - Initially, try to apply the gel for several days to a small skin area, to make sure you do not develop symptoms of an allergic reaction to the medicine (see 'allergic reaction' in section 4).
 - The use of this gel may cause skin problems such as: redness, peeling, burning or local irritation, particularly at the beginning of the treatment. If the symptoms are unbearable or serious, stop the treatment. See also section 3 'How to Use the Medicine' and section 4 'Side effects'.
 - Avoid contact of the gel with the eyes (including eyelids), mouth, nostrils, and other mucous membranes. If the gel came into contact with these areas accidentally, immediately wash well with warm water.
 - Caution should be used when applying the gel on the neck and on other sensitive areas.
 - Use of this medicine may cause swelling and blistering of the skin. If these symptoms appear, stop the treatment.
 - Since this medicine may cause increased sensitivity to sunlight avoid prolonged exposure to sunlight or UV radiation from other sources (e.g. sunbeds) in as far as possible. Ensure appropriate protection if you must be exposed to the sun (long sleeves and trousers/skirts, hat, sunscreen preparations etc.) and use the preparation in the evening.
 - The gel has a bleaching quality so you must make sure it does not come into contact with the hair, or with colored fabrics (e.g. clothing, towels, bed linens).

- Make sure to wash your hands thoroughly after use.
- Keep away from heat and fire sources.

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

- Any medicine or cosmetic product that may irritate, peel or dry the skin: avoid usage during the treatment with Benzac.
Other skin products for use against acne: do not use during treatment with Benzac, unless your doctor instructed you to do so.

Pregnancy and breastfeeding:

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

If you are pregnant or if you are breastfeeding, consult your doctor or pharmacist before using medicines.

Use in Children:

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

Important information about some of the medicine's ingredients:

The gel contains propylene glycol, which might cause skin irritation.

3. How to use this medicine?

Use this medicine as indicated in the leaflet. You should check with your doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment.

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

The standard dosage and instructions for use generally are:

- Before applying the gel, clean the skin in the affected 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, use it once a day before going to bed.
- If drying or peeling of the skin occurs, reduce the frequency of applying the gel (i.e. to once a day or once every two days), until your skin adjusts to the preparation. Consult with a doctor if the skin problems continue.

Do not exceed the recommended dosage.

- Initially, try to apply the gel for several days to a small skin area, to make sure you do not develop symptoms of an allergic reaction to the medicine (see 'allergic reaction' in section 4). If no allergic symptoms or any irritation, redness, excessive peeling, local swelling or discomfort develop, you may use the gel according to the instructions for use.
- Do not use the gel concurrently with other acne products, preparations containing alcohol or cosmetic preparations and soaps with a drying effect, unless your doctor has instructed you to do so.
- Make sure to wash your hands after use.

The duration of the treatment depends on an improvement in the acne. After you have used Benzac for a month, you should consult a doctor or pharmacist who will evaluate your condition.

If there is no improvement in your condition, or if there is any deterioration, refer to your 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, so wash off the area and remove as much of the gel as you can. If the skin is very irritated, stop treatment and refer to your doctor: When the irritation has gone down, you can start using it again as instructed.
- If the gel was accidentally swallowed, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine.

If you forgot to use this medicine at the right time, use the medicine normally as soon as you remember, according to the instructions for use.

Do not use or 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 concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects

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

Stop the treatment and contact a doctor immediately if the following side effects appear:

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

Other Side Effects:

Very frequent side effects (appear in more than 1 user out of 10):

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

Common side effects (appear in 1-10 users out of 100):

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

Uncommon side effects (appear in 1-10 users out of 1,000):

Allergic contact dermatitis.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, 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) stated on the package. The expiry date refers to the last day of that month.
 - Storage conditions: store below 25°C. After the first opening of the tube, the gel may be used within 3 months, but no later than the expiry date marked on the package.

6. Additional information

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

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

What does the medicine look like and what does the package contain?

White - off-white gel in a tube.

Pack contains: 60 grams.

Manufacturer: Laboratories Galderma, France.

Registration holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Benzac 5%: 1033027997

The leaflet was updated in November 2020