

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

This medicine is sold with a doctor's prescription only

## **Epiduo Gel**

**Active ingredients:**

1 g of gel contains:

1 mg Adapalene (0.1%)

25 mg Benzoyl Peroxide (2.5%)

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

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

**Read this entire leaflet carefully 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.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

The gel is intended for use in children aged 9 years and older, adolescents and adults.

### **1. What is the medicine intended for?**

The medicine is intended for treatment of acne.

**Therapeutic group:**

Topical treatment for acne: Adapalene - retinoid (vitamin A derivative). Benzoyl peroxide - peroxides.

### **2. Before using the medicine**

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients the medicine contains (for a list of the other ingredients, see section 6).
- You are pregnant or planning a pregnancy.

**Special warnings regarding the use of this medicine:**

- Do not apply the gel to areas where the skin is damaged (e.g., scrapes, cuts), to sunburnt areas or if you have skin eczema.
- Avoid contact of the gel with the eyes, mouth, nostrils, and other sensitive areas. If the gel came into contact with these areas accidentally, wash immediately with plenty of warm water.
- Avoid excessive exposure to sun or UV radiation and ensure appropriate protection if you must be exposed to the sun (long sleeves and trousers/skirts, hat, sunscreen preparations etc.).
- Make sure the gel does not come into contact with the hair and with colored fabrics (e.g. clothing, towels, bed linens), since it may cause a color change (e.g. fading or bleaching).
- Make sure to wash your hands thoroughly after use.

**Children and adolescents:** The gel is intended for use in children aged 9 years and older, adolescents and adults.

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

- Other acne medicines containing retinoids and/or benzoyl peroxide: do not use during the treatment period with Epiduo.
- Cosmetics that may irritate, dry or exfoliate (peel) the skin: avoid usage during the treatment period with Epiduo.

**Pregnancy and breastfeeding:**

- Do not use the gel if you are pregnant or planning a pregnancy. If you become pregnant during the treatment with Epiduo, discontinue the treatment and refer to your doctor for consultation and further follow-up.
- The gel can be used during breastfeeding. To avoid contact exposure of the baby to the medicine, application of the gel to the chest area should be avoided.

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

**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?**

Always use according to the doctor's instructions.

Check with your doctor or pharmacist if you are not sure about the dosage and the treatment regimen of the medicine.

The duration of the treatment with the gel, the dosage and the treatment regimen will be determined by the doctor only.

This medicine is intended for external use only.

**The standard dosage and instructions for use are usually:**

- Apply a **thin layer** of the gel evenly over acne affected areas once a day at bedtime.
- Avoid contact with the eyes, lips and nostrils. See also 'Special warnings regarding the use of the medicine'.
- Make sure that the skin is clean and dry before applying the gel.
- After using the gel, wash your hands thoroughly.
- Your doctor will tell you how long you will need to use the gel.

**Do not exceed the recommended dose.**

If you feel that the effect of the gel is too strong or too weak, talk to your doctor or pharmacist about it.

If you experience persistent irritation when applying the gel, contact your doctor. You may be asked to apply a moisturizer, to use the gel less often, to stop for a short time or to stop using the gel altogether.

**If you have used an overdose or if a child or any person has accidentally used or swallowed the medicine**, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

- Excessive use of the gel will not yield quicker or better results, and on the other hand, the skin may become irritated and red.

**If you forgot to use this medicine at the required time**, do not apply a double dose to make up for the forgotten dose.

Continue with the treatment as recommended by your doctor.

Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor or pharmacist.

Do not use or take medicines in the dark! Check the label and the dose each time you 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**

Like any medicine, the use of Epiduo 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 proceed to a doctor or a hospital emergency room immediately, if the following side effects appear:**

Severe allergic reaction (including anaphylactic shock) or any signs of sensitivity that can include, inter alia: throat tightness, swelling of the eyes, face, lips or tongue; fainting (including feeling faint), breathing difficulties. Stop the treatment if symptoms of urticaria (type of rash) or face or body itchiness appear.

**Contact your doctor if** you experience persistent irritation during treatment with the gel.

### **Additional side effects:**

*Common side effects (appear in 1-10 users out of 100):* skin reactions such as: dryness, irritation, local rash as a result of contact skin inflammation (irritative contact dermatitis), burning sensation, redness, peeling/scaling.

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

*Side effects of unknown frequency (effects whose frequency has not been determined yet):* swelling (edema) in face and eyelids, throat tightness, pain of skin (stinging), blisters, allergic reactions as a result of contact (allergic contact dermatitis); breathing difficulties, urticaria, change in skin color, burn in application area (these burns are usually superficial, but cases of more severe burns including blisters, have also been reported).

If skin side effects appear after using the gel, they are generally mild to moderate, with local signs of redness, dryness, scaling of the skin, sensation of burning or pain; they peak during the first week of treatment and resolve afterwards without additional treatment.

**If a side effect appears, if one of the side effects worsens, or you suffer from a side effect not mentioned in the leaflet, consult 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](http://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, the gel may be used within 6 months, but no later than the expiry date marked on the package.

## **6. Additional information**

**In addition to the active ingredients, the medicine also contains:**

Propylene glycol, Glycerol, Simulgel 600PHA, Poloxamer, Edetate disodium, Docusate sodium, Purified water.

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

Gel in a plastic tube :15 ,30 or 60 grams.

Gel in a pump: 15, 30, 45 or 60 grams.

Not all packs may be marketed.

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

**Manufacturer:** Laboratories Galderma, France.

**Medicine registration number in the National Medicines Registry of the Ministry of Health:** 156-10-34289

This leaflet was checked and approved by the Ministry of Health in May 2016 and was updated according to the Ministry of Health guidelines in March 2020.