

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (MEDICINAL PRODUCTS) – 1986**

The medicine is marketed with a doctor's prescription only

Epiduo

Gel

0.1%/2.5% w/w

The active ingredients:

Each 1 gram of gel contains:

Adapalene 1 mg (0.1% w/w)

Benzoyl Peroxide 25 mg (2.5% w/w)

For a list of inactive and allergenic ingredients in the medicinal product, see 'Further Information' in Section 6.

See also 'Important Information about some of the ingredients of the medicine' 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 further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The gel is intended for use in adults and adolescents aged 9 years and above.

1. WHAT IS THE MEDICINE INTENDED FOR?

Cutaneous treatment of Acne vulgaris when comedones, papules and pustules are present.

Therapeutic group: Anti-acne preparations for topical use.

The gel combines two active ingredients that work together but in a different way:

- Adapalene – belongs to a group of substances called retinoids (a derivative of vitamin A) and acts specifically on the skin processes that cause acne.
- Benzoyl peroxide – peroxides. An antimicrobial agent that works by softening and peeling the outer layer of the skin.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine (for a list of inactive and allergenic ingredients in the medicinal product - see Section 6).
- You are pregnant.
- You are planning a pregnancy.

Special warnings regarding use of the medicine:

Before treatment with Epiduo tell your doctor if you are taking, have recently taken, or might take other medicines.

- Do not apply the gel to damaged areas of the skin (such as scrapes, cuts) or areas with sunburn or eczema of the skin.
- Avoid contact of the gel with the eyes, mouth, nostrils and other sensitive areas. If the gel accidentally comes into contact with these areas, wash these areas immediately with plenty of warm water.
- If a reaction suggesting sensitivity to any component of the formula occurs, discontinue the use of Epiduo and talk to your doctor.
- Avoid excessive exposure to sunlight or UV radiation (e.g., from UV lamps) and ensure appropriate protection if you must be exposed to the sun (long clothing, hat, sunscreen products, etc.).
- Ensure the gel does not come into contact with hair and colored fabrics (e.g., clothing, towels, bedding) as it may cause discoloration (e.g., fading or bleaching).
- Wash hands thoroughly after use.

Children and adolescents:

The gel is intended for use in adults and adolescents aged 9 years and above.

Drug interactions:

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

- Other acne medicines containing retinoids and/or benzoyl peroxide: Do not use during treatment with Epiduo.
- Cosmetic products that may cause irritation, dryness or exfoliation of the skin: Avoid using during treatment with Epiduo as they may lead to cumulative irritation of the skin.

Pregnancy and breastfeeding:Pregnancy:

Do not use the gel if you are pregnant or planning a pregnancy. If you become pregnant during treatment with Epiduo, discontinue use and consult a doctor as soon as possible for advice and further follow-up.

Breastfeeding:

The gel can be used during breastfeeding. To avoid contact exposure of the infant to the product, application of the gel to the chest area should be avoided.

Driving and using machines:

Not relevant.

Important information about some of the ingredients of the medicine:

The gel contains 40 mg propylene glycol per gram, equivalent to 4% w/w.

The gel contains polysorbate 80 (a component of the excipient Simulgel 600 PHA), which can cause allergic reactions

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicinal product according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicinal product.

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

General recommended dosage and method of use:

- Apply a **thin layer** of gel evenly over acne affected areas once daily, in the evening at bedtime.
- Avoid contact with the eyes, lips and nostrils. See also 'Special warnings regarding use of the medicine'.
- Ensure that the skin is clean and dry before applying the gel.
- Wash your hands thoroughly after using the gel.
- The doctor will instruct you on how long you will need to use the gel.

Do not exceed the recommended dose.

Do not swallow. This medicine is intended for external use only.

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

If you experience persistent irritation when applying the gel, consult 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 another person has accidentally used or swallowed the medicine, refer to the doctor or a hospital emergency room immediately and bring the medicine package with you.

- Excessive use of the gel will not achieve better or faster results, but your skin may become irritated and red.

If you forgot to use the medicine on time, do not use a double dose to make up for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health condition, do not discontinue treatment with the medicine without consulting a doctor.

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

4. SIDE EFFECTS

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

Discontinue treatment and refer to a doctor or go to the hospital emergency room immediately if the following side effects occur:

Severe allergic reaction (including anaphylactic shock) or any signs of sensitivity, which may include among others: throat tightness, swelling of the eyes, face, lips, or tongue; fainting (including feeling faint), difficulty breathing. Stop using the product if you develop hives (a type of rash) or itching of the face or body. The frequency of occurrence of these side effects is unknown.

Refer to a doctor if you experience persistent skin irritation during gel use.

Additional side effects:

Common side effects, occurring in 1-10 users out of 100: Skin disorders such as: dryness, irritation, localized rash due to irritative contact dermatitis, burning sensation, redness, peeling/scaling.

Uncommon side effects, occurring in 1-10 users out of 1,000: Skin itching, sunburn.

Side effects of unknown frequency (frequency has not yet been determined): Facial swelling (edema), swelling (edema) of the eyelids, throat tightness, skin pain (stinging), blisters, allergic contact reactions, difficulty breathing, urticaria, skin discoloration, application site burns (these burns are usually superficial, but severe burns including blistering have been reported), anaphylactic reaction.

If skin side effects occur after using the gel, they are generally mild to moderate in severity, with local signs of redness, dryness, skin peeling, sensation of burning, stinging or pain – these effects usually peak during the first week of treatment and resolve thereafter without additional treatment.

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 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 TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed 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, the product may be used within 6 months, but no later than the expiry date marked on the package.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

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

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

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

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

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

A white to very pale yellow opaque gel.

Not all package sizes may be marketed.

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

Manufacturer: Laboratoires Galderma, Z.I. Montdésir, 74540 Albysur-Chéran, France.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 156-10-34289-00

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