

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

This medicine is dispensed with a doctor's prescription only

Epiduo Forte 0.3%/2.5%

Gel

The active ingredients:

Each 1 gram of gel contains:

Adapalene 3 mg (0.3% w/w)

Benzoyl Peroxide 25 mg (2.5% w/w)

For a list of inactive and allergenic ingredients in the medicinal product, see 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 seems to you that their medical condition is similar.

The gel is intended for use in adults and adolescents aged 12 and older.

1. WHAT IS THE MEDICINE INTENDED FOR?

For cutaneous treatment of moderate to severe acne vulgaris in which there are comedones and numerous papules and pustules.

Therapeutic group: Topical acne treatment.

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

- 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 Forte 0.3%/2.5%, tell the 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 cuts, abrasions) or areas with sunburn or eczema of the skin.
- Avoid contact of the gel with the eyes, mouth, nostrils, mucous membranes, and other sensitive areas. If the gel accidentally comes into contact with these areas, rinse the area immediately with plenty of warm water.
- If a reaction suggesting sensitivity to any component of the medicinal product occurs, stop using Epiduo Forte 0.3%/2.5% gel and contact your doctor.
- Avoid excessive exposure to sunlight or UV radiation (e.g., using a UV lamp) and ensure appropriate protection if you must be exposed to sunlight (long clothing, hat, sunscreen products, etc.).
- Ensure that the gel does not come into contact with hair or colored fabrics (e.g., clothing, towels, bedding) as it may cause discoloration (e.g., yellowing or whitening).
- Wash hands thoroughly after use.

If you experience persistent skin irritation when starting treatment, contact your doctor (see section 3 'How to use the medicine').

Children and adolescents:

Do not use Epiduo Forte 0.3%/2.5% gel in 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 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 Forte 0.3%/2.5%.
- Cosmetic products that may cause irritation, dryness or peeling of the skin: Avoid using during treatment with Epiduo Forte 0.3%/2.5% 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 Forte 0.3%/2.5%, discontinue use and contact a doctor as soon as possible for advice and further follow-up.

Breastfeeding

If you are breastfeeding, consult your doctor before using the medicine. Your doctor will advise you whether to discontinue breastfeeding or to avoid using Epiduo Forte 0.3%/2.5% gel. If your doctor authorizes use, avoid application of the gel to the chest area to prevent contact exposure of the baby to the medicinal product.

Driving and using machines:

Epiduo Forte 0.3%/2.5% gel has no or negligible effect on the ability to drive or to operate machinery.

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 (polysorbate 80 - a component of the inactive ingredient simulgel 600 PHA) that may 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 gel is intended for use in adults and adolescents above 12 years of age.

This medicine is intended to be used on the skin.

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

The doctor will determine which strength of the gel you need, depending on the severity of your acne and appearance. The doctor will also decide if you need any additional treatment.

General recommended dosage and method of use:

- Ensure that the skin is clean and dry before applying the gel.
- Apply a **thin layer** of gel evenly over all acne areas (acne lesions) of the face and/or back once daily in the evening before bedtime.
- Avoid contact with the eyes, lips, nostrils and mucous membranes. See also 'Special warnings regarding use of the medicine'.
- When using on the face: Wash and dry the face before use and apply a pea-sized amount to each part of the face (e.g., forehead, chin, both cheeks).
- Immediately after using the gel, wash hands thoroughly.

Do not exceed the recommended dose.

Duration of treatment-

Your doctor will advise you how long you should use the gel. If you do not see improvement after 4-8 weeks, consult with your doctor regarding the benefit of continuing the treatment.

If you experience persistent skin irritation during the first few weeks of treatment, contact the doctor. Your doctor may recommend applying a moisturizer, applying the gel less often, stopping the treatment for a short time, or to stop using the gel. Do not apply cosmetics (such as other face creams or makeup) before applying Epiduo Forte 0.3%/2.5% gel. These products can be applied after the gel has dried.

Do not swallow. For external use only.

If you have accidentally used a higher dosage 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, and on the contrary, the skin may become irritated and red.

If you forget to use this medicine at the required time, do not use a double dose to make up for the missed dose.

Adhere to the treatment regimen as recommended by the doctor.

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

If you stop using the medicine

The lesions (comedones, papules and pustules) will only diminish after several applications of the medicine. Use Epiduo Forte 0.3%/2.5% gel according to your doctor's instructions.

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 regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Epiduo Forte 0.3%/2.5% may cause side effects in some users.

Do not be alarmed by the list of side effects. You may not experience any of them.

Approximately 1 in 10 people using Epiduo Forte 0.3%/2.5% may experience side effects of the skin.

Discontinue treatment and contact 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. Discontinue treatment if urticarial (a type of rash) effects or itching develop on the face or body. The frequency of occurrence of these side effects is unknown.

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

Additional side effects:

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

Skin effects such as:

- Skin irritation
- Eczema
- Skin burning sensation
- Atopic dermatitis
- Reddening of the skin
- Scaling

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

- Redness of the eyelids
- Tingling or numbness at the application site
- Itching of the skin, allergic skin reactions
- Rash
- Dry skin

In addition to the side effects described above, the following side effects have been reported with a lower strength of Epiduo (adapalene 0.1%/benzoyl peroxide 2.5%):

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

- Local rash (irritative contact dermatitis)

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

- Sunburn

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Swelling of the eyelids
- Tightness in the throat
- Allergic contact reactions
- Swelling of the face
- Skin pain (stinging)
- Blisters
- Difficulty in breathing
- Skin discoloration
- Application site burn
- Urticaria
- Anaphylactic reaction

Side effects typically associated with use of Epiduo Forte 0.3%/2.5% include mild to moderate application site reactions, such as skin irritation with redness, dryness, scaling, stinging and/or burning of the skin.

Application site burns, mostly superficial but more severe cases involving blistering, have been reported.

If you experience persistent skin irritation during the first weeks of using Epiduo Forte 0.3%/2.5% gel, contact your doctor. Skin side effects, e.g., skin irritation, are more frequent with Epiduo Forte 0.3%/2.5% gel than with lower strength Epiduo 0.1%/2.5% gel. You may be asked to apply a moisturizer, to use the gel less often, to stop using for a short time, or to stop using the gel. These effects usually occur early in the treatment, and tend to lessen over time.

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 with your 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 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 the first opening, may be used within 3 months, but no later than the expiry date marked on the package.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

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

Glycerin, Propylene glycol, Simulgel 600 PHA, Poloxamer 124, Edetate disodium, Docusate sodium, Purified water.

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

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

A white to very pale yellow opaque gel.

Not all package sizes may be marketed.

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

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

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