Package leaflet: Information for the user

Epiduo 0.1% / 2.5% gel
Adapalene/Benzoyl Peroxide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Epiduo is and what it is used for
2. What you need to know before you use Epiduo
3. How to use Epiduo
4. Possible side effects
5. How to store Epiduo
6. Contents of the pack and other information

1. What Epiduo is and what it is used for

Epiduo is used for the treatment of acne.
This gel combines two active ingredients, Adapalene and Benzoyl peroxide which work together but in different ways:

Adapalene belongs to a group of products known as retinoids and acts specifically on the skin processes that cause acne.

The other active ingredient, benzoyl peroxide, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

2. What you need to know before you use Epiduo

Do not use Epiduo:
- If you are pregnant
- If you are planning a pregnancy
- If you are allergic to the adapalene or benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
- You should not use Epiduo on areas where you have cuts, scrapes, sunburn or eczema.
- Make sure Epiduo does not get into your eyes, mouth or nostrils, and other very sensitive areas of the body. Should this occur wash these areas immediately with plenty of warm water.
- Avoid excessive exposure to sunlight and UV lamps.

- Avoid getting Epiduo on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used the medicine.

Talk to your doctor or pharmacist before using Epiduo.

Other medicines and Epiduo
- Do not use other acne products (containing benzoyl peroxide and / or retinoids) at the same time as Epiduo**.**
- Avoid using Epiduo at the same time as cosmetics that are irritant, drying or exfoliate the skin.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
DO NOT use Epiduo if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.
If you fall pregnant while taking Epiduo, the treatment must be discontinued, and you should inform your doctor as soon as possible for a further follow-up.

Epiduo can be used during breast-feeding. To avoid contact exposure of the infant, application of Epiduo to the chest should be avoided.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Not relevant.

Epiduo contains propylene glycol
This medicine contains 40 mg propylene glycol (E1520) in each gram, which is equivalent to 4 % w/w.

Epiduo contains polysorbates
Polysorbates can cause allergic reactions.

3. How to use Epiduo

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Epiduo is only intended for use in adults, adolescents and children aged 9 years and over. This medicine is for external use only.
Apply a thin film of gel evenly over acne affected areas once a day at bedtime, avoiding the eyes, lips and nostrils. The skin should be clean and dry before application. You should wash your hands thoroughly after you have used Epiduo.

Your doctor will tell you how long you will need to use Epiduo.

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

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

If you use more Epiduo than you should
If you use more Epiduo than you should on your skin, you will not get rid of your acne quicker, but your skin may become irritated and red.

Please contact your doctor or the hospital:
- If you have used more Epiduo than you should.
- if a child has accidentally taken this medicine.
- If you accidentally swallow this medicine.

Your doctor will advise you on action to be taken.

If you forget to use Epiduo
Do not apply a double dose to make up for forgotten individual doses.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using the product and seek immediate medical attention if you develop throat tightness or swelling of the eyes, face, lips or tongue, feel faint, or have difficulty breathing. Stop using the product if you develop hives or itching of the face or body. The frequency with which these side effects occur is not known.

Common (may affect up to 1 in 10 people)
- dry skin
- local skin rash (irritative contact dermatitis)
- burning sensation
- irritation of the skin
- reddening of the skin
- scaling

Uncommon (may affect up to 1 in 100 people)
- itching of the skin (pruritus)
- sunburn

Not known (frequency cannot be estimated from the available data)
- swelling face
- allergic contact reactions
- swelling of the eyelid
- tightness in the throat
- pain of skin (stinging pain)
- blisters (vesicles)
- difficulty in breathing,
- skin discolouration (change in skin colour)
- application site burn

If skin irritation appears after application of Epiduo, it is generally mild to moderate, with local signs as redness, dryness, scaling, burning and pain of skin (stinging pain), which peak during the first week and resolve without additional treatment.

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the the national reporting system at: http://www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Epiduo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Discard the tube or pump 6 months after first opening.

Do not store above 25°C.

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. Contents of the pack and other information

What Epiduo contains

- The active substances are: Adapalene and benzoyl peroxide. 1 g of gel contains 1 mg (0.1 % w/w) adapalene and benzoyl peroxide hydrous, equivalent to 25 mg (2.5% w/w) anhydrous benzoyl peroxide.

- The other ingredients are: docusate sodium, disodium edetate, glycerol, poloxamer, propylene glycol (E1520), Simulgel 600 PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80 (E433), sorbitan oleate) and purified water.

What Epiduo looks like and contents of the pack

Epiduo is a white to very pale yellow opaque gel.

Epiduo is available in:

White plastic tubes with screw-cap containing 5 g, 15 g, 30 g, 45 g, 60 g or 90 g (not all pack sizes may be marketed).

White pumps with snap on cap containing 15 g, 30 g, 45 g or 60 g (not all pack sizes may be marketed).

Marketing Authorisation Holder
Galderma International

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La Defense 4, 92927 Paris, La Defense Cedex, France

Manufacturer
Laboratoires Galderma
ZI – Montdésir
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France

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Denmark: Epiduo
Croatia, Czech Republic, Portugal, Slovakia, Spain: Epiduo 1 mg/g + 25 mg/g gel
Hungary, Netherlands: Effezel 1 mg/g + 25 mg/g gel
Bulgaria, Estonia, Latvia, Lithuania, Romania: Epiduo 1 mg/25 mg/g gel
Slovenia: Epiduo 1 mg/25 mg v 1 g gel
Other countries: Epiduo 0.1% / 2.5% gel

This leaflet was last revised in July 2024

Detailed information on use of this product is available by scanning the QR code included in Patient Information Leaflet and on packaging with a smartphone. The same information is also available on the following website: http://www.medicinesauthority.gov.mt