



## 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 allergic to the active substances 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 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.

##### Pregnancy and breast-feeding

Epiduo should not be used during pregnancy.

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 (E1520), an ingredient that may cause skin irritation.

#### 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 and adolescents aged 9 years and over.

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.

Epiduo may cause the following side effects at the site of application.

**Common side effects** (occur in less than 1 in 10 patients)

- dry skin
- local skin rash (irritative contact dermatitis)
- burning sensation
- irritation of the skin
- redness
- scaling

**Uncommon side effects** (occur in less than 1 in 100 patients)

- itching of the skin (pruritus)
- sunburn

**Unknown frequency of occurrence** (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).

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.

**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

**United Kingdom**

Yellow Card Scheme

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**Ireland**

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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. One g of gel contains 1 mg (0.1 %) adapalene and 25 mg (2.5 %) benzoyl peroxide.
- The other ingredients are: docusate sodium, disodium edetate, glycerin, poloxamer, propylene glycol (E1520), Simulgel 600 PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, 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:

Plastic tubes containing 5g, 15g, 30g, 45g, 60g or 90g (not all pack sizes may be marketed).

Pumps containing 15 g, 30 g, 45 g or 60 g (not all pack sizes may be marketed).

**Marketing Authorisation Holder and Manufacturer***Marketing Authorisation Holder*

Galderma (UK) Ltd.

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*Manufacturer*

Laboratoires Galderma

ZI - Montdésir

74 540 Alby sur Chéran

France

PL 10590/0057

PA 590/30/1

**This medicinal product is authorised in the Member States of the EEA under the following names :**

Denmark: Epiduo, gel

Spain: Epiduo 1mg/g + 25 mg/g gel

Other countries: Epiduo 0.1% / 2.5% gel

**This leaflet was last revised in May 2017**

 GALDERMA

P2/4569-7