

## **Package leaflet: Information for the patient**

### **Epiduo 0.3% / 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 gel belongs to a group of medicines called “anti-acne preparation for topical use” i.e. it is used for the treatment of acne vulgaris, when comedones (blackheads, whiteheads), numerous papules and pustules (inflammatory pimples) are present.

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.
- Benzoyl peroxide, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

Epiduo 0.3% / 2.5% gel should only be used in adults and adolescents aged 12 years and over.

## **2. What you need to know before you use Epiduo**

### **Do not use Epiduo gel:**

- If you are pregnant
- If you are planning a pregnancy
- If you are allergic to adapalene or benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Epiduo gel.

- You should not use Epiduo gel on areas where you have cuts, scrapes, sunburn or eczema.
- Make sure Epiduo gel does not get into your eyes, mouth or nostrils, or mucous membranes 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 gel on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used Epiduo gel.

If you experience persistent skin irritation when starting treatment with Epiduo gel contact your doctor (see section 3.How to use Epiduo).

### **Other medicines and Epiduo gel**

- Do not use other acne products (containing benzoyl peroxide and / or retinoids) at the same time as Epiduo gel.
- Avoid using Epiduo gel at the same time as cosmetics that irritate, dry or exfoliate the skin.

Other medicines may have an effect on Epiduo gel, so tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### **Pregnancy and breast-feeding**

#### Pregnancy

DO NOT use Epiduo if you are pregnant or thinking to become pregnant. Your doctor can give you more information.

If you fall pregnant while taking Epiduo 0.3% / 2.5% gel, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.

#### Breast-feeding

If you are breast-feeding ask your doctor for advice before using this medicine. Your doctor will advise you whether to discontinue breast-feeding or to abstain from treatment with Epiduo 0.3% / 2.5% gel.

If your doctor advises you to continue the treatment, avoid application of the gel to the chest in order to avoid contact exposure of the infant.

### **Driving and using machines**

Epiduo gel has no or negligible effects on the ability to drive and use machines.

**Epiduo 0.3% / 2.5% gel contains propylene glycol (E1520)**, an ingredient that may cause local skin irritation (e.g. contact dermatitis).

### **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 0.3% / 2.5% gel is only intended for use in adults and adolescents aged 12 years and over.

Epiduo is a gel, used on the skin.

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

- The skin should be clean and dry before application.
- Apply a thin film of gel evenly over the entire acne-affected areas of the face and / or the trunk, once a day at bedtime. Avoid contact with the eyes, lips, nostrils and mucous membranes.
- If used on the face: Wash and dry the face and use a pea size amount to cover each part of the face (e.g. forehead, chin, each cheek).
- Wash your hands thoroughly immediately after you have applied Epiduo gel.

Your doctor will tell you how long you will need to use Epiduo 0.3% / 2.5% gel. If you do not see any improvement after 4-8 weeks you should discuss with your doctor the benefit of continuing the treatment.

If you experience persistent skin irritation during the first weeks when using Epiduo gel, contact your doctor. You may be asked to apply a moisturiser, to use the gel less often, to stop for a short time, or to stop using the gel.

Do not apply cosmetics (such as other facial creams or make-up) before the daily application of Epiduo gel. These products can be used after the applied gel has dried.

### **Use in children**

Epiduo 0.3% / 2.5% gel should not be used by children below 12 years of age.

### **If you use more Epiduo gel than you should**

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

Please contact your doctor or the hospital if:

- you have used more Epiduo gel than you should
- a child has accidentally taken this medicine

- you or someone else accidentally swallow this medicine.

Your doctor will advise you on what action needs to be taken.

### **If you forget to use Epiduo gel**

Do not apply a double dose to make up for a forgotten dose.

### **If you stop using Epiduo gel**

The spots (comedones, papules and pustules) will be reduced only after several applications of this medicine. Continue using Epiduo gel as long as prescribed by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

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

Approximately 1 in 10 people using Epiduo 0.3% / 2.5% gel may experience adverse skin reactions.

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 side effect (may affect up to 1 in 10 people):*

- Irritation of the skin
- Eczema
- Skin burning sensation

*Uncommon side effects (may affect up to 1 in 100 people):*

- Redness of the eyelid
- Tingling or sensation of pins and needles at the application site
- Itching of the skin, allergic skin reaction
- Rash
- Dry skin

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

## Uncommon

- Sunburn

## *Not known (cannot be estimated from the available data)*

- Swelling of the eyelid
- Tightness in the throat
- Allergic contact reactions
- Swelling face
- Pain of skin (stinging pain)
- Blisters (vesicles)
- Difficulty in breathing
- Skin discolouration (change in skin colour)
- application site burn

Adverse reactions typically associated with use of Epiduo 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 when using Epiduo 0.3% / 2.5% gel, contact your doctor. Adverse skin-reactions, e.g. skin irritation, are more frequent with Epiduo 0.3% / 2.5 % gel than with lower strength Epiduo 0.1%/2.5 % gel. You may be asked to apply a moisturiser, to use the gel less often, to stop for a short time, or to stop using the gel. These reactions usually occur early in the treatment, and tend to gradually lessen over time.

## **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 national reporting system listed in Appendix V](#). 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 and tube/pump after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Shelf-life after first opening: 3 months

Do not throw away unused Epiduo 0.3% / 2.5% gel 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 0.3% / 2.5% gel contains**

- The *active substances* are adapalene and benzoyl peroxide. One gram of gel contains 3 mg (0.3 %) adapalene and 25 mg (2.5 %) benzoyl peroxide.
- The *other ingredients* are disodium edetate, docusate sodium, glycerol, poloxamer, propylene glycol (E1520), Simulgel 600 PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate) and purified water. *See end of section 2 for further information.*

### **What Epiduo 0.3% / 2.5% gel looks like and contents of the pack**

Epiduo gel is a white to very pale yellow opaque gel.

Epiduo gel is available in:

One plastic tube containing 2 or 5 grams

One pump containing 15, 30, 45, or 60 grams.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### *Marketing Authorisation Holder*

[To be completed nationally]

For Sweden: Galderma Nordic AB, Seminariegatan 21, 752 28 Uppsala, Sweden

### *Manufacturer*

Laboratoires Galderma

Z.I. Montdésir

74540 Alby-sur-Chéran

France

or

Galderma Laboratorium GmbH

Toulouser Allee 23a

40211 Düsseldorf

Germany

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

Austria, Belgium, Germany, Greece, Luxembourg & Poland: Epiduo Forte

Denmark: Epiduo

Finland, France, Iceland, Italy, Norway, Sweden & United Kingdom: Epiduo 0.3% / 2.5% gel

Spain: Epiduo Forte 3 mg/g + 25 mg/g Gel

Portugal: Epiduo 3 mg/g + 25 mg/g Gel

**This leaflet was last revised in 26 June 2019**



