



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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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2. Before you use Epiduo
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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. Before you use Epiduo

Do not use Epiduo:

- if you are allergic (hypersensitive) to any of the ingredients in Epiduo.

Take special care with Epiduo:

- 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.

Using other medicines

- 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.

Important information about some of the ingredients of Epiduo

Epiduo also contains an ingredient known as propylene glycol (E1520) that may cause skin irritation.

3. How to use Epiduo

Always use Epiduo exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

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 or accidentally swallow the gel:

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, Epiduo 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)

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.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Epiduo

- Keep out of the reach and sight of children.
- Do not use Epiduo after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Discard the tube 6 months after first opening.
- Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further 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 2g, 15g, 30g, 45g, 60g or 90g (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer*Marketing Authorisation Holder*

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

France: Epiduo, gel

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

Other countries: Epiduo 0.1% / 2.5% gel

This leaflet was last approved in July 2012.

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