EPIDUO® Gel

0.1% adapalene / 2.5% benzoyl peroxide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **EPIDUO.** It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **EPIDUO** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What EPIDUO is used for

EPIDUO is used to treat acne. It is used on the face, chest or back.

It combines two active ingredients, adapalene and benzoyl peroxide which work through different but complementary ways.

Adapalene is a topical retinoid. Its main actions are to normalise skin cell development, prevent pores from being blocked and promote skin renewal.

Benzoyl peroxide kills bacteria (antibacterial) and also works by softening and peeling the outer layer of the skin.

Adapalene and benzoyl peroxide work together to rapidly reduce inflammation.

Your doctor, however, may prescribe EPIDUO for another purpose.

Ask your doctor if you have any questions about why EPIDUO has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use EPIDUO

Please be aware that EPIDUO contains benzoyl peroxide which may cause bleaching and discolouration to the hair and dyed fabrics.

When you must not use it

- If you are hypersensitive (allergic) to benzoyl peroxide, adapalene or to any of the other ingredients listed at the end of this leaflet.
- On areas where you have cuts or scrapes.
- With children below 12 years of age.
- **EPIDUO** should not be used during pregnancy. If you fall pregnant while using **EPIDUO,** the treatment must be discontinued and you should inform your doctor as soon as possible for further follow-up.
- Do not apply **EPIDUO** onto your chest if you are breast-feeding.

If you are not sure whether you should be taking EPIDUO, talk to your doctor.

Do not use EPIDUO after the expiry date (EXP) printed on the pack has passed.
If you use this medicine after the expiry date it may not work as well.

Before you start to use it

You must tell your doctor if:

1. You are allergic to any other medicines or other substances such as foods, dyes or preservatives.
2. You have or have had any other health problems.
3. You plan to become pregnant or to breastfeed.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking EPIDUO.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking **EPIDUO** with other medicines.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking **EPIDUO.**

How to use EPIDUO

Follow all directions given to you by your doctor and pharmacist carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions on the tube/bottle / box, ask your doctor or pharmacist for help.

Cleanse the skin before applying **EPIDUO** – a non-soap cleanser is useful. Allow the skin to dry completely before applying **EPIDUO.**

Apply a thin film of gel evenly over the acne affected area(s) once a day. If applying to the face, avoid the eyes and lips.

Wash your hands afterwards.

Depending on your condition and how you react to **EPIDUO,** your doctor may ask you to use it differently.

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

If you experience irritation when applying **EPIDUO,** a non-comedogenic moisturiser applied daily may help reduce this sensation. If symptoms persist, speak to your doctor or pharmacist. You may be asked to use the gel less often or to stop for a short time.

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.

If you forget to use it

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

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

EPIDUO is intended for external use only.

If swallowed, immediately telephone your doctor or Poisons Information centre for advice on telephone 13 11 26 if in Australia or 0800 POISON or 0800 764 766 if in New Zealand.

While you are taking EPIDUO

Things you must do

If you become or plan to become pregnant while using EPIDUO, tell your doctor immediately.

If you are about to start using any new medicines, tell your doctor or pharmacist that you are using EPIDUO.

Things you must not do

Do not give EPIDUO to anyone else, even if they have the same condition as you.

Do not use EPIDUO to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

When using **EPIDUO** on the face, don't get it into your eyes, mouth or nostrils, and avoid other very sensitive areas of the body.

Other acne products (containing benzoyl peroxide and / or retinoids) should not be used with **EPIDUO.**

EPIDUO contains propylene glycol (E1520) that may cause skin irritation.

Avoid excessive exposure to sunlight and UV lamps.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a non-comedogenic, broad spectrum, SPF 50+ sunscreen.

Side effects

Check with your doctor as soon as possible if you have any problems while using EPIDUO, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, EPIDUO can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

If skin irritation appears after the application of **EPIDUO,** the intensity is generally mild or moderate with some local symptoms (redness, dryness, scaling, stinging and burning) peaking during the first two weeks and then subsiding spontaneously.

EPIDUO may occasionally cause some unwanted effects at the site of application.

Tell your doctor if you notice any of the following and they worry you:

The more common side effects of EPIDUO (occur in less than 1 in 10 patients):

- dry skin
- irritative contact dermatitis (local allergic reaction)
- burning sensation
- skin irritation
- skin exfoliation (scaling)
- superficial reddening of skin

The more uncommon side effects of EPIDUO (occur in less than 1 in 100 patients):

- sunburn
- itching

- allergic contact dermatitis
- swelling face
- throat tightness
- swollen eyelids
- pain of skin (stinging pain)
- blister (vesicles)

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

Other side effects not listed above may also occur in some patients.

After using EPIDUO

Storage

Do not use **EPIDUO** after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Keep EPIDUO in a cool, dry place where the temperature stays below 25°C. Do not refrigerate. Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave EPIDUO in the car or on window sills.
Heat and dampness can destroy some medicines.

Keep EPIDUO where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using EPIDUO, or it has passed its expiry date, ask your pharmacist what to do with any gel left over.

Medicines should not be disposed of via wastewater or household waste.

Product description

What it looks like

EPIDUO Gel is a white to very pale yellow opaque gel. It is supplied in two type of containers:

- Plastic tubes with a screw cap containing 2g (sample) or 30g of gel
- Plastic bottles with a pump dispenser and plastic cap containing 30g of gel.

Ingredients

EPIDUO contains the active ingredients adapalene (0.1%) and benzoyl peroxide (2.5%).

It also contains the following inactive ingredients:

- copolymer of acrylamide and sodium acryloyldimethyltaurate
- disodium edetate
- docusate sodium
- glycerol Isohexadecane
- poloxamer 124
- polysorbate 80
- propylene glycol (E1520)
- sorbitan oleate
- purified water.

Sponsor / Distributor

Galderma Australia Pty Ltd
Suite 4, 13B Narabang Way
Belrose, NSW 2085
Telephone 1800 800 765

Distributed in New Zealand by:

Healthcare Logistics'
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