Applicant/PHRC: GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD
Product proprietary name: EPIDUO 0.1 %/ 2.5 %
Dosage form and strength: Gel
1 mg (0,1 %) of adapalene and 25 mg (2,5 %) of benzoyl peroxide per 1 gram

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

Epiduo® 0,1 % / 2,5 % (Gel)

adapalene and benzoyl peroxide

Read all of this leaflet carefully before you start using Epiduo 0,1 % / 2,5 %.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Epiduo has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Epiduo 0,1 % / 2,5 % is and what it is used for
2. What you need to know before you take Epiduo 0,1 % / 2,5 %
3. How to use Epiduo 0,1 % / 2,5 %
4. Possible side effects
5. How to store Epiduo 0,1 % / 2,5 %
6. Contents of the pack and other information

1. What Epiduo 0,1 % / 2,5 % gel 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 0,1 % / 2,5 %

Always tell your health care provider if you are taking any other medicine. If you are pregnant or breast feeding your baby. please consult your health care provider for advice before using this medicine.

Do not use Epiduo

- If you are allergic (hypersensitive) to adapalene and benzoyl peroxide or any of the other ingredients of Epiduo (listed in section 6.1).
- If you are pregnant (see section 4.6)
- If you are planning a pregnancy (see section 4.6)

Warnings and precautions

Take special care with Epiduo 0,1 % / 2,5 %

- You should not use Epiduo on areas where you have cuts, scrapes, eczema or sunburn.
- 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.
- Epiduo contains propylene glycol (E1520) that may cause skin irritation.
- If you get a reaction and think you may be sensitive or allergic to Epiduo, stop using Epiduo.
- 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 Epiduo.
- If you get skin irritation after the application of Epiduo, it is generally mild to moderate, with local signs such as redness of the skin (erythema), dryness, scaling, burning, and pain of skin (including stinging) normally peaking in the first week and then resolve without additional treatment.
- Epiduo is FOR EXTERNAL USE ONLY.

Children

Epiduo is only intended for use in adults, adolescents and children aged 9 years and over.

Other medicines or products and Epiduo 0,1 % / 2,5 %

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional 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 breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Pregnancy

DO NOT use Epiduo if you are pregnant or thinking of becoming pregnant (see Do not use Epiduo).

If you fall pregnant while using Epiduo, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.

Breastfeeding

Epiduo should not be used during breastfeeding.

To avoid contact exposure of the infant, application of Epiduo to the chest should be avoided.

Driving and using machines

Epiduo does not affect the ability to drive and use machinery.

Epiduo 0,1 % / 2,5 % contains propylene glycol

Propylene glycol (E1520) may cause skin irritation.

3. How to use Epiduo 0,1 % / 2,5 %

Do not share medicines prescribed for you with any other person.

Always use Epiduo as your doctor or pharmacist 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.

Epiduo 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 moisturiser, 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 0,1 % / 2,5 % than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

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, pharmacist or the nearest hospital:

- if you have used more Epiduo than you should.
- if you or a child has accidentally swallowed Epiduo.

Your doctor will advise you on action to be taken.

If you forget to use Epiduo 0,1 % / 2,5 %

Don't worry if you forget to apply your Epiduo.

When you remember, start using Epiduo again, in the same way as before.

Do not apply a double dose of Epiduo to make up for the missed dose.

If you stop using Epiduo 0,1 % / 2,5 %

Your doctor will tell you when to stop your treatment.

4. Possible side effects

Epiduo 0,1 % / 2,5 % can have side effects.

Not all side-effects reported for Epiduo are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Epiduo, please consult your health care provider for advice.

If any of the following happens, stop using Epiduo and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Fainting
- Rash or itching

These are all very serious side effects.

If you have them, you may have had a serious allergic reaction to Epiduo. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Common side-effects

- dry skin
- irritative contact dermatitis (an allergic skin reaction)
- skin irritation
- skin burning sensation
- redness of the skin or mucous membranes (erythema)
- skin exfoliation (scaling)

Uncommon side-effects

- itchy skin (pruritus)
- sunburn

Frequency not known side-effects (cannot be estimated from the available data)

- severe allergic reaction in your body (anaphylactic reaction), with signs such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- swelling of eyelid (oedema)
- throat tightness
- difficult or laboured breathing (dyspnoea)
- allergic contact dermatitis (an allergic skin reaction)
- swelling face
- pain of skin (stinging pain)
- blisters (vesicles)
- skin discolouration (hyperpigmentation (darker skin) and hypopigmentation (lighter skin)
- hives, an outbreak of swollen, pale red bumps or plaques (wheals) on the skin (urticaria)
- application site burn (mostly superficial burns, but cases with second degree burn or severe burn reactions have been reported)

- If you get skin irritation after the application of Epiduo, it is generally mild to moderate, with local signs such as redness of the skin (erythema), dryness, scaling, burning, and pain of skin (including stinging) normally peaking in the first week and then resolve without additional treatment.

If you have any of these or any other unusual effects, and they are bad enough to trouble you, consult your doctor.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of Epiduo.

5. How to store Epiduo 0,1 % / 2,5 %.

- Keep all medicines out of reach of children.
- Do not use Epiduo after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- Discard the container 6 months after first opening.
- Store at or below 25 ºC.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

- *The active substances are*: adapalene and benzoyl peroxide.
- *The other ingredients are*: docusate sodium, disodium edetate, glycerol, poloxamer, propylene glycol (E1520), simulgel 600PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate) and purified water.

What Epiduo 0,1 % / 2,5 % looks like and contents of the pack

Epiduo is a white to very pale yellow opaque gel.

Epiduo is presented in white multidose containers with an airless pump and snap on cap, made of polypropylene, low density polyethylene and high density polyethylene containing 30 g of gel.

Each multidose container is packed in a carton box.

Holder of Certificate of Registration

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