

Applicant: Galderma Laboratories South Africa (Pty) Ltd
Product name: Epiduo Forte
Dosage form: Gel
Strength: 0,3 % (3 mg) adapalene and 2,5 % (25 mg) benzoyl peroxide per 1 g gel
Registration Number: 50/13.12/9031

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

EPIDUO FORTE®

Gel

Adapalene and benzoyl peroxide

Read all of this leaflet carefully before you start using EPIDUO FORTE.

- 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 FORTE 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 FORTE is and what it is used for
2. What you need to know before you start using EPIDUO FORTE
3. How EPIDUO FORTE is used
4. Possible side effects
5. How to store EPIDUO FORTE
6. Contents of the pack and other information

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1. What EPIDUO FORTE is and what it is used for

EPIDUO FORTE is a gel for topical use on the skin and is used for the treatment of acne vulgaris, when comedones (blackheads, whiteheads), 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.

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 FORTE

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 EPIDUO FORTE.

Do not use EPIDUO FORTE:

- If you are hypersensitive (allergic) to the active ingredients or to any of the excipients listed in section 6.
- 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 FORTE:

Talk to your doctor or health care provider before using EPIDUO FORTE.

- You should not apply EPIDUO FORTE to cuts, scrapes, sunburn or eczema.

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- Make sure EPIDUO FORTE does not come into contact with the eyes, lips, mouth, nostrils or mucous membranes and other very sensitive areas of the body. If this occurs, wash these areas immediately with plenty of warm water.
- If you experience sensitivity or irritation when applying EPIDUO FORTE, stop using it and tell your doctor.

You may be asked to use the gel less often (e.g., every other day), or to stop using it for a time or altogether (see section 3).
- Avoid excessive exposure to sunlight and artificial UV light lamps. Use of sunscreen products and protective clothing over the treated area is recommended.
- Avoid getting EPIDUO FORTE gel on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used EPIDUO FORTE gel.

Children

Do not use EPIDUO FORTE in children under the age of 12 years.

Other medicines and EPIDUO FORTE

Always tell your health care provider if you are taking or using any other medicine. (This includes all complementary or traditional medicines.)

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

Pregnancy and Breastfeeding

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

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Pregnancy

Do not use EPIDUO FORTE if you are pregnant or thinking of becoming pregnant. (see section 2 “Do not use EPIDUO FORTE”).

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

Breastfeeding

You should not breastfeed your baby if you are on treatment with EPIDUO FORTE.

If you are breastfeeding, ask your doctor for advice before starting treatment with EPIDUO FORTE. Your doctor will advise you whether to discontinue breastfeeding or to abstain from treatment with EPIDUO FORTE gel.

Driving and using machines:

EPIDUO FORTE has no or negligible effects on the ability to drive and use machines.

EPIDUO FORTE contains propylene glycol

Propylene glycol can be irritating to the skin.

3. How EPIDUO FORTE is used

This medicine is for external use only.

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

Always use EPIDUO FORTE exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

The dose is:

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Apply a thin film of gel once a day on a clean and dry skin, in the evening, to the entire acne-affected areas of the face and /or the trunk.

You should wash your hands after you have used the gel.

Your doctor will tell you how long your treatment with EPIDUO FORTE will last.

If you have the impression that EPIDUO FORTE is too strong or too weak, tell your doctor or pharmacist.

- Apply a thin layer of EPIDUO FORTE gel to the acne-affected areas of the face and/or trunk once daily, at bedtime, after washing and drying.
- If used on the face: Use a pea-sized amount of EPIDUO FORTE gel for each of the affected areas of the face (e.g., forehead, chin, each cheek). Avoid contact with the eyes, lips, nostrils and mucous membranes.
- Wash your hands thoroughly immediately after applying the EPIDUO FORTE gel.
- Cosmetics (such as face creams or make-up) may be applied after the EPIDUO FORTE gel has dried.
- If you experience persistent skin irritation, during the first weeks when using EPIDUO FORTE 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 EPIDUO FORTE gel altogether.

If you use more EPIDUO FORTE than you should

If you use more EPIDUO FORTE 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. Some peeling or discomfort could also occur.

If you forget to use EPIDUO FORTE

Don't worry if you forget to apply your EPIDUO FORTE at night-time.

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When you remember, start using EPIDUO FORTE again, in the same way as before. Do not apply a double dose to make up for the missed dose.

If you stop using EPIDUO FORTE

Your doctor will tell you how long your treatment with EPIDUO FORTE will last. The spots (comedones, papules and pustules) will be reduced only after several applications of EPIDUO FORTE. Continue using EPIDUO FORTE gel as long as prescribed by your doctor.

4. Possible side effects

EPIDUO FORTE can have side effects.

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

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

- Throat tightness
- Swelling of the eyes, face, lips or tongue
- Feel faint
- Have difficulty breathing.

Stop using EPIDUO FORTE if you develop hives or itching of the face or body. The frequency with which these side effects occur is not known. These are all very serious side effects. If you have them, you may have had a serious allergic reaction to EPIDUO FORTE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

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Frequent side-effects:

- Irritation of the skin
- Eczema
- Skin burning sensation
- Atopic dermatitis (dry, itchy skin)
- Redness
- Scaling

Less frequent side-effects:

- Tingling or sensation of pins and needles at the application site
- Redness of the eyelids
- Dry skin
- Rash
- Itching of the skin

Frequency unknown side-effects:

- Anaphylactic reaction (with symptoms such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing)
- Eyelid swelling
- Tightness in the throat
- Shortness of breath (dyspnoea)
- Allergic contact skin reactions (contact dermatitis)
- Swelling of the face
- Pain of the skin (stinging pain)
- Blisters (vesicles)
- Skin discolouration (change in skin colour)

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- Hives, red, itchy skin (urticaria)
- Application site burn

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.

5. How to store EPIDUO FORTE

Store at or below 25 °C.

Always check the expiry date which is shown on the pump and carton. Do not use after the expiry date stated on the carton.

Discard the tube or pump 3 months after opening it.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets). Return all unused medicine to your pharmacist. These measures will help protect the environment.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information

What EPIDUO FORTE contains:

The active substances are:

Each 1 gram of EPIDUO FORTE gel contains:

adapalene 3 mg (0.3 %) and benzoyl peroxide 25 mg (2.5 %).

The other ingredients are:

Disodium edetate

Docusate sodium

Glycerol (glycerin)

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Poloxamer

Propylene glycol (E1520)

Simulgel 600 PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate,
isohexadecane, polysorbate 80, sorbitan oleate)

Purified water

What EPIDUO FORTE looks like and contents of the pack:

EPIDUO FORTE is a white to very pale yellow opaque gel.

EPIDUO FORTE gel is supplied in a multidose pump container containing 15 g, 30 g, 45 g or 60 g with a snap on cap.

Each multidose container is packed in a carton box.

Not all pack sizes may be marketed.

Holder of Certificate of registration:

Galderma Laboratories South Africa (Pty) Ltd

Nicol Main Office Park,

Block C, First Floor,

FutureSpace,

2 Bruton Road,

Bryanston

2191

This leaflet was last revised in

13 September 2022

Registration number:

EPIDUO FORTE: 50/13.12/0931