

EPIDUO[®] FORTE Gel

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EPIDUO FORTE?

EPIDUO FORTE contains the active ingredients adapalene and benzoyl peroxide. EPIDUO FORTE is used for the topical treatment of acne (acne vulgaris) on your face, chest and back, with comedones (clogged hair follicles- blackheads, whiteheads) and numerous inflammatory papules and pustules (e.g., pimples).

For more information, see Section [1. Why am I using EPIDUO FORTE?](#) in the full CMI.

2. What should I know before I use EPIDUO FORTE?

Do not use if you have ever had an allergic reaction to adapalene, benzoyl peroxide, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use EPIDUO FORTE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EPIDUO FORTE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EPIDUO FORTE?

EPIDUO FORTE should be used once a day in the evening.

More instructions can be found in Section [4. How do I use EPIDUO FORTE?](#) in the full CMI.

5. What should I know while using EPIDUO FORTE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using EPIDUO FORTE.
Things you should not do	<ul style="list-style-type: none">• Do not give EPIDUO FORTE to anyone else, even if they have the same condition as you.• Do not use EPIDUO FORTE to treat any other medical complaints unless your doctor tells you to.
Looking after your medicine	<ul style="list-style-type: none">• Keep EPIDUO FORTE in a cool, dry place where the temperature stays below 25°C.• Do not refrigerate

For more information, see Section [5. What should I know while using EPIDUO FORTE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include dry skin, irritative contact dermatitis (skin irritation), skin burning sensation, local allergic reaction, skin irritation, skin exfoliation (scaling), superficial reddening of skin, atopic dermatitis, eczema

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EPIDUO® FORTE Gel

Active ingredient(s): 0.3% adapalene / 2.5% benzoyl peroxide

Consumer Medicine Information (CMI)

This leaflet provides important information about using EPIDUO FORTE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EPIDUO FORTE.**

Where to find information in this leaflet:

1. Why am I using EPIDUO FORTE?
2. What should I know before I use EPIDUO FORTE?
3. What if I am taking other medicines?
4. How do I use EPIDUO FORTE?
5. What should I know while using EPIDUO FORTE?
6. Are there any side effects?
7. Product details

1. Why am I using EPIDUO FORTE?

EPIDUO FORTE contains the active ingredients adapalene and benzoyl peroxide.

- 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.

EPIDUO FORTE is used for the topical treatment of acne (acne vulgaris) on your face, chest and back, with comedones (clogged hair follicles- blackheads, whiteheads) and numerous inflammatory papules and pustules (e.g., pimples).

Epiduo Forte is to be used if the acne has not responded to other treatments first.

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

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

This medicine is available only with a doctor's prescription

2. What should I know before I use EPIDUO FORTE?

Warnings

Do not use EPIDUO FORTE if:

- you are allergic to adapalene, benzoyl peroxide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have cuts, scrapes or eczema on your skin
- your skin is sunburnt
- your child is below 12 years of age.

Check with your doctor if you:

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

Check with your doctor if you have:

- very large pimples called severe nodular or nodulocystic acne

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not use EPIDUO FORTE if you are pregnant or are planning a pregnancy. If you fall pregnant while using EPIDUO FORTE, the treatment must be discontinued and you should inform your doctor as soon as possible for further follow-up.

Check with your doctor if you are pregnant or intend to become pregnant.

Do not apply EPIDUO onto your chest if you are breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with EPIDUO FORTE and affect how it works.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EPIDUO FORTE.

4. How do I use EPIDUO FORTE?

- 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/box, ask your doctor or pharmacist for help.

When to use EPIDUO FORTE

- EPIDUO FORTE should be used once a day in the evening.
- Depending on your condition and how you react to EPIDUO FORTE, your doctor may ask you to use it differently.
- If you use more EPIDUO FORTE than you should on your skin, you will not get rid of your acne quicker, but your skin may become irritated and red.
- If your acne does not improve after using EPIDUO FORTE for 4 weeks, you should see your doctor to discuss if alternative or additional treatment is required

How to apply EPIDUO FORTE

- Cleanse the skin before applying EPIDUO FORTE – a non-soap cleanser is useful. Allow the skin to dry completely before applying EPIDUO FORTE.
- Apply a thin film of gel evenly over the entire acne affected area(s) of the face and the trunk once a day, in the evening, on a clean and dry skin. If applying to the face, avoid the eyes and lips.
- Wash your hands afterwards.
- If the product enters the eye, wash immediately with luke-warm water.

If you forget to use EPIDUO FORTE

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 swallow EPIDUO FORTE

If you think that you have swallowed EPIDUO FORTE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EPIDUO FORTE?

Things you should do

- If you feel that the effect of EPIDUO FORTE is too strong or too weak, talk to your doctor or pharmacist.
- If you experience irritation when applying EPIDUO FORTE, 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.
- **Stop using this medicine if your skin becomes inflamed.** Your doctor will review how your skin is responding and decide on the best course of treatment. Once the reaction has resolved, your doctor may recommend restarting treatment, initially at a reduce frequency, for example applying once every second day.

Call your doctor straight away if you:

- become or plan to become pregnant while using EPIDUO.
- are about to start using any new medicine.

Remind any doctor, dentist or pharmacist you visit that you are using EPIDUO FORTE.

Things you should not do

- Do not give EPIDUO FORTE to anyone else, even if they have the same condition as you.
- Do not use EPIDUO FORTE to treat any other medical complaints unless your doctor tells you to.
- Do not use in children below 12 years of age.

Things to be careful of

- Please be aware that EPIDUO FORTE contains benzoyl peroxide which may cause bleaching and discolouration to the hair and dyed fabrics.
- When using EPIDUO FORTE 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 FORTE.
- Avoid waxing as a means of hair removal on the skin treated with EPIDUO FORTE.
- Avoid using other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have strong skin-drying effect and products with high concentrations of alcohol, astringents, spices, or limes) while being treated with EPIDUO FORTE.
- EPIDUO FORTE contains propylene glycol (E1520) that may cause skin irritation.
- EPIDUO contains polysorbate 80 (E433), which can cause allergic reactions.
- Cosmetics with irritant or drying effect should not be used with EPIDUO FORTE.
- Avoid excessive exposure to sunlight and UV lamps.

- **Protect your skin when you are in the sun, especially between 10 am and 4 pm. If outdoors, wear protective clothing and use a non-comedogenic, broad spectrum, SPF 50+ sunscreen.**

Looking after your medicine

- Keep EPIDUO FORTE in a cool, dry place where the temperature stays below 25°C.
- Do not refrigerate.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Please discard 3 months after first opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If skin irritation appears after the application of EPIDUO FORTE, 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 FORTE may occasionally cause some unwanted effects at the site of application

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • dry skin • irritative contact dermatitis (skin irritation) • skin burning sensation • local allergic reaction • skin irritation • skin exfoliation (scaling) • superficial reddening of skin • atopic dermatitis • eczema • sunburn • itching 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • rash • allergic contact dermatitis (local allergic reaction) 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling face • throat tightness • dyspnoea (difficulty breathing) • swollen eyelids • pain of skin (stinging pain) • blisters (vesicles) • skin discoloration • urticaria (hives) • anaphylactic reaction (a potentially severe allergic reaction) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What EPIDUO FORTE contains

Active ingredient (main ingredient)	Adapalene 0.3% w/w Benzoyl peroxide 2.5% w/w
Other ingredients (inactive ingredients)	copolymer of acrylamide and sodium acryloyldimethyltaurate disodium edetate docusate sodium glycerol Isohexadecane poloxamer 124 polysorbate 80 (E433) propylene glycol (E1520) sorbitan oleate purified water
Potential allergens	polysorbate 80 (E433)

	propylene glycol (E1520)
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Do not take this medicine if you are allergic to any of these ingredients.

What EPIDUO FORTE looks like

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

- Plastic tubes with a screw cap containing 2g or 5g (sample) of gel (AUST R 273181)
- Plastic bottles with a pump dispenser and plastic cap containing 15g, 30g, and 45g gel (AUST R 273168)

Not all pack sizes may be supplied

Who distributes EPIDUO FORTE

Galderma Australia Pty Ltd
Level 1, 1 Denison Street
North Sydney, NSW 2060
Telephone 1800 800 765

Distributed in New Zealand by:

Healthcare Logistics'
58 Richard Pearse Drive
Airport Oaks
Auckland
Telephone (09) 9185100

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