

Package leaflet: Information for the user

Adapalene/Benzoyl peroxide Orifarm 1 mg/g + 25 mg/g gel

adapalene/benzoyl peroxide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you use [Invented name]
3. How to use [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] 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 [Invented name]

Do not use [Invented name]

- If you are pregnant
- If you are planning a pregnancy
- If you are allergic to adapalene, benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using [Invented name].

- You should not use [Invented name] on areas where you have cuts, scrapes, sunburn or eczema.
- Make sure [Invented name] 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 [Invented name] on your hair or coloured fabrics as it may bleach them and wash your hands thoroughly after you have used the medicine.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Do not use other acne products (containing benzoyl peroxide and/or retinoids) at the same time as [Invented name]
- Avoid using [Invented name] at the same time as cosmetics that are irritant, drying or exfoliate the skin.

Pregnancy and breast-feeding

DO NOT use [Invented name] if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

If you become pregnant while using [Invented name], the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.

[Invented name] can be used during breast-feeding. To avoid contact exposure of the infant, application of [Invented name] to the chest should be avoided.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Not relevant.

[Invented name] contains propylene glycerol

[Invented name] contains 40 mg propylene glycol (E1520) in each gram which is equivalent to 4% w/w.

3. How to use [Invented name]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

[Invented name] is only intended for use in adults, adolescents and children aged 9 years and over. This medicine 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 [Invented name].

Your doctor will tell you how long you will need to use [Invented name].

If you feel that the effect of [Invented name] is too strong or too weak, talk to your doctor or pharmacist.

If you experience persistent irritation when applying [Invented name], 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 [Invented name] than you should

If you use more [Invented name] 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 [Invented name] 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 [Invented name]

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using the product and seek immediate medical attention if you develop throat tightness or swelling of the eyes, face, lips or tongue, feel faint, or have difficulty breathing. Stop using the product if you develop hives or itching of the face or body. The frequency with which these side effects occur is not known.

Common side effects (may affect up to 1 in 10 people)

- dry skin
- local skin rash (irritative contact dermatitis)
- burning sensation
- irritation of the skin
- redness
- scaling

Uncommon side effects (may affect up to 1 in 100 people)

- itching of the skin (pruritus)
- sunburn

Not known (frequency 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)
- blisters (vesicles)
- difficulty in breathing
- skin discolouration (change in skin colour)
- application site burn.

If skin irritation appears after application of [Invented name], 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.

Application site burns, mostly superficial but more severe cases involving blistering, have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pump. The expiry date refers to the last day of that month.

Discard the pump 6 months after first opening. Write down the date for opening in the space on the carton to better remember when to discard the pump.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Invented name] contains

- The active substances are: adapalene and benzoyl peroxide. 1 g of gel contains 1 mg (0.1%) adapalene and 25 mg (2.5%) benzoyl peroxide.
- The other ingredients are: disodium edetate, docusate sodium, glycerol (E422), poloxamer, propylene glycol (E1520), acrylamide, sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80 (E433), sorbitan oleate and purified water.

What [Invented name] looks like and contents of the pack

[Invented name] is a white to very pale yellow opaque gel.

[Invented name] is available in white pumps with a protection cap.

Pack sizes: 30 g, 45 g and 60 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in 2023-03-01