Package leaflet: Information for the user

Adapaleen/ Benzoylperoxide Galen 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Adapaleen/ Benzoylperoxide Galen is and what it is used for
2. What you need to know before you use Adapaleen/ Benzoylperoxide Galen
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6. Contents of the pack and other information

1. What Adapaleen/ Benzoylperoxide Galenis and what it is used for

Adapaleen/ Benzoylperoxide Galen 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.

Benzoyl peroxide, the other active ingredient, 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 Adapaleen/ Benzoylperoxide Galen

Do not use Adapaleen/ Benzoylperoxide Galen
- if you are allergic to adapalene or benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant
- if you are planning to have a baby

Warnings and precautions
Talk to your doctor or pharmacist before using this medicinal product.

You should not use this gel on areas where you have cuts, scrapes, sunburn or eczema.

Make sure the gel does not get into your eyes, mouth or nostrils, and other very sensitive areas of the body. If this occurs wash these areas immediately with plenty of warm water.

Avoid excessive exposure to sunlight and UV lamps.

Avoid getting the gel on your hair or coloured fabrics as it may bleach them.

Wash your hands thoroughly after you have used this medicine.

Other medicines and Adapaleen/ Benzoylperoxide Galen
Do not use other acne products (containing benzoyl peroxide and/or retinoids) at the same time with the gel.

Avoid using Adapaleen/ Benzoylperoxide Galen at the same time with cosmetics that are irritant, drying or exfoliate the skin.

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

Pregnancy and breast-feeding
Pregnancy
DO NOT use Adapaleen/ Benzoylperoxide Galen if you are pregnant or if you are planning to have a baby. Your doctor can give you more information.

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

Breast-feeding
This gel can be used during breast-feeding. To avoid contact exposure of the infant, application of this medicine to the chest should be avoided.

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

Driving and using machines
Not relevant

Adapaleen/ Benzoylperoxide Galencontains propylene glycol which may cause skin irritation.
This medicine contains 40 mg of propylene glycol (E1520) in each gram of gel which is equivalent to 4.00% w/w.

Adapaleen/ Benzoylperoxide Galencontains polysorbates which can cause allergic reactions.
This medicine contains 3 mg of polysorbate 80 in each gram of gel which is equivalent to 0.3% w/w.

Adapaleen/ Benzoylperoxide Galencontains benzoic acid, a degradation product of benzoyl peroxide, which may cause local irritation.

3. How to use Adapaleen/ Benzoylperoxide Galen

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

This medicinal product 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 this gel.

Your doctor will tell you how long you will need to use this medicinal product.

If you feel that the effect of Adapaleen/ Benzoylperoxide Galenis too strong or too weak, talk to your doctor or pharmacist.

If you experience persistent irritation when using this medicine, contact your doctor. Your doctor may recommend you 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 Adapaleen/ Benzoylperoxide Galen than you should
If you use more gel 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 Adapaleen/ Benzoylperoxide Galen 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 Adapaleen/ Benzoylperoxide Galen
Do not apply a double dose to make up for forgotten individual doses.

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
- reddening of the skin
- 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 this medicinal product, 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 are in general superficial, but more severe cases involving blistering have been reported.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Adapaleen/ Benzoylperoxide Galen

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 tube. The expiry date refers to the last day of that month.

Do not store above 30°C.
After first opening of the tube, use the product within 6 months.

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 Adapaleen/ Benzoylperoxide Galen contains
- The active substances are: adapalene and benzoyl peroxide. 1 g of gel contains 1 mg (0.1% w/w) adapalene and benzoyl peroxide, hydrous, equivalent to 25 mg (2.5% w/w) of anhydrous benzoyl peroxide.
- The other ingredients are: propylene glycol (E1520); glycerol; sepineo P600 (Acrylamide and sodium acryloyldimethyltaurate copolymer (1:1), isohexadecane, polysorbate 80, sorbitan oleate); poloxamer 124; disodium edetate; docusate sodium; purified water.

What Adapaleen/ Benzoylperoxide Galen looks like and contents of the pack
Homogeneous opaque gel of white to very pale-yellow colour.
Pack size of 1 tube of 30 g, 45 g or 60 g.

Gel is packed in white HDPE/LLDPE plastic tubes with a white HDPE head, having an aluminium peel-off seal and closed with a white polypropylene screw-cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
GALENpharma GmbH
Wittland 13
24109 Kiel
Duitsland

Manufacturer

Adalvo Limited
Malta Life Sciences Park, Building 1, Level 4,
Sir Temi Zammit Buildings, San Gwann Industrial Estate
SGN 3000 SAN GWANN
Malta

Or

Beltapharm S.R.L.
Via Stelvio 66
20095 CUSANO MILANINO (MI)
Italië

<This medicine is authorised in the Member States of the European Economic Area <and in the United Kingdom (Northern Ireland)> under the following names:>

<{Name of the Member State}> <{Name of the medicine}>
<{Name of the Member State}> <{Name of the medicine}>
< United Kingdom (Northern Ireland)> <{Name of the medicine}>

Deze Bijsluiter is voor het laatst goedgekeurd in juni 2026.