Package leaflet: Information for the user

Adabencutan 3 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 Adabencutan 3 mg/g + 25 mg/g gel is and what it is used for
2. What you need to know before you use Adabencutan 3 mg/g + 25 mg/g gel
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1. What Adabencutan 3 mg/g + 25 mg/g gel is and what it is used for

Adabencutan 3 mg/g + 25 mg/g gel gel belongs to a group of medicines called “anti-acne preparation for topical use”. It is used for the treatment of acne vulgaris, when comedones (blackheads, whiteheads), numerous papules and pustules (inflammatory pimples) are present.

It 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.

This medicinal product should only be used in adults and adolescents aged 12 years and over.

2. What you need to know before you use Adabencutan 3 mg/g + 25 mg/g gel

Do not use Adabencutan 3 mg/g + 25 mg/g gel
- 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.

If you experience persistent skin irritation when starting treatment with this gel contact your doctor (see section 3 **How to use Adabencutan 3 mg/g + 25 mg/g gel**).

Other medicines and Adabencutan 3 mg/g + 25 mg/g gel
Do not use other acne products (containing benzoyl peroxide and/or retinoids) at the same time with this gel.

Avoid using Adabencutan 3 mg/g + 25 mg/g gel at the same time as cosmetics that are irritant, drying or exfoliate the skin.

Other medicines may have an effect on your treatment/this gel , so 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 Adabencutan 3 mg/g + 25 mg/g gel 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
If you are breast-feeding ask your doctor for advice before using this medicine. Your doctor will advise you whether to discontinue breast-feeding or to abstain from treatment with this gel.

If your doctor advises you to continue the treatment, avoid application of the gel to the chest in order to avoid contact exposure of the infant.

Driving and using machines
Adabencutan 3 mg/g + 25 mg/g gel gel has no or negligible effects on the ability to drive and use machines.

Adabencutan 3 mg/g + 25 mg/g gel **contains propylene glycol which may cause skin irritation.**
This product contains 40 mg of propylene glycol (E1520) in each gram of gel which is equivalent to 4.00% w/w.

Adabencutan 3 mg/g + 25 mg/g gel contains 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.

Adabencutan 3 mg/g + 25 mg/g gel contains benzoic acid, a degradation product of benzoyl peroxide, which may cause local irritation.

3. How to use Adabencutan 3 mg/g + 25 mg/g gel

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, and adolescents aged 12 years and over. This medicine is for external use only.

The doctor will decide which strength of gel you need, depending on the severity and appearance of your acne. The doctor will also decide if you need any additional treatment.

- The skin should be clean and dry before application.
- Apply a thin film of gel evenly over the entire acne-affected areas of the face and/or the trunk, once a day at bedtime. Avoid contact with the eyes, lips, nostrils and mucous membranes.
- If used on the face: Wash and dry the face and use a pea size amount to cover each part of the face (such as forehead, chin, each cheek).
- Wash your hands thoroughly immediately after you have applied the gel.

Your doctor will tell you how long you will need to usethis medicinal product . If you do not see any improvement after 4-8 weeks you should discuss with your doctor the benefit of continuing the treatment.

If you experience persistent skin irritation during the first weeks when using this gel, contact your doctor. Your doctor may recommend you to apply a moisturiser, to use the gel less often, to stop for a short time, or to stop using the gel.

Do not apply cosmetics (such as other facial creams or make-up) before the daily application of the gel. These products can be used after the applied gel has dried.

Use in children
This medicinal product should not be used by children below 12 years of age.

If you use more Adabencutan 3 mg/g + 25 mg/g gel 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 Adabencutan 3 mg/g + 25 mg/g gel than you should.
- If a child has accidentally taken this medicine.
- If you or someone else accidentally swallow this medicine.

Your doctor will advise you on action to be taken.

If you forget to use Adabencutan 3 mg/g + 25 mg/g gel
Do not apply a double dose to make up for forgotten individual doses.

The spots (comedones, papules and pustules) will be reduced only after several applications of this medicine. Continue using this treatment as long as prescribed by your doctor.

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

4. Possible side effects

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

Approximately 1 in 10 people using this medicine may experience adverse skin reactions.

Stop using this medicinal 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 it 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):
- skin burning sensation
- irritation of the skin
- eczema
- reddening of the skin
- scaling

Uncommon side effects (may affect up to 1 in 100 people):
- Redness of the eyelid
- Tingling or sensation of pins and needles at the application site
- Itching of the skin, allergic skin reaction
- Rash
- Dry skin

In addition to the side effects described above, the following side effects have been reported with a lower strength of adapalene / benzoyl peroxide gel (1 mg/g + 25 mg/g):

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

Not known (cannot be estimated from the available data):
- swelling of the eyelid
- tightness in the throat
- allergic contact reactions
- swelling face
- pain of skin (stinging pain)
- blisters (vesicles)
- difficulty in breathing
- skin discolouration (change in skin colour)
- application site burn

Adverse reactions typically associated with use of Adabencutan 3 mg/g + 25 mg/g gel include mild to moderate application site reactions, such as skin irritation with redness, dryness, scaling, stinging and or burning of the skin.

Application site burns are in general superficial, but more severe cases involving blistering, have been reported.

If you experience persistent skin irritation during the first weeks when using this medicinal product, contact your doctor. Adverse skin-reactions, such as skin irritation, are more frequent with higher strength gel than with lower strength (adapalene/benzoyl peroxide 1 mg/g + 25 mg/g gel). 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 gel. These reactions usually occur early in the treatment, and tend to gradually lessen over time.

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 Adabencutan 3 mg/g + 25 mg/g gel

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 3 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 Adabencutan 3 mg/g + 25 mg/g gel contains
- The active substances are: adapalene and benzoyl peroxide. 1 g of gel contains 3 mg (0.3% 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 Adabencutan 3 mg/g + 25 mg/g gel looks like and contents of the pack
Homogeneous opaque gel of white to very pale yellow colour.

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.

One tube of 15 g
One tube of 30 g
One tube of 45 g
One tube of 60 g

Not al pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikanten
Vergunninghouder
Dermapharm AG
Lil-Dagover-Ring 7
D-82031 Gruenwald
Duitsland

Fabrikanten:
Adalvo Limited
Malta Life Sciences Park, Building 1, Level 4
Sir Temi Zammit Buildings
San Gwann, SGN 3000
Malta

BELTAPHARM S.R.L.
Via Stelvio 66, 20095 Cusano Milanino
Milan
Italië

mibe GmbH Arzneimittel
Münchener Straße 15
06796 Brehna
Duitsland

In het register ingeschreven onder
RVG 133315

This medicine is authorised in the Member States of the European Economic under the following names:

Germany:	Adabencutan 3 mg/g + 25 mg/g Gel
Netherlands:	Adabencutan 3 mg/g + 25 mg/g gel

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