

## Package leaflet: Information for the user

### Adapalene/Benzoyl peroxide 0.1% / 2.5% gel

**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 Adapalene/Benzoyl peroxide gel is and what it is used for
2. What you need to know before you use Adapalene/Benzoyl peroxide gel
3. How to use Adapalene/Benzoyl peroxide gel
4. Possible side effects
5. How to store Adapalene/Benzoyl peroxide gel
6. Contents of the pack and other information

#### 1. What Adapalene/Benzoyl peroxide gel is and what it is used for

Adapalene/Benzoyl peroxide gel 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 medicines 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 Adapalene/Benzoyl peroxide gel

##### Do not use Adapalene/Benzoyl peroxide 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 the gel.

- You should not use the 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 Adapalene/Benzoyl peroxide gel

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 Adapalene/Benzoyl peroxide gel.
- Avoid using this medicine at the same time as cosmetics that are irritant, drying or exfoliate the skin.

## **Pregnancy and breast-feeding**

### Pregnancy

Do not use Adapalene/Benzoyl peroxide 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 medicine, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.

### Breast-feeding

Adapalene/Benzoyl peroxide gel can be used during breast-feeding. To avoid contact exposure of the infant, application of this gel to the chest should be avoided.

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

## **Driving and using machines**

Not relevant

**Adapalene/Benzoyl peroxide gel contains 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.

**Adapalene/Benzoyl peroxide gel contains benzoic acid**, a degradation product of benzoyl peroxide, which can cause local irritation.

## **3. How to use Adapalene/Benzoyl peroxide gel**

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

Adapalene/Benzoyl peroxide gel 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 the 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 the gel.

Your doctor will tell you how long you will need to use the gel.

If you feel that the effect of this medicine is 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 moisturiser, to use the gel less often or to stop for a short time, or to stop using the gel altogether.

### **If you use more Adapalene/Benzoyl peroxide 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 gel 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 Adapalene/Benzoyl peroxide gel**

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 the gel, it is generally mild to moderate, with local signs as redness, dryness, scaling, burning and skin pain (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 Yellow Card Scheme, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store Adapalene/Benzoyl peroxide 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 the tube, use the gel 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 Adapalene/Benzoyl peroxide gel contains**

The active substances are adapalene and benzoyl peroxide. 1 g of gel contains 1 mg (0.1%) adapalene and benzoyl peroxide hydrous, equivalent to 25 mg (2.5% w/w) anhydrous benzoyl peroxide.

The other ingredients are propylene glycol (E1520), glycerol, sepineo P600 (co-polymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate), poloxamer 124, disodium edetate, docusate sodium, purified water.

### **What Adapalene/Benzoyl peroxide gel looks like and contents of the pack**

White to pale yellow, homogeneous, opaque gel.

The 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.

Pack sizes: 1 tube of 30 g, 45 g or 60 g.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Aristo Pharma GmbH

Wallenroder Straße 8-10

13435 Berlin

Germany

### **Manufacturer**

Beltapharm S.p.A

Via Stelvio 66

20095 Cusano Milanino

Milan

Italy

**This leaflet was last revised in 06/2025.**