

## Package leaflet: Information for the user

### Adapaleen/benzoylperoxide Aristo 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 [Product Name] is and what it is used for
2. What you need to know before you use [Product Name]
3. How to use [Product Name]
4. Possible side effects
5. How to store [Product Name]
6. Contents of the pack and other information

#### 1. What [Product Name] is and what it is used for

[Product 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.

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 [Product Name]

##### Do not use [Product Name]

- 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 [Product Name]**

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

Avoid using [Product Name] 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** [Product Name] 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

#### **[Product Name] 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.

#### **[Product Name] 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.

#### **[Product Name] contains benzoic acid, a degradation product of benzoyl peroxide, which may cause local irritation.**

### **3. How to use [Product Name]**

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 [Product Name] 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 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 [Product Name] 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 [Product 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 [Product Name]**

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 [Product 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 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 [Product Name] 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 [Product Name] 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.

**Houder van de vergunning voor het in de handel brengen en fabrikanten**

Vergunninghouder:

Aristo Pharma GmbH  
Wallenroder Straße 8 – 10  
13435 Berlijn, Duitsland

Fabrikanten:

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

Beltapharm S.p.A.  
Via Stelvio 66  
20095 Cusano Milanino  
MI  
Italië

**In het register ingeschreven onder**

RVG 132005

**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 december 2024.**