

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Vaniqa 11.5% cream** Eflornithine

#### **READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Vaniqa is and what it is used for
2. Before you use Vaniqa
3. How to use Vaniqa
4. Possible side effects
5. How to store Vaniqa
6. Further information

#### **1. WHAT Vaniqa IS AND WHAT IT IS USED FOR**

Vaniqa contains the active substance eflornithine. Eflornithine slows down the growth of hair through its effect on a specific enzyme (a protein in the body involved in the production of hair).

Vaniqa is used to reduce the growth of excessive hair (hirsutism) on the face of female adolescents (aged 12 to 18 years) and adult women.

#### **2. BEFORE YOU USE Vaniqa**

##### **Do not use Vaniqa:**

- if you are allergic (hypersensitive) to eflornithine or to any of the other ingredients listed in section 6.

##### **Take special care with Vaniqa:**

- before using Vaniqa, tell your doctor of any other medical problems you may be experiencing (especially related to your kidneys or liver).
- if you are unsure whether or not to use this medicine contact your doctor or pharmacist for advice.

Excessive growth of hair may be a result of underlying diseases. Talk to your doctor if you suffer from polycystic ovary syndrome (PCOS) or specific hormone producing tumours, or if you take medicines that can induce hair growth, e.g. cyclosporine (following organ transplants), glucocorticoids (e.g. against rheumatic or allergic diseases), minoxidil (against high blood pressure), phenobarbitone (against seizures), phenytoin (against seizures) or hormone replacement therapy with male hormone like effects.

### **Children**

Vaniqa is **not** recommended for children below 12.

### **Using other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Talk to your doctor if you need to use other medicines on the areas of skin where you are using the cream.

### **Pregnancy and breast-feeding**

**Do not** use Vaniqa if you are pregnant or breast-feeding. You should use an alternative method to manage your facial hair if you are pregnant or trying to become pregnant.

### **Driving and using machines**

Vaniqa is not expected to have any effect on your ability to drive or use machines.

### **Important information about some of the ingredients of Vaniqa**

This medicine contains cetostearyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). It also contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

## **3. HOW TO USE Vaniqa**

Always use Vaniqa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Use twice a day, at least 8 hours apart.
- If you experience irritation (e.g. stinging burning), reduce the use of Vaniqa to once daily until the irritation has gone. If it persists contact your doctor.
- If you have just shaved or used any other hair removal method, wait at least **5 minutes** before using Vaniqa. It may sting or burn if you put this cream on cut or irritated skin.
- Clean and dry the areas of the skin where you will be using the cream.
- Apply a thin layer of cream and rub it in thoroughly until no visual residual product remains on the treated areas.
- If possible, **do not** wash these areas of skin for 4 hours after applying the cream

- Wash your hands after applying the cream.
- Wait at least **5 minutes** before using make-up or sunscreen on the same areas.
- When using on the face, **avoid** contact with your eyes or the inside of your nose or mouth. If you should accidentally get Vaniqa into your eyes, mouth or nose, rinse well with water.

Vaniqa is **not** a depilatory cream, so you may need to continue with your hair removal method, for example by shaving or plucking.

It may take 8 weeks before you see results. It is important to continue using the cream. If you do not see any improvement after using it for 4 months contact your doctor. If you stop using it your original hair growth may return within 8 weeks.

### **If you use more Vaniqa than you should**

If you put too much cream on your skin, it is unlikely to harm you.

If you or anyone else accidentally swallows Vaniqa, contact your doctor **immediately**.

### **If you forget to use Vaniqa**

Apply straight away, but wait at least 8 hours before using it again.

### **If you stop using Vaniqa**

To maintain the reduction of hair growth keep using Vaniqa continuously as indicated.

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

## **4. POSSIBLE SIDE EFFECTS**

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

Side effects are usually limited to the skin and mild in intensity. In such cases they normally resolve without discontinuation of Vaniqa.

The frequency of possible side effects listed below is defined using the following convention:

very common	(affects more than 1 user in 10)
common	(affects 1 to 10 users in 100)
uncommon	(affects 1 to 10 users in 1,000)
rare	(affects 1 to 10 users in 10,000)
very rare	(affects less than 1 user in 10,000)
not known	(frequency cannot be estimated from the available data).

### **Very common (affects more than 1 user in 10)**

- acne

**Common (affects 1 to 10 users in 100)**

- dry skin
- hair loss
- inflammation around the hair shaft
- itching
- rash
- redness
- skin irritation and bumps caused by shaving
- skin irritation
- stinging, tingling or burning feeling on the skin

**Uncommon (affects 1 to 10 users in 1,000)**

- bumpy rash (papular rash)
- cold sores
- redness and irritation at the site where the cream is applied
- eczema
- inflamed, dry, cracked or numb lips
- ingrowing hairs
- pale areas on the skin
- skin bleeding
- skin boils
- skin flushing
- skin inflammation
- sore skin
- swelling of the mouth or face
- unusual hair texture or hair growth

**Rare (affects 1 to 10 users in 10,000)**

- abnormal skin growth (skin neoplasm)
- excessive hair growth
- flushing, facial redness and pimples possibly with pus
- other skin disorders
- red, scaly and itchy skin inflammation (seborrhoeic dermatitis)
- red, bumpy or blistering rash
- skin cysts
- skin tightness

If any of the above side effects gets serious or it persists, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE Vaniqa**

Keep out of the reach and sight of children.

**Do not** use Vaniqa after the expiry date which is stated on the box and on the bottom of the tube after EXP. The expiry date refers to the last day of that month.

Make sure the cap of the tube is tightly closed after each use.

**Do not** store above 25°C.

Medicines **should not** be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Vaniqa contains**

The active substance of Vaniqa is eflornithine.  
Each gram of cream contains 115 mg of eflornithine (as hydrochloride monohydrate).

The other ingredients are:  
cetostearyl alcohol; macrogol cetostearyl ether; dimeticone; glyceryl stearate; macrogol stearate; methyl parahydroxybenzoate (E218); liquid paraffin; phenoxyethanol; propyl parahydroxybenzoate (E216); purified water and stearyl alcohol. Tiny amounts of sodium hydroxide (E524) are sometimes added to keep acidity levels (pH levels) normal.

### **What Vaniqa looks like and the contents of the pack**

Vaniqa is a cream which is white to off white in colour. It is supplied in tubes of 15 g, 30 g and 60 g but not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Almirall, S.A.  
Ronda General Mitre, 151  
08022 Barcelona  
Spain.  
Tel: + 34 93 291 30 00

### **Manufacturer**

Almirall Hermal GmbH  
Scholtzstrasse 3  
D-21465 Reinbek  
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

#### **Belgique/België/Belgien**

Almirall N.V.  
Tél/Tel: +32 (0)2 257 26 63

#### **Italia**

Almirall SpA  
Tel.: +39 02 346181

**България / Česká republika / Eesti / Ελλάδα /  
España / Κύπρος / Latvija / Lietuva /  
Magyarország / Malta / Nederland / România /  
Slovenija / Slovenská republika**

#### **Ireland / United Kingdom**

Almirall Limited  
Tel.: 0800 0087399

Almirall, S.A.  
Тел/Тел/Τηλ/Τηλ/Σίμι: +34 93 291 30 00

**Deutschland**  
**Luxembourg/Luxemburg**  
Almirall Hermal GmbH  
Tel./ Tél: +49 (0)40 72704-0

**Österreich**  
Almirall GmbH  
Tel.: +43 01/595 39 60

**Danmark / Ísland / Norge / Suomi/Finland /  
Sverige**  
Almirall ApS  
Tel./Puh.: +45 33 37 72 08

**Polska**  
Almirall Sp. z o.o.  
Tel.: +48 22 330 02 57

**France**  
Almirall SAS  
Tél.: +33(0)1 46 46 19 20

**Portugal**  
Almirall - Produtos Farmacêuticos, Lda.  
Tel.: +351 21 415 57 50

**This leaflet was last approved on 4<sup>th</sup> March 2011**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>