

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

**Vaniqa Cream 11.5% w/w**

**Active ingredient: eflornithine 11.5% w/w (as hydrochloride monohydrate)**

Inactive ingredients and allergens in the medicine - See section 2 "**Important information about some of this medicine's ingredients**" and section 6 "**Additional information**".

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**1. What is this medicine intended for?**

Vaniqa is indicated for reduction of excessive facial hair growth (hirsutism) in women.

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

**Therapeutic group:** ornithine decarboxylase enzyme inhibitor.

**2. Before using this medicine**

**Do not use this medicine if:**

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| <ul style="list-style-type: none"><li>• You are sensitive (allergic) to eflornithine or to any of the other ingredients in this medicine (see section 6).</li><li>• You are pregnant or breastfeeding</li></ul> |
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**Special warnings about using this medicine**

**Before using Vaniqa, tell your doctor or pharmacist if:**

- You suffer from other medical problems (particularly those related to kidneys or liver)
- You suffer from polycystic ovary syndrome (PCOS)
- You suffer from specific hormone producing tumors
- You take medicines that can accelerate hair growth, e.g.:
  - cyclosporine (for prevention of transplant rejection)
  - glucocorticoids (for treatment of joint disease or allergies)
  - minoxidil (for treatment of hypertension)
  - phenobarbitone, phenytoin (for treatment of epilepsy)
  - hormone replacement therapy with male hormone like effects.

If you are unsure whether to use this medicine, contact your doctor or pharmacist.

**Children and adolescents**

Vaniqa is not intended for use in children and adolescents below the age of 18 years.

There is no information about the safety and efficacy of using this medicine in children and adolescents.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you:**

- Use other medicines on the same skin area where the cream is applied.

### **Pregnancy and breastfeeding**

Do not use Vaniqa if you are pregnant or breastfeeding.

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 affect the ability to drive or operate machines.

### **Important information about some of this medicine's ingredients**

Vaniqa contains cetostearyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis). Vaniqa also contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

### **3. How to use this medicine?**

Always use Vaniqa according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to use this medicine.

Only your doctor will determine your dose and how you should use this medicine.

The recommended dose is usually: twice a day, at least 8 hours apart.

- If you develop irritation (e.g. stinging or burning), reduce the use of Vaniqa to once daily until the effect resolves. If the irritation 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 apply the cream on cut or irritated skin.
- Clean and dry the skin area where you will apply the cream.
- Apply a thin layer of cream and rub it in thoroughly until it is no longer visible on the treated area.
- If possible, do not wash these areas 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 the eyes, mouth or inside the nose. If you accidentally get Vaniqa into the eyes, mouth or nose, rinse well with water

### **Do not exceed the recommended dose.**

Vaniqa is not a depilatory cream. You may need to continue with hair removal by shaving or plucking.

### **Treatment duration:**

It may take 8 weeks before results are visible. It is important to continue treatment with the cream. If you do not see any improvement after using it for 4 months, contact your doctor. If you stop using the medicine, hair regrowth will occur within 8 weeks.

**If you have accidentally used a higher dose**, it is unlikely to harm you.

If you or a child have/has accidentally swallowed some medicine, **immediately see a doctor** or go to a hospital emergency room and bring the medicine package with you.

**If you forget to use the medicine**, apply immediately and wait at least 8 hours until the next use. Adhere to the treatment as recommended by your doctor. Even if your

health improves, do not stop treatment with the medicine without consulting your doctor.

**If you stop using the medicine**

To maintain the reduction of hair growth, keep using Vaniqa continuously as recommended by your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

**4. Side effects**

Like with all medicines, using Vaniqa may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Side effects are usually limited to the skin and are mild in intensity. In such cases, they resolve without the need to discontinue treatment with Vaniqa.

**Very common side effects** (affect more than one in ten users):

- acne

**Common side effects** (affect 1-10 in 100 users):

- dry skin
- hair loss
- inflammation around the hair follicle
- itching
- rash
- redness
- skin irritation and bumps caused by shaving
- skin irritation
- stinging or burning sensation on the skin

**Uncommon side effects** (affect 1-10 in 1000 users):

- bumpy rash
- cold sores
- redness and irritation at the site where the cream is applied
- eczema
- inflamed, dry, cracked or numb lips
- ingrowing hairs
- light 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 side effects** (affect 1-10 in 10,000 users):

- abnormal skin growth (malignancy)
- excessive hair growth

- flushing, facial redness and pimples, sometimes with pus
- other skin diseases
- red, scaly and itchy skin inflammation (seborrhoeic dermatitis)
- red, bumpy or blistering rash
- skin cysts
- skin tightness

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

### **Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

### **5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Close the tube cap tightly after each use.
- **Storage conditions:** Store below 25°C.
- The medicine may be used within 6 months after first opening.
- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to dispose of the medicine. This will help to protect the environment.

### **6. Additional information**

**In addition to the active ingredient, this medicine also contains:**

Purified water, glyceryl stearate and PEG 100 stearate, cetostearyl alcohol, macrogol cetostearyl ether, liquid paraffin, stearyl alcohol, dimethicone, phenoxyethanol, methyl parahydroxybenzoate, propyl parahydroxybenzoate and sodium hydroxide.

#### **What the medicine looks like and contents of the pack:**

Vaniqa is a white - off white cream.

The medicine is available in tubes of 30 g and 60 g. Not all pack sizes may be marketed.

**Registration holder's name and address:** Medison Pharma Ltd., 10 Hashiloach St., P.O.B. 7090, Petach Tikva.

**Manufacturer's name and address:** Almirall S.A.  
Ronda General Mitre, 15108022 Barcelona, Spain

Revised in June 2022 according to the MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 136-36-30246-11