

Package leaflet: information for the user

Vaniqa 11.5% Cream
(Eflornithine)

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Are you experiencing a lot of side effects? Then contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. See section 4

Contents of this leaflet:

1. What is Vaniqa and what is this medicine used for?
2. When should you not use this medicine or be extra careful with it?
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1. What is Vaniqa and what is this medicine used for?

Vaniqa contains the active ingredient eflornithine. Eflornithine slows hair growth by inhibiting a specific enzyme (a protein in the body) that plays a role in hair production.

Vaniqa is used to reduce excessive hair growth (hirsutism) on the face of women over 18 years old.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

inform your doctor about any other medical problems (especially a condition affecting your kidneys or liver).

if you are unsure whether or not to use this medicine, contact your doctor or pharmacist for advice.

Excessive hair growth may be the result of a disease or treatment with certain medications. Consult your doctor if you have polycystic ovary syndrome (PCOS) or specific hormone-producing tumors, or if you are using medications that can promote hair growth, such as cyclosporine (after an organ transplant), glucocorticoids (e.g., for rheumatic or allergic

conditions), minoxidil (for high blood pressure), phenobarbital (for epileptic seizures), phenytoin (for epileptic seizures), or hormone replacement therapy with male hormone-like effects.

Children and adolescents under 18 years

Vaniqa is not recommended for use in individuals under 18 years of age.

Are you using any other medicines?

Do you use any other medicines besides Vaniqa, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

If you are also using other medicines on the areas where you apply the cream, discuss this with your doctor.

Pregnancy and breastfeeding

Do you want to become pregnant, are you pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using any medicines.

Do not use this medicine if you are pregnant or breastfeeding. You should use another method to treat facial hair if you are pregnant or trying to become pregnant.

Driving and using machines

Vaniqa is not expected to affect your ability to drive or use machines.

Vaniqa contains cetostearyl alcohol and stearyl alcohol. These substances can cause local skin reactions (e.g., contact dermatitis). Vaniqa also contains methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The usual dosage is:

Use twice daily with an interval of at least 8 hours.

If you experience irritation (e.g., stinging or burning), reduce the use of Vaniqa to once a day until the irritation disappears. If the irritation persists, contact your doctor.

If you have just shaved or used any other hair removal method, wait at least five minutes before applying Vaniqa. It may sting or burn if you apply this cream to abraded or irritated skin.

Clean and dry the skin where you will use the cream first.

Apply a thin layer of cream and rub it in well until no residue is visible on the treated skin.

If possible, do not wash the skin for at least 4 hours after applying the cream.

Wash your hands after applying the cream.

Wait at least 5 minutes before applying makeup or sunscreen.

When using on the face, do not touch your eyes or the inside of your nose or mouth. If you get Vaniqa in your eyes, mouth, or nose by accident, rinse it thoroughly with water.

Vaniqa is not a depilatory cream; you must continue using your hair removal method, such as shaving or epilating.

It may take 8 weeks before you see any improvement. It is important that you continue using the cream. If you do not see improvement after 4 months of use, consult your doctor. If you stop using the cream, your original hair growth may return within 8 weeks.

Have you used too much of this medicine?

If you have applied too much cream to your skin, it is unlikely that you will experience any adverse effects.

If you, or someone else, accidentally swallowed some Vaniqa, consult your doctor immediately.

Have you forgotten to use this medicine?

Apply the cream immediately. Wait at least 8 hours before applying the cream again.

If you stop using this medicine

To maintain the reduction in hair growth, continue using Vaniqa as prescribed.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

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

Side effects are usually limited to the skin and are mild in intensity. In these cases, they usually disappear on their own after discontinuation of Vaniqa.

The frequency of possible side effects, listed below, is defined according to the following convention:

Very common	(occurs in less than 1 in 10 users)
Common	(occurs in 1 to 10 out of 100 users)
Sometimes	(occurs in 1 to 10 out of 1,000 users)
Rarely	(occurs in 1 to 10 out of 10,000 users)
Very rarely	(occurs in less than 1 out of 10,000 users)
Unknown	(Frequency cannot be estimated from the available data)

Very often (occurs in less than 1 out of 10 users)

o acne

Often (occurs in 1 to 10 out of 100 users)

- o dry skin
- o hair loss
- o inflammation around the hair follicle
- o itching
- o skin rash
- o redness
- o skin irritation and bumps from shaving
- o skin irritation
- o biting, tingling or burning sensation on the skin

Sometimes (occurs in 1 to 10 out of 1,000 users)

- o bumpy rash (papular rash) cold sore
- o redness and irritation at the site
- o where the cream is applied eczema
- o inflamed, dry, cracked or numb lips
- o inflamed, dry, cracked, or numb lips
- o ingrown hairs
- o pale spots on the skin
- o bleeding skin
- o boils
- o redness of the skin
- o inflamed skin
- o painful skin
- o swelling of the mouth or face
- o abnormal hair structure or hair growth

Rare (occurs in 1 to 10 out of 10,000 users)

- o abnormal skin growth (skin neoplasms) excessive
- o hair growth flushed face, facial redness, and pimples that
- o may be filled with pus other
- o skin conditions red, scaly, and itchy skin inflammation (seborrheic dermatitis)
- o red,
- o bumpy nodular or blister-forming rash
- o skin cysts
- o tight skin

The reporting of side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V*. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and on the bottom of the tube after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Dispose of the opened tube including any remaining cream 6 months after first opening.

Ensure the screw cap is tightly closed after use.

Store below 25°C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed in a responsible manner and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is eflornithine. Each gram of cream contains 115 mg of eflornithine (as hydrochloride monohydrate). The other substances in this medicine are: cetostearyl alcohol; macrogol cetostearyl ether; dimethicone; glyceryl stearate; macrogol stearate; methyl parahydroxybenzoate (E218); liquid paraffin; phenoxyethanol; propyl parahydroxybenzoate (E216); purified water and stearyl alcohol. Very small amounts of sodium hydroxide (E524) are sometimes added to keep the acidity (pH value) normal.

What does Vaniqa look like and how much is in a package

Vaniqa is a cream with a white to off-white color. The cream is supplied in tubes of 15 g, 30 g, and 60 g. Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

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More information about this medicine is available on the website of the European Medicines Agency <http://www.ema.europa.eu>