

Package leaflet: Information for the user

Vaniqa 11.5% cream Eflornithine

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 symptoms 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 Vaniqa is and what it is used for
2. What you need to know before you use Vaniqa
3. How to use Vaniqa
4. Possible side effects
5. How to store Vaniqa
6. Contents of the pack and other 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 women older than 18 years of age.

2. What you need to know before you use Vaniqa

Do not use Vaniqa:

- if you are allergic to eflornithine or any of the other ingredients of this medicine listed in section 6.

Warnings and precautions

Talk to your doctor or pharmacist 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 and adolescents

Vaniqa is not recommended for use in anyone younger than 18 years of age.

Other medicines and Vaniqa

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

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

3. How to use Vaniqa

Always use this medicine exactly as your doctor has told you. 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, this medicine 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

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 (see details below)

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Vaniqa

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 box and on the bottom of the tube after EXP. The expiry date refers to the last day of that month.

Discard the opened tube with any remaining cream after 6 months.

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

Do not store above 25°C.

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 Vaniqa contains

The active substance 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.

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Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>