

VANIQA[®]

eflornithine

Consumer Medicine Information

WHAT IS IN THIS LEAFLET?

Read this leaflet carefully before using Vaniqa. This leaflet answers some common questions about Vaniqa. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Vaniqa against the benefits they expect it will have for you. **If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

WHAT IS VANIQA USED FOR?

Vaniqa is used to delay the regrowth of unwanted facial hair in women.

Vaniqa interferes with an enzyme found in the hair follicle of the skin needed for hair growth. This results in slower hair growth and shorter or fewer hairs where Vaniqa is applied.

Vaniqa does not permanently remove hair or "cure" unwanted facial hair. It is not a depilatory. Your treatment program should include continuation of any hair removal techniques you are currently using. Vaniqa will help you manage your condition.

Reduction of hair growth occurs gradually. Don't be discouraged if you see no immediate improvement. Improvement may be seen as early as after 4 to 8 weeks of treatment. Improvement may take longer in some people. If no improvement is seen after 6 months of use, stop using Vaniqa. Clinical studies show that in about 8 weeks after stopping treatment with Vaniqa, the hair will return to the same condition as before beginning treatment.

BEFORE YOU USE VANIQA

When you must not use it

Do not use Vaniqa if you have an allergy to Vaniqa or any of the ingredients listed at the end of this leaflet.

Do not use Vaniqa if you have severe renal impairment, which is a serious form of kidney disease. Talk to your doctor if you think this may apply to you.

Do not use Vaniqa on a child under 12 years, unless directed by the child's doctor.

The safety and effectiveness of Vaniqa in children less than 12 years have not been established.

Do not use Vaniqa after the expiry date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not use Vaniqa if the packaging is torn or shows signs of tampering, or if the cream does not look quite right.

If you are not sure whether you should start using Vaniqa, talk to your doctor or pharmacist.

Before you start to use Vaniqa

Tell your doctor if you have kidney problems. Your doctor will decide if you are able to safely use Vaniqa.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant. Like many medicines, Vaniqa is not recommended for use during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed. Your doctor or pharmacist will discuss the possible risks and benefits of using Vaniqa during breast-feeding.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with each other. Your doctor will advise you.

How to use Vaniqa

You will need to continue your normal procedures for hair removal until desired results have been achieved. You may then be less bothered by the time spent in removing hair or the frequency of hair removal. Vaniqa should be used twice daily, at least eight hours apart, or as directed by your doctor. Vaniqa is for external use only.

Follow the instructions for application of Vaniqa carefully. Apply a thin layer of Vaniqa to the affected areas of the face and adjacent involved areas under the chin and rub in thoroughly. You should not wash the treatment areas for at least 4 hours after application of Vaniqa.

Vaniqa may cause temporary redness, rash, burning, stinging or tingling, especially if the skin is damaged.

If irritation continues, stop use of Vaniqa and contact your doctor. Avoid getting the medication in your eyes or inside your nose or mouth. If the product gets in your eyes, rinse thoroughly with water and contact your doctor.

You may use your normal cosmetics or sunscreen after applying Vaniqa, but you should wait a few minutes to allow the treatment to be absorbed before applying them.

If your condition gets worse with treatment, stop use of Vaniqa and contact your doctor.

When to use it

Apply Vaniqa twice a day, at least 8 hours apart or as directed by your doctor or pharmacist.

Use Vaniqa at about the same time each day. This will help you to remember when to use it.

If you forget to use Vaniqa

If you forget or miss a dose of Vaniqa do not try to "make it up". Return to your normal application schedule as soon as you can.

How long to use it

Vaniqa does not permanently remove hair or "cure" unwanted facial hair. It is not a depilatory. Vaniqa should be used twice daily. Continue using Vaniqa for as long as your doctor or pharmacist tells you.

Hair growth may return to pretreatment levels 8 weeks after you stop using Vaniqa.

If someone swallows Vaniqa

Telephone your doctor or the Poisons Information Centre if anyone swallows Vaniqa. In Australia call 131126 in New Zealand call 0800 764 766

WHILE YOU ARE USING VANIQA

Things you must do

Only apply Vaniqa to the face and adjacent involved areas under the chin. Vaniqa is for external use only.

If you become pregnant while using Vaniqa, tell your doctor or pharmacist.

Things you must not do

Do not give Vaniqa to anyone else, even if they have the same condition as you.

Do not use Vaniqa to treat any other complaints unless your doctor or pharmacist tells you to.

SIDE EFFECTS

All medications, including Vaniqa, can sometimes cause unwanted side effects. Side effects are generally mild, but may include:

- temporary redness
- stinging
- burning

- tingling
- rash
- folliculitis (hair bumps)

If these persist consult your doctor.

AFTER USING VANIQA

Storage

Keep Vaniqa in a cool dry place where the temperature stays below 25°C. Do not freeze.

Do not leave it on a window sill or in a car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Vaniqa or it has passed the expiry date, ask your pharmacist what to do with any that is left over.

PRODUCT DESCRIPTION

What it looks like

Vaniqa is a smooth, white to off-white cream.

Ingredients

Active ingredient:

Vaniqa contains 11.5% eflornithine.

Other ingredients:

Vaniqa also contains cetareth-20, cetostearyl alcohol, dimethicone 200, glyceryl monostearate, methyl hydroxybenzoate, paraffin – light liquid, PEG-100 stearate, phenoxyethanol, propyl hydroxybenzoate, stearyl alcohol, water and sodium hydroxide.

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 **Almirall**