

Information for the Patient

VANIQA®

(eflornithine hydrochloride) Cream 13.9 %

Your doctor has prescribed VANIQA® cream for you. Please read this before you apply your medication. This leaflet gives a summary of information about your medication. If you want to know more, or have any questions, ask your doctor or pharmacist, or call 1800-363-2862.

INFORMATION FOR THE PATIENT

What is VANIQA®?

VANIQA® (pronounced "VAN-i-ka") is a prescription medication applied to the skin for the treatment of unwanted facial hair in women.

The active ingredient in VANIQA® is eflornithine hydrochloride. VANIQA® also contains water, glyceryl stearate, PEG-100 stearate, cetearyl alcohol, cetareth-20, mineral oil, stearyl alcohol, dimethicone, phenoxyethanol, methylparaben and propylparaben.

How does VANIQA® work?

VANIQA® interferes with a natural component of the skin needed for hair growth. This results in slower hair growth and improved appearance 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 technique you are currently using. VANIQA® will help you manage your condition and improve your appearance.

Improvement in the condition occurs gradually. Don't be discouraged if you see no immediate improvement. Be patient. While many people see improvement after 4 to 8 weeks of treatment, improvement may take longer in some individuals. Improvement should increase with continued use for up to 6 months. If no improvement is seen after 6 months of use, discontinue use. Clinical studies show that about 8 weeks after stopping treatment with VANIQA®, the hair will return to the same condition as before beginning treatment.

Who should not use VANIQA®?

You should not use VANIQA® if you are allergic to any of the ingredients in the cream. All ingredients are listed on the tube and at the beginning of this leaflet.

What should you tell your doctor before using VANIQA®?

If you are allergic to any of the ingredients, tell your doctor.

If you are pregnant or plan to become pregnant, discuss with your doctor whether you should use VANIQA® during pregnancy. No clinical studies have been performed in pregnant women.

If you are breast feeding, consult your doctor before using VANIQA®. It is not known if VANIQA® is passed to infants through breast milk.

If you are taking any prescription medicines, non-prescription medicines or using any facial or skin creams, check with your physician before use of VANIQA®.

How should I use VANIQA®?

Use VANIQA® only for the condition for which it was prescribed by your doctor. Do not give it to other people or allow other people to use it.

You will need to continue your normal procedures for hair removal. Once desired results have been achieved, you may be able to reduce the time spent in removing hair or the frequency of hair removal. VANIQA® is to be used twice daily, at least eight hours apart, or as directed by your doctor. It is a drug for external use only and is not a cosmetic preparation.

Follow the instructions for application of VANIQA® carefully. Apply a thin layer of VANIQA® Cream to the affected areas of the face and/or neck 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 when 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.

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.

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.

What are the possible side effects of VANIQA®?

VANIQA® may cause temporary redness, stinging, burning, tingling or rash on areas of the skin where it is applied. If these persist, consult your doctor.

How should VANIQA® be stored?

VANIQA® should be stored between 15 and 25°C.

Keep this and all medicines out of the reach of children.

This medicine was prescribed for your particular condition. Do not use it for another condition or give it to anyone else.

This summary does not include everything there is to know about VANIQA® Cream. Medicines are sometimes prescribed for purposes other than those given in this leaflet. If you have questions or concerns, or want more information about VANIQA®, your doctor and pharmacist have the complete prescribing information upon which this leaflet is based. You may want to read it and discuss it with your doctor or pharmacist. Remember, no written summary can replace careful discussion with your doctor or pharmacist.

Vaniqua® (eflornithine hydrochloride) Cream 13.9 % is marketed and distributed by

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If you have any further questions contact your doctor or pharmacist or call 1-866-429-9707.

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