

VANIQA[®]

(eflornithine hydrochloride) Cream, 13.9%

INFORMATION FOR PATIENTS

This section contains important information about VANIQA that you should read before you begin treatment. This section does not list all the benefits and risks of VANIQA and does not take the place of discussions with your doctor or healthcare professional about your condition or your treatment. If you have questions, talk with your healthcare professional. The medicine described here can only be prescribed by a licensed healthcare professional. Only your healthcare professional can determine if VANIQA is right for you.

What is VANIQA?

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

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

How does VANIQA work?

VANIQA interferes with an enzyme found in the hair follicle 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. Improvement may be seen as early as 4 to 8 weeks of treatment. Improvement may take longer in some individuals. If no improvement is seen after 6 months of use, discontinue use. 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.

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.

You should not use VANIQA if you are less than 12 years of age.

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 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 is to 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.

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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. Folliculitis (hair bumps) may also occur. If these persist, consult your doctor.

How should VANIQA be stored?

VANIQA should be stored at 15° C-30° C (59° F-86° F). Do not freeze.

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. If you have questions or concerns, or want more information about VANIQA, your doctor or pharmacist has the complete prescribing information upon which this leaflet is based. You may want to read it and discuss it with your doctor or healthcare professional. Remember, no written summary can replace careful discussion with your doctor.

Rx only



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