



EFLORNITHINE 13.9% CREAM

(eflornithine hydrochloride) Cream 13.9 %

PHARMACOLOGICAL CLASSIFICATION

Hair Growth Inhibitor



Prescribing Summary



Patient Selection Criteria

INDICATIONS AND CLINICAL USE: VANIQA® is indicated for slowing of the growth of unwanted facial hair in women. It is recommended as an adjunct to any hair removal technique.

VANIQA® Cream has only been studied on the face and neck of affected women. Usage should be limited to those areas.

CONTRAINDICATIONS: Hypersensitivity to eflornithine or to any of the excipients of VANIQA®.



Safety Information

PRECAUTIONS: VANIQA® is for topical use only. Avoid contact with eyes or mucous membranes (e.g., nose or mouth). Discontinue use if hypersensitivity occurs. If skin irritation or intolerance develops, the patient should be directed to temporarily reduce the frequency of application to once per day. If irritation continues, the patient should discontinue use of VANIQA® and consult their physician. Transient stinging or burning may occur when applied to abraded or broken skin.

ADVERSE REACTION SERIOUSNESS AND INCIDENCE: Adverse reactions reported for most body systems occurred at similar frequencies in active and vehicle groups. The most frequent adverse reactions related to treatment with VANIQA® Cream were skin related: acne (21.3%), pseudofolliculitis barbae (16.2%), burning, stinging, tingling (14.2%), pruritus (3.8%), dry skin (1.8%), alopecia (1.5%), erythema (1.3%), skin irritation (1.3%), dermatitis (1.0%) and rash (1.0%).

Adverse reactions were primarily mild in intensity and generally resolved without medical treatment or discontinuation of VANIQA® Cream. No serious adverse reactions were related to treatment.

To report a suspected adverse reaction, please contact Triton Pharma Inc.

Toll Free: 1-866-429-9707

By regular mail: Triton Pharma Inc. 1001 de Maisonneuve Blvd West Suite 455 Montreal, Quebec H3A 3C8



Administration

Apply a thin layer of VANIQA® Cream to affected areas of the face and neck and rub in thoroughly. The treated area should not be washed for at least 4 hours after application. VANIQA® should be used twice daily at least 8 hours apart. The product may be used alone or in conjunction with other hair

removal techniques. VANIQA® may be applied 5 minutes after shaving or other hair removal techniques. Cosmetics or sunscreens may be applied over treated areas after cream has dried.



Study References

References: VANIQA® Product Monograph, Triton Pharma Inc., November 30, 2009

Product Monograph available on request.



665 Milway Avenue, Suite 31B
Concord, Ontario L4K 3T8

Tel: 1-866-429-9707

www.tritonpharma.ca



Supplemental Product Information

PRECAUTIONS

Use in the elderly: Of the total number of patients in clinical trials with VANIQA® (n = 1370), approximately 6% were 65 years or older, while approximately 1% were 75 years or older. No overall differences in safety were observed between older and younger patients.

Use in children: The safety and effectiveness of this product in pediatric patients have not been established.

Adolescents: The safety and efficacy of this product in adolescent patients has not been established.

Nursing mothers: It is not known whether or not eflornithine hydrochloride is excreted in human milk. Caution should be exercised when VANIQA® cream is administered to a nursing woman.

Use in pregnancy: There are no well-controlled studies of VANIQA® Cream in pregnant women. Therefore, VANIQA® should be used during pregnancy only if the physician considers the potential benefits to outweigh the potential risks to the fetus.

Hepatic and Renal Impairment: Safety and efficacy of VANIQA® Cream in patients with hepatic or renal impairment have not been established. Considering the low systemic exposure after topical application, problems would not be expected.

Drug interaction: None known

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Dermal Administration

Given the minimal cutaneous penetration of this drug, overdosage via the topical route is not expected (see clinical pharmacology). However, should very high topical doses (e.g. multiple tubes per day) or oral ingestion be encountered (e.g., a 60 g tube contains 9 g of eflornithine HCl), the patient should be monitored, and appropriate supportive measures administered as necessary.

Intravenous Administration

Adverse effects and laboratory abnormalities have been noted with intravenous administration of high doses of eflornithine hydrochloride (400 mg/kg/day or approximately 24 g/day) for the treatment of *Trypanosoma brucei gambiense* infection (African sleeping sickness). Adverse events have included hair loss, facial swelling, seizures, hearing impairment, stomach upset, loss of appetite, headache, weakness and dizziness. A variety of hematological toxicities, including anemia, thrombocytopenia and leukopenia have also been observed, but these were usually reversible upon discontinuation of treatment.

Dosage forms, composition and packaging

VANIQA® Cream is available in 30 g plastic tube. VANIQA® is formulated as a smooth white to off-white, fragrance-free cream containing 13.9% (139 mg/g) of anhydrous eflornithine hydrochloride.