

Cream
Loriqua

لوریتقا کریم
(مٹلاو مٹھین ہائیڈروکلورائیڈ)

(Eflornithine hydrochloride)

COMPOSITION:

Each gram contains:
Eflornithine hydrochloride
(as monohydrate)139mg
(Innovator's specifications)

DESCRIPTION:

LORIQa is a cream containing 13.9% w/w (139 mg/g) of anhydrous Eflornithine hydrochloride as Eflornithine hydrochloride monohydrate. It is used topically to reduce unwanted facial hair growth in women. The postulated mechanism of action is through irreversible inhibition of ornithine decarboxylase (ODC) in the skin.

MECHANISM OF ACTION:

Eflornithine irreversibly inhibits ornithine decarboxylase, an enzyme involved in the production of the hair shaft by the hair follicle. It has been shown to reduce the rate of hair growth.

INDICATIONS:

LORIQa is indicated:
For the reduction of unwanted facial hair in women. It has only been studied on the face and adjacent involved areas under the chin of affected individuals. Usage should be limited to these areas of involvement.

DOSAGE & ADMINISTRATION:

Apply a thin layer of LORIQa to affected areas of the face and adjacent involved areas under the chin and rub in thoroughly. Do not wash treated area for at least 4 hours. Use twice daily at least 8 hours apart or as directed by a physician. The patient should continue to use hair removal techniques as needed in conjunction with LORIQa. LORIQa should be applied at least 5 minutes after hair removal. Cosmetics or sunscreens may be applied over treated areas after cream has dried.

PHARMACOKINETICS:

The mean percutaneous absorption of eflornithine in women with unwanted facial hair, from a 13.9% w/w cream formulation, is < 1% of the radioactive dose, following either single or multiple doses under conditions of clinical use, that included shaving within 2 hr before radiolabeled dose application in addition to other forms of cutting or plucking and tweezing to remove facial hair. Steady state was reached within four days of twice-daily application. The apparent steady-state plasma $t_{1/2}$ of eflornithine was approximately 8 hours. Following twice daily application of 0.5 g of the cream (total dose 1.0 g/day; 139 mg as anhydrous eflornithine hydrochloride), under conditions of clinical use in women with unwanted facial hair (n=10), the steady-state C_{max} , C_{trough} and AUC_{12hr} were approximately 10 ng/mL, 5 ng/mL, and 92 ng hr/mL, respectively, expressed in terms of the anhydrous free base of eflornithine hydrochloride. At steady state, the dose-normalized peak concentrations (C_{max}) and the extent of daily systemic exposure (AUC) of eflornithine following twice-daily application of 0.5 g of the cream (total dose 1.0 g/day) is estimated to be approximately 100- and 60-fold lower, respectively, when compared to 370 mg/day once-daily oral doses. This compound is not known to be metabolized and is primarily excreted unchanged in the urine.

WARNINGS:

Discontinue use if hypersensitivity occurs.

PRECAUTIONS:

General

For external use only.

Transient stinging or burning may occur when applied to abraded or broken skin.

Information for Patients:

Patients using LORIQa should receive the following information and instructions:

1. This medication is not a depilatory, but rather appears to retard hair growth to improve the condition and the patient's appearance. Patients will likely need to continue using a hair removal method (e.g., shaving, plucking, etc.) in conjunction with LORIQa.

2. Onset of improvement was seen after as little as 4-8 weeks of treatment in the 24-week clinical trials. The condition may return to pretreatment levels 8 weeks after discontinuing treatment.
3. If skin irritation or intolerance develops, direct the patient to temporarily reduce the frequency of application (e.g., once a day). If irritation continues, the patient should discontinue use of the product.

PREGNANCY:

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women, the risk/benefit ratio of using LORIQa in women with unwanted facial hair who are pregnant should be weighed carefully with serious consideration for either not implementing or discontinuing use of LORIQa.

Nursing Mothers:

It is not known whether or not eflornithine hydrochloride is excreted in human milk. Caution should be exercised when LORIQa is administered to a nursing woman.

SIDE EFFECTS:

Very common

(≥1/10) Acne

Common (?1/100 to <1/10) Pseudo folliculitis barbae, alopecia, stinging skin, burning skin, dry skin, pruritus, erythema, tingling skin, irritated skin, rash, folliculitis Uncommon (≥1/1,000 to <1/100) Ingrown hair, edema face, dermatitis, edema mouth, papular rash, bleeding skin, herpes simplex, eczema, cheilitis, furunculosis, contact dermatitis, abnormal hair texture and abnormal hair growth, hypopigmentation, flushing skin, lip numbness, skin soreness

Rare

(≥1/10,000 to <1/1,000) Rosacea, seborrheic dermatitis, skin neoplasm, maculopapular rash, skin cysts, vesiculobullous rash, skin disorder, hirsutism, skin tightness.

CONTRAINDICATIONS:

LORIQa is contraindicated in patients with a history of sensitivity to any components of the preparation.

STORAGE & INSTRUCTIONS:

Store between 15-30°C. Do not refrigerate or freeze.
Protect from heat, sunlight and moisture. Keep away from the reach of the children.
To be sold on the prescription of a registered medical practitioner only.
FOR EXTERNAL USE ONLY.

HOW SUPPLIED

LORIQa Cream: 15g tube.

خوراک و ہدایات:

متناہ حصے پر دن میں دو بار لگائیں یا ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔ دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درج حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی اور نمند ہونے سے بچائیں۔ ریفریجریٹر میں نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف منہ ڈاکٹر کے نسخے پر فروخت کریں صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

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Lahore, Pakistan