PRESCRIBING INFORMATION

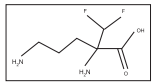
Vanifall CREAM 13.9%

(Eflornithine Hydrochloride)

13.9% کریم

COMPOSITION:
Each gram contains:
Eflornithine Hydrochloride (as Eflornithine Hydrochloride Monohydrate).....139 mg
(As per Innovator's Specification)

DESCRIPTION:
Vanifall (Eflornithine Hydrochloride) Cream 13.9% is chemically, eflornithine hydrochloride is (±) -2- (difluoromethyl) ornithine monohydrochloride monohydrate.



Vanifall (Eflornithine Hydrochloride) Cream 13.9% is used to reduce unwanted facial hair in women. It does not permanently remove hair or "cure" unwanted facial hair. However it will help you manage your condition and improve your appearance.

Pharmacology:
Pharmacodynamics
There are no studies examining the inhibition of the enzyme ornithine decarboxylase (ODC) in human skin following the application of topical eflornithine. However, there are studies in the literature that report the inhibition of ODC activity in skin following oral eflornithine. It is postulated that topical eflornithine hydrochloride irreversibly inhibits skin ODC activity. This enzyme is necessary in the synthesis of polyamines. Animal data indicate that inhibition of ornithine decarboxylase inhibits cell division and synthetic functions, which affect the rate of hair growth. Vanifall (Eflornithine Hydrochloride) Cream 13.9% has been shown to retard the rate of hair growth in non-clinical and clinical studies.

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 hours before radio labeled 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 t½ 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 Cmax, 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 (Cmax) 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, 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.

INDICATIONS:
Vanifall (Eflornithine Hydrochloride) Cream 13.9%, is indicated for the reduction of unwanted facial hair in women. Vanifall (Eflornithine Hydrochloride) Cream 13.9% 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 AND APPLICATION:
Apply a thin layer of Vanifall (Eflornithine Hydrochloride) Cream 13.9% 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 Vanifall (Eflornithine Hydrochloride) Cream 13.9%. Vanifall (Eflornithine Hydrochloride) Cream 13.9% should be applied at least 5 minutes after hair removal. Cosmetics or sunscreens may be applied over treated areas after cream has dried.

CONTRAINDICATIONS:
Vanifall (Eflornithine Hydrochloride) Cream 13.9% is contraindicated in patients with a history of sensitivity to any components of the preparation.

SIDE EFFECTS:
Vanifall (Eflornithine Hydrochloride) Cream 13.9% is very well tolerated and exhibit side effects in less than 1% of the subjects. Side effects are primarily mild in intensity and generally resolved without medical treatment or discontinuation of Vanifall (Eflornithine Hydrochloride) Cream 13.9%. Vanifall cream when applied topically may cause temporary redness, rash, burning, stinging, or tingling, especially if it is applied to broken or irritated skin. If irritation develops, reduce the application of Eflornithine topical to once a day. If irritation continues, stop using Eflornithine topical and contact your doctor. Hair bumps (folliculitis) may also occur. If these continue, contact your doctor. Side effects other than those listed here may also occur such as bleeding skin, cheilitis, contact dermatitis, swelling of lips, herpes simplex, numbness and rosacea if these appear contact your physician.

PRECAUTIONS:
Before using Vanifall (Eflornithine Hydrochloride) Cream 13.9%, tell your doctor or pharmacist if you are allergic to Eflornithine or if you have any other allergies. This product may contain inactive ingredients (such as methylparaben), which can cause allergic reactions or other problems. Transient stinging or burning may occur when applied to abraded or broken skin. During pregnancy, this medication should be used only when clearly needed.
It is also not known whether this drug passes into breast milk. Discuss the risks and benefits with your doctor use of Vanifall (Eflornithine Hydrochloride) Cream 13.9% in pregnancy and lactation.

USE IN SPECIAL SITUATIONS:
Pregnancy: Category C.
Lactation: Not known whether Eflornithine is distributed into milk, caution if used in nursing women.
Paediatric Use: Safety and efficacy not established in children <12 years of age.
Geriatric Use: No apparent differences in safety were observed between older patients and younger patients

INTERACTIONS:
It is not known if Vanifall (Eflornithine Hydrochloride) Cream 13.9% has any interaction with other topically applied drug products.

STORAGE:
Store at temperature 15 to 30 °C away from light

PRESENTATION:
Vanifall (Eflornithine Hydrochloride) Cream 13.9% is available in 15g Aluminium tube.

مقدار اور طریقہ استعمال:
چہرے کے متاثرہ حصوں اور اسکے ارد گرد کے حصوں، ٹھوڑی کے نچلے حصوں پر ہلکی جھلی کی طرح لگائیں۔ کریم لگانے کے بعد 4 گھنٹے تک منہ نہیں دھوئیں۔ کریم کو دن میں دو بار استعمال کریں۔ اگر چہرے کے بالوں کو صاف کرنے کے لیے کوئی اور طریقہ استعمال کر رہے ہوں تو وہ جاری رکھیں۔ بال صاف کرنے کے پانچ منٹ بعد کریم کو لگانا چاہیے۔ کریم کے خشک ہونے کے بعد کاسمیٹکس یا سن سکرین لوشن وغیرہ استعمال کئے جاسکتے ہیں۔

اسٹوریج:
15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیے۔

brookes

Manufactured by:

Brookes Pharma Private Limited
58 - 59 Sector 15 Korangi Industrial Area
Karachi 74900 Pakistan.

ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification

1309-00177-1001