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Treatments for Unwanted Facial Hair

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ABSTRACT

Twenty-two percent of women in North America have unwanted facial hair, which can cause embarrassment and result in a significant emotional burden. Treatment options include plucking, waxing (including the sugar forms), depilatories, bleaching, shaving, electrolysis, laser, intense pulsed light (IPL), and eflornithine 13.9% cream (Vaniqa[®], Barrier Therapeutics in Canada and Shire Pharmaceuticals elsewhere). Eflornithine 13.9% cream is a topical treatment that does not remove the hairs, but acts to reduce the rate of growth and appears to be effective for unwanted facial hair on the mustache and chin area. Eflornithine 13.9% cream can be used in combination with other treatments such as lasers and IPL to give the patient the best chance for successful hair removal.

Key Words: eflornithine, unwanted facial hair, hair removal

Unwanted facial hair (UFH) in women is a common problem, and is most often a result of ethnic background or heredity. In a small percentage of women, it may be caused by androgen overproduction, increased sensitivity to circulating androgens, or other metabolic and endocrine disorders. Approximately 22% of women are affected by the presence of UFH growth on the mustache and chin area, and this can be a source of distress, leading to anxiety, depression and a reduced quality of life.¹

It is very important to determine the underlying causes. Most are ethnic or hereditary; however, one must rule out any signs of androgen excess, e.g., an increase in body hair, irregular menstrual cycles, acne, alopecia, and seborrhea.

Polycystic Ovary Syndrome (PCOS) is the most common cause of androgen excess, and 70%-80% of patients with androgen excess demonstrate hirsutism, though this sign may be less prevalent among women of Asian extraction. There is a strong familial predilection for hirsutism, primarily because the underlying endocrine disorders in this population and the factors regulating the development of hair growth have a strong genetic component.²

Patients should be adequately advised of the available treatment modalities for hair removal. No single method of hair removal is appropriate for all body locations or patients, and the one adopted will depend on the character, area and amount of hair growth, as well as on the patient's age and their personal preference.³

Technique	Body Area	Advantages	Disadvantages
Plucking	<ul style="list-style-type: none"> • Face • Eyebrows • Bikini area 	<ul style="list-style-type: none"> • Inexpensive • Regrowth can take weeks 	<ul style="list-style-type: none"> • Painful • Slow
Waxing	<ul style="list-style-type: none"> • Face • Eyebrows • Groin • Trunk • Extremities 	<ul style="list-style-type: none"> • Regrowth can take weeks 	<ul style="list-style-type: none"> • Painful • Slow • Risk of folliculitis
Depilatories	<ul style="list-style-type: none"> • Extremities • Groin • Face 	<ul style="list-style-type: none"> • Quick 	<ul style="list-style-type: none"> • Can be irritating • Regrowth in days
Shaving	<ul style="list-style-type: none"> • All areas 	<ul style="list-style-type: none"> • Easy • Inexpensive 	<ul style="list-style-type: none"> • Quick regrowth • Risk of folliculitis • Time consuming
Electrolysis	<ul style="list-style-type: none"> • All areas, but usually the face 	<ul style="list-style-type: none"> • May give permanent removal 	<ul style="list-style-type: none"> • Painful • Repeat treatments needed • Very time consuming • Expensive • Risk of scarring and skin pigment changes
Laser and Intense Pulsed Light (IPL)	<ul style="list-style-type: none"> • All areas 	<ul style="list-style-type: none"> • May give permanent hair reduction • Efficient 	<ul style="list-style-type: none"> • Painful • Repeat treatments needed • Dark hair required • Expensive • Risk of scarring and skin pigment changes • Rare reports of paradoxical hypertrichosis⁵
Eflornithine 13.9% cream	<ul style="list-style-type: none"> • Face • Neck 	<ul style="list-style-type: none"> • On stopping, regrowth can take 2 months • Minimal adverse effects • Can be used in conjunction with other treatments 	<ul style="list-style-type: none"> • Must be continued indefinitely to prevent regrowth
Antiandrogens and oral contraceptives	<ul style="list-style-type: none"> • Inhibits androgen driven hair in all areas 		<ul style="list-style-type: none"> • Takes months to show benefit • Some adverse effects • Long-term treatment required

Table 1: Advantages and disadvantages of hair removal techniques

Treatment options for removing excess facial hair are limited and can vary in effectiveness, the degree of discomfort, and cost. Current methods for removing this unwanted hair include such over-the-counter methods as plucking, waxing (including the sugar forms), depilatories, shaving, and home electrolysis. Hair removal methods that could take place in a doctor's office include laser, and intense pulsed light (IPL). An additional modality is a topical cream that inhibits hair growth: eflornithine 13.9% cream (Vaniqa®, Barrier Therapeutics in Canada and Shire Pharmaceuticals elsewhere).¹ These methods are temporary with the time of regrowth ranging from a few days to a few months. For hirsutism associated with PCOS, treatments include oral contraceptives and/or antiandrogens, such as spironolactone, cyproterone acetate, flutamide and finasteride.⁴

Eflornithine HCl 13.9% Cream

Eflornithine HCl 13.9% cream is an irreversible inhibitor of ornithine decarboxylase, an enzyme that has been associated with the prolongation of the anagen or growth phase of the hair.⁶ Consequently, it reduces the rate of hair growth for all hairs. It appears to be effective regardless of whether the unwanted facial hair is hereditary or is due to medical conditions such as an androgen excess disorder, e.g., PCOS. After 24 weeks of treatment in clinical trials, it was shown to be effective on the chin and upper lip.⁷

Eflornithine, also known as difluoromethylornithine or DFMO, was synthesized in the 1970s as a potential anticancer drug. In 1980, Bacchi, et al. reported that this drug was effective in the treatment of African trypanosomiasis in a mouse model,⁸ and this finding

later led to clinical studies in humans. In 1990, the US FDA granted marketing approval and orphan drug status for eflornithine to treat this disease. Clinical observations identified hair loss as a side-effect of eflornithine therapy and led to the development of Vaniqa[®], which gained US regulatory approval in July 2001, as the first and only prescription cream clinically proven to slow the growth of unwanted facial hair in women.⁹

Pharmacokinetics

In an open-label, multiple-dose study of 10 women with excessive facial hair, Malhotra, et al. determined percutaneous absorption and the pharmacokinetics of eflornithine following topical treatment with eflornithine HCl 13.9% cream. The mean percutaneous absorption was minimal and most of what was absorbed was excreted unchanged in the urine without being metabolized by the body. The steady-state peak serum concentration was <10.44ng/ml. Trough plasma concentrations reached steady state (4.61-5.5ng/ml) after 4 days of twice-daily topical treatment. Multiple dosing had no apparent effect on disposition kinetics.¹⁰

Combination Therapy

It is a common misconception that eflornithine 13.9% cream competes with other methods of hair removal and therefore should not be used in combination with them, particularly laser and IPL treatments. However, that is not the case. Eflornithine 13.9% cream can slow hair growth and may reduce the frequency of the need for hair removal by other means.^{11,12} It is also useful in treating hair that is unresponsive to laser therapy, such as white or vellus hairs.

Studies have shown that the two processes can be started simultaneously, and eflornithine treatment can continue right through laser treatments.¹ According to Azziz,² treatment should be undertaken using combination therapy, to possibly include:

1. hormonal suppression, e.g., oral contraceptives, long-acting gonadotropin-releasing hormonal analogues and insulin sensitizers
2. peripheral androgen blockade, e.g., spironolactone, cyproterone acetate, flutamide, or finasteride
3. mechanical/cosmetic amelioration and destruction of the unwanted hairs, e.g., electrolysis, lasers, IPL, depilatories, shaving, waxing
4. application of eflornithine 13.9% topical cream.

Adverse Events for Eflornithine

Skin-related side-effects such as stinging, burning and tingling are seen occasionally, particularly when eflornithine is applied to broken or abraded skin.¹³ Eflornithine offers a low degree of percutaneous absorption and low systemic exposure to eflornithine, offering a favorable clinical safety profile with minimal side-effects.^{11,14} This drug is classified as a pregnancy category C agent, so risk to the fetus cannot be ruled out.

Patient Communication

The results of therapy may not always be satisfactory, so it is very important to advise the patient of the available treatment modalities for temporary or permanent hair reduction. No single method is appropriate for all body locations or patients. The one adopted will depend on the character, area and amount of hair growth as well as on the patient's age and personal preferences.

Conclusion

Unwanted facial hair can cause embarrassment and lead to anxiety and depression. There are a limited number of treatments available that vary in efficacy, degree of discomfort, and cost. Eflornithine 13.9% cream, by itself or in combination with other treatments, has been shown to be effective for the treatment of UFH. Future experience will dictate the most effective niche for Vaniqa[®] within this family of treatments.

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Famciclovir for the Treatment of Recurrent Genital and Labial Herpes Lesions

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ABSTRACT

Famciclovir (Famvir[®], Novartis) is an effective treatment for herpes zoster and herpes simplex. Two separate studies recently examined the effectiveness of single high doses of famciclovir for treating recurrent genital herpes and labial herpes (cold sores). In the randomized, placebo-controlled studies, patients initiated treatment at the first onset of symptoms. For the treatment of genital herpes, a 1,000mg b.i.d. dose of famciclovir had significant advantages over the placebo, reducing the time required to heal the lesions, preventing the development of lesions beyond the papule stage, and improving the time to resolution of all symptoms. For the treatment of labial herpes, a single 1,500mg dose of famciclovir shortened the lesion healing time, shortened the time to normal skin, and resulted in faster resolution of pain and tenderness.

Key Words: famciclovir; herpes zoster; herpes simplex

Infections with herpes simplex virus type 1 and 2 (HSV-1 and HSV-2) are important, common, and worldwide in distribution. It has been estimated that 90% of individuals aged 20-40 years have antibodies to HSV-1, and HSV-2 is the most common sexually transmitted disease worldwide.¹ HSV-1 is most frequently connected with orolabial herpes and HSV-2 with genital herpes, although either type can affect either location.

Infection with HSV can initially result in primary infection, followed by an establishment of latency as the viral genome remains in the neuronal bodies indefinitely. Patients may then have recurrences which may be symptomatic or asymptomatic.² Certain patients can experience frequent recurrences which may be symptomatic, oral antivirals are the agents of choice in this setting.

Very recently, two clinical studies were completed in patients with recurrent labial and genital herpes using famciclovir. In this article these studies will be briefly reviewed and the implications identified.

Recurrent Genital Herpes

An international randomized, double-blind, multi-center, placebo-controlled study compared the effectiveness of a 1,000mg b.i.d. single-day dose of famciclovir with a placebo in patients with recurrent genital herpes (i.e., >4 episodes over 12 months).³

Three hundred twenty nine patients were randomized to receive famciclovir (n=163) or placebo (n=166). The patients in the treated and placebo arms were well-balanced in demographic and baseline disease characteristics. In this study, the major inclusion criteria were:

- aged 18 years or older
- history of recurrent genital herpes on the external genitalia or anogenital area, with four or more episodes in the previous 12 months.
- HSV-2 seropositivity
- if applicable, be willing to discontinue suppressive treatment.

Lesions requiring re-epithelialization were defined as lesions that underwent vesicular, ulcer, soft crust and/or hard crust formation. Aborted lesions were considered to be lesions that did not progress beyond the papule stage.

Efficacy Variables

The primary efficacy variable in the study was investigator-assessed time to healing of all nonaborted genital herpes lesions. Secondary efficacy variables included:

- the safety and tolerability of a 1,000mg b.i.d. dose of famciclovir
- the proportion of patients with aborted lesions
- the time to resolution of all symptoms, including burning, pain, tingling, itching, and tenderness.

Patients initiated dosing within 6 hours of the first symptoms. Patients returned to the clinic within 24 hours, and then visited the clinic for 3 consecutive days. They returned every other day until the lesions were healed or until day 14, whichever came first.

Adverse Events

Just over one-quarter of patients receiving famciclovir (26.4%) reported adverse events, of which 12.9% were deemed by the investigator to be drug related. These included gastrointestinal disorders (such as diarrhea or

Population	Famciclovir	Placebo	Hazard Ratio**	P
Modified ITT***	4.3 (3.9, 5.0)	6.1 (5.0, 7.0)	1.64	<0.001
Per Protocol	4.3 (3.9, 5.5)	6.2 (5.3, 7.4)	1.72	0.009

Table 1: Time to healing (days)* of non-aborted lesions.

*Median time to healing and 95% CI for the median time are shown.

**Based on proportional hazards model with treatment, center and gender as explanatory variables.

***ITT = Intent to treat.

Population	Famciclovir	Placebo	P
ITT*	23.3%	12.7%	0.003
PCR-Positive**	20.9%	5.3%	<0.001

Table 2: Proportion of patients with aborted lesions

*ITT = Intent to treat

** PCR = Polymerase chain reaction

Symptom	Famciclovir	Placebo	Hazard Ratio**	P
All	3.3 (2.8, 4.1)	5.4 (4.5, 6.5)	1.66	<0.001
Burning	0.7 (0.5, 1.0)	1.0 (0.8, 1.5)	1.34	0.016
Pain	0.9 (0.6, 1.1)	1.5 (1.0, 1.7)	1.29	0.038
Tingling	1.0 (0.9, 1.2)	1.4 (1.0, 1.9)	1.29	0.040
Itching	1.6 (1.4, 2.0)	2.7 (2.4, 3.1)	1.53	0.001
Tenderness	2.0 (1.7, 2.5)	3.4 (3.0, 4.3)	1.55	0.002

Table 3: Time to resolution (days)* of symptoms in the ITT population

*Median time to healing and 95% CI for the median time are shown.

**Based on proportional hazards model with treatment, center and gender as explanatory variables.

nausea) and headaches. The side-effects were mild and transient in the majority of patients. Patients receiving the placebo also reported these adverse events.

Conclusions

Two 1,000mg doses of famciclovir over a single day, started within 6 hours of prodromal symptoms or genital herpes lesions, were shown to:

- be well tolerated and safe
- play a significant role in reducing the time to healing of vesicular lesions
- significantly prevent the development or progression of lesions beyond the papule stage
- significantly improve the time to resolution of all symptoms, including burning, tingling, itching, and tenderness.

A single-day patient-initiated regimen is convenient and has the advantage of maximizing the window of opportunity for treatment when viral replication is most active. Famciclovir was shown to stop the progression to a full outbreak or shorten the duration of a recurrent genital herpes outbreak.

Recurrent Herpes Labialis

A randomized, double-blind, parallel group, placebo-controlled study examined the effectiveness of a single

1,500mg dose of famciclovir, two 750mg doses of famciclovir over a single day, and a matching placebo.⁴ Patients initiated therapy within 1 hour of prodromal symptoms. Patients returned to the clinic within 24 hours, and then visited the clinic for the 3 following consecutive days. After that they returned every other day until the lesions were healed or until day 14, whichever came first.

The 708 patients in the study population were adult immunocompetent patients with recurrent cold sores. The mean age was approximately 39 years, with the majority of patients being female and Caucasian.

The study also examined the time to resolution of pain and tenderness. The median time to resolution was 1.7 days for those who received the 1,500mg dose of famciclovir, 2.1 days for those receiving two 750mg doses of famciclovir over a single day, and 2.9 days for those who received the placebo.

Conclusions

A single dose of famciclovir (1,500mg) taken within the first hour of prodromal symptoms resulted in the following statistically significant differences as compared with a placebo:

- shorter time to healing of vesicular herpes labialis lesions by approximately 2 days
- shorter time to resolution to normal skin by approximately 2 days

Treatment	n	Median time to resolution (days)	Hazard Ratio*,** (95% CI)	P
Famciclovir, 1,500mg, single dose	152	4.4	1.64 (1.26-2.14)***	<0.001***
Famciclovir, 750mg b.i.d., single day	157	4.0	2.05 (1.58-2.66)****	0.001****
Placebo	168	6.2		

Table 4: Time to healing of primary vesicular lesions

*Based on the SAS PROC LIFETEST (Brookmeyer-Crowley method).

**Based on proportional hazards model with treatment, center, and gender as explanatory variables.

***Famciclovir 1,500mg single dose versus placebo.

****Famciclovir 750mg b.i.d., single day, versus placebo.

Treatment	n	Median time to resolution (days)	Hazard Ratio*,** (95% CI)	P
Famciclovir, 1,500mg, single dose	152	4.5	1.71 (1.31-2.22)***	<0.001***
Famciclovir, 750mg b.i.d., single day	157	4.1	2.06 (1.59-2.68)****	0.001****
Placebo	168	6.6		

Table 5: Time to healing of all vesicular lesions

*Based on the SAS PROC LIFETEST (Brookmeyer-Crowley method).

**Based on proportional hazards model with treatment, center, and gender as explanatory variables.

***Famciclovir 1,500 mg single dose versus placebo.

****Famciclovir 750 mg b.i.d., single day, versus placebo.

Treatment	n	Median time to resolution (days)	Hazard Ratio*,** (95% CI)	P
Famciclovir, 1,500 mg, single dose	227	4.5	1.50 (1.18-1.90)***	<0.001***
Famciclovir, 750 mg bid, single day	220	5.7	1.26 (0.98-1.62)****	0.067***
Placebo	254	7.0		

Table 6: Time to return to normal skin

*Based on the SAS PROC LIFETEST (Brookmeyer-Crowley method).

**Based on proportional hazards model with treatment, center, and gender as explanatory variables.

***Famciclovir 1,500mg single dose versus placebo.

****Famciclovir 750mg b.i.d., single day, versus placebo.

- Faster resolution of pain and tenderness by approximately 1 day.

The advantage of a single-dose, patient-initiated regimen is that it maximizes the window of opportunity for treatment when viral replication is the most active. A single dose can provide all the therapy up-front.

This study shows that a single dose (1,500mg) of famciclovir is effective in treating a herpes labialis outbreak, is well tolerated, and is convenient – a factor that may have the potential to improve patient compliance.

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Class	Name/Company	Approval Dates and Comments
<i>Antipsoriatic Agent</i>	Efalizumab <i>RAPTIVA</i> [®] Serono	TPP Canada approved this biologic therapy in October 2005 for the treatment of moderate-to-severe chronic plaque psoriasis in adult patients (18 years or older) who are candidates for systemic therapy or phototherapy.
<i>Antiarthritic Agent</i>	Adalimumab <i>HUMIRA</i> [®] Abbott Pharmaceuticals	The US FDA approved this biologic therapy in October 2005 for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis. This product can be used alone or with methotrexate or other disease modifying antirheumatic drugs.
<i>Antipsoriatic Agent</i>	Infliximab <i>REMICADE</i> [®] Centocor/ Schering-Plough	The European Commission has granted approval of this biologic therapy in October 2005 for the treatment of moderate-to-severe plaque psoriasis in adults who failed to respond to, or have a contraindication to, or are intolerant of other systemic therapies including cyclosporine, methotrexate, or PUVA.
<i>Vaccines</i>	Diphtheria, Tetanus, Pertussis, Polio, Hemophilus Influenza Type b Vaccine <i>PENTACEL</i> [™] Sanofi Pasteur MSD	The US FDA accepted a Biologics Licensing Application in September 2005 for this pediatric combination vaccine candidate that targets diphtheria, tetanus, pertussis, polio, and <i>Hemophilus influenzae</i> type b.
<i>Antibacterial Agent</i>	Mupirocin Ointment 2% Taro Pharmaceuticals	The US FDA approved an Abbreviated New Drug Application in September 2005 for this product for the treatment of impetigo. It is bioequivalent to Bactroban [®] Ointment 2% (GlaxoSmithKline).

Drug News	
<i>Unwanted Facial Hair Products</i>	The commercial launch of VANIQA [®] (eflornithine hydrochloride) cream 13.9% in Canada was announced by Barrier Therapeutics in November 2005. VANIQA [®] is the only topical prescription product approved by Health Canada for slowing the growth of unwanted facial hair in women.
<i>Wart Preparations</i>	In a July 2005 news release from the University of Texas Southwestern, dermatologists reported that when traditional methods to remove warts fail, such as burning, freezing, application of salicylic acid and surgery, they inject Candida antigen directly into the wart. This antigen stimulates the body's own natural defense mechanism, and they report that it is as effective in many instances as some of the more common therapies, but it doesn't leave scarring.
<i>Skin Filler</i>	A hyaluronic acid dermal filler (Puragen [®] , Mentor Corporation) that is derived from bacterial fermentation using Mentor's double cross-linked technology was launched in Europe in July 2005 for the treatment of wrinkles. Because it is a non-animal based product, it does not have the risks associated with other products derived from animal by-products.

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