

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**19-501/S025**

*Trade Name:* Men's Rogaine Regular Strength and Women's Rogaine topical solutions

*Generic Name:* 2% minoxidil

*Sponsor:* Pharmacia and Upjohn

*Approval Date:* June 21, 2005

*Purpose:* Proposes the inclusion of the phrase “#1 Dermatologist Recommended Brand” within a “seal” graphic on the Principal Display Panels (PDPs) for unscented Men's Rogaine, and both scented and unscented Women's Rogaine products

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**19-501/S025**

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**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**19-501/S025**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 19-501/S-020  
NDA 19-501/S-025

Pharmacia and Upjohn, A Pfizer Company  
Attention: Dina R. Russello, Director  
Global Regulatory Affairs  
201 Tabor Road  
Morris Plains, NJ 07950

Dear Ms. Russello:

Please refer to your supplemental new drug application (S-025) dated December 20, 2004, received December 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Men's Rogaine® Regular Strength and Women's Rogaine® (2% minoxidil) topical solutions.

We acknowledge receipt of your submissions dated May 23 and June 7, 2005.

This supplemental new drug application proposes the inclusion of the phrase "#1 Dermatologist Recommended Brand" within a "seal" graphic on the Principal Display Panels (PDPs) for unscented Men's Rogaine®, and both scented and unscented Women's Rogaine® products.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container, carton labels, and patient package insert submitted on December 20, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-501/S-025.**" Approval of this submission by FDA is not required before the labeling is used.

We also refer to your supplemental new drug application (S-020) dated March 20, 2002, received on March 25, 2002. This application (S-020) provided for labeling in *Drug Facts* format with new warnings and other modifications to the product label and package insert for Men's Rogaine® and Women's Rogaine® (2% minoxidil) topical solutions. The approved draft labeling for application S-025 incorporates the changes proposed under S-020 and the revisions required in our February 3, 2003, approvable letter for S-020. Supplemental application S-020 is hereby superseded by the approval for application S-025. Supplemental application S-020 will be closed and retained in our files.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

*{See appended electronic signature page}*

Curtis Rosebraugh, M.D., M.P.H.

Acting Division Director

Division of Nonprescription Clinical Evaluation

Office of Nonprescription Products

Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Curtis Rosebraugh  
6/21/05 03:07:31 PM

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**19-501/S025**

**LABELING**



Inner Carton - Mens Rogaine  
12/20/2004

See inside for applicator  
and important  
consumer information.  
**Make Sure to Apply Rogaine  
Directly on Scalp**

**Directions for use**

1. Remove the overcap. To remove, line up arrows on bottle and overcap and pull off the overcap.
2. Remove the inner cap by pushing and turning in the direction of the arrows on the cap.
3. Part your hair in the area of hair thinning/loss. Follow the instructions on the side panel for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Rogaine.

**Using the Dropper Applicator**

- squeeze the rubber bulb and insert the dropper into the bottle
- release the bulb, allowing the dropper to fill to the 1 mL line
- if the level of solution is above the 1 mL line, squeeze the extra amount back into the bottle
- place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution
- to prevent the solution from running off the scalp, apply a small amount at a time
- after each use, attach the dropper to the bottle to make child-resistant by turning it clockwise until tightly closed



**REGULAR STRENGTH**  
2% Minoxidil Topical Solution  
**Hair Regrowth Treatment**

- Use Twice a Day – Every Day
- Directly on the Scalp

Want Your Best Results?  
Enroll in Rogaine Results at [rogaine.com](http://rogaine.com)

Rogaine Results is a free personalized e-mail support program designed to help you get your best results using Rogaine. The e-mails have useful information about hair loss, including:

- Advice from hair loss experts
- Valuable offers
- The tips you need to succeed
- How Rogaine works

Updated:  
back, sides and  
front panel copy  
to match  
ES & Women's  
Unscented, Dropper  
Only copy  
1.22.04



Please Recycle

818 451 105

[rogaine.com](http://rogaine.com) <sup>TM</sup>

Pfizer Consumer Healthcare  
Morris Plains, NJ 07850 U.S.A.  
©2004 Pfizer Inc.

773402

See inside for applicator  
and important  
consumer information.

**Dropper Only  
Unscented**

7393C Rog RS Drp InnrPckUnsc4A  
1:43:48 PM 2/23/04

US1 7887 Rog RS DroDra InnrPck 34-3  
8:52:06 AM 8/20/02

236 4-11 Rog RS InnrPck 341  
1:21:11 PM 7/2/01

US1 3 L IN A MER PACKS  
5.04 X 40.03 X 143.1

USA



Black

VARNISH

Starting Date	Product	CCS#	EDP#	Copy Code	NDC#
6/7/02	Mens Rogaine RS Inner Pack Dropper Only	3779-70-000	773402	818 451 105	NDC 0009-3779-01

Immediate container - Men's Rogaine  
12/20/2004

**Directions**

- apply one mL 2 times a day directly onto the scalp in the hair loss area
- see inner carton and enclosed booklet for complete directions
- using more or more often will not improve results
- continued use is necessary or hair loss will begin again

**Inactive Ingredients** alcohol (60% v/v), propylene glycol (20% v/v), purified water

**Questions?**  
Call toll-free 1-800-ROGAINE (1-800-764-2463) or reach us on the internet at [rogaine.com](http://rogaine.com)

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

8183390507

LOT:  
EXP:

Pfizer Consumer Healthcare  
Morris Plains, NJ 07950 U.S.A.  
©2004 Pfizer Inc.



**MEN'S Rogaine**  
REGULAR STRENGTH  
2% Minoxidil Topical Solution  
Hair Regrowth Treatment  
Clinically Proven to Help Regrow Hair  
Revitalizes Hair Follicles  
Unscented  
One Month Supply  
60mL (2 fl oz)

**Read and keep carton and booklet for full product information**

**Active ingredient:** Minoxidil 2% w/v

**Warnings:**  
For external use only  
**Flammable:** Keep away from fire or flame

**Do not use if:**

- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, itsted, or painful.
- you use other medicines on the scalp

**Ask a doctor before use if you have heart disease**

**When using this product:**

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture

**Stop use and ask a doctor if:**

- chest pain, rapid heartbeat, lightheadedness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs

**May be harmful if used when pregnant or breast-feeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.**

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NOTE: IMPRINT AREA  
NO VARNISH

8183390507RogRSUWSC Lb17596  
11-16:00 AM 8/26/04

Pfizer CONSUMER HEALTHCARE PACKAGING APPROVAL				APPROVED (REV. 10/01)	
NAME	DATE	INITIALS	AS IS	WITH CHANGES	
PACKAGING SPECIALIST					
PROOFREADER					
PRODUCT MANAGEMENT					
CONSUMER PROMOTIONS					
REGULATORY					
TRADEMARK/PATENT					
LEGAL					
MEDICAL					
CONSUMER AFFAIRS					

FAST TRACK APPROVAL  MINOR CHANGE APPROVAL  DATE \_\_\_\_\_ INITIAL \_\_\_\_\_

(b)(4)

PFIZER CONSUMER HEALTHCARE					
Spec #	Date	Rev #	Artist	Nature of Revisions	
818 390 507	08.26.04	0	(b)(4)	New Mechanical, Updated to Latest Drug Facts	

Pfizer Consumer Healthcare  
New York, NY 10017  
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Patient Package Insert  
12/20/2004

Important  
Information  
About

MEN'S  
**Rogaine.**

REGULAR STRENGTH

2% Minoxidil Topical Solution

Hair Regrowth  
Treatment

Unscented

rogaine.com



Competition Unit: 2566



Hair art is 40% black  
over Pantone 872

COMMISSION ORDER # 23431	PRODUCT Men's Rogaine Reg Strength 2% Original Formula	COPY CODE # 816 713 107
CODE # 3779-70	NEC # 0009-3779-01	ITEM # 691717
NOTE #	SIZE 2 x 5.5"	ITEM # Booklet Insert Cover
ADDITIONAL INFORMATION	DATE 3-19-04	DRAWING #

Pantone colors used in this proof may not match the Pantone's seed color standards. Use current Pantone's swatch guide for most accurate color.

Patient package insert

# MEN'S Rogaine®

## REGULAR STRENGTH

2% Minoxidil Topical Solution

Unscented

Save booklet for future reference.

- Hair regrowth treatment
- Previously available only by prescription

Men's Rogaine Regular Strength contains the only ingredient available without a prescription that is medically proven effective to help regrow hair.

Please read this booklet carefully. It will help you understand how to use Rogaine and what to expect from its use. If you have any questions after reading this booklet, or anytime while using Rogaine, you should ask your health care professional or call us at **1-800-ROGAINE (1-800-764-2463)**. You can also visit our website at **rogaine.com**.

### What is Men's Rogaine Regular Strength?

Rogaine is a colorless liquid medication for use only on the scalp to help regrow hair.

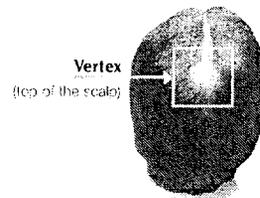
© 2004 Pfizer Inc.

### Who may use Men's Rogaine Regular Strength?

Rogaine may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Rogaine is for men with hair loss or thinning that begins at the top of the scalp (vertex) as shown below. Frontal hair growth has not been demonstrated in clinical trials. Rogaine is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, Rogaine may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. **If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.**



1

2



Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23431		Men's Rogaine RS 2% Orig Formula	
COPY CODE #		CCS #	NDC #
816 713 107		3779-70	0009-3779-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
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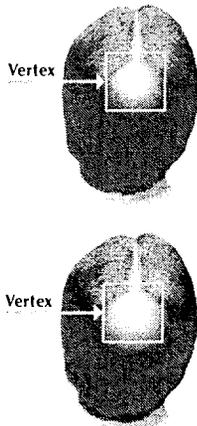
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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23431		Men's Rogaine RS 2% Orig Formula	
COPY CODE #		CCS #	NDC #
816 713 107		3779-70	0009-3779-01
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691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			6-10-04
			TYPESET BY
			(b)

# Vertex Hair Loss Inset



### Who should NOT use Men's Rogaine Regular Strength?

Rogaine will not prevent or improve hair loss which may occur with the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Rogaine will not improve hair loss due to:

- damage from the use of hair care products which cause

scarring or deep burns of the scalp.

- hair grooming methods such as crowning or ponytails which require pulling the hair tightly back from the scalp.

**You should ask your doctor if you are unsure of the cause of your hair loss.**

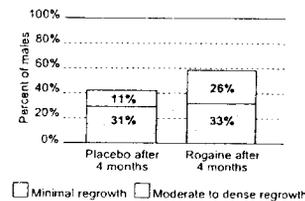
### Will Men's Rogaine Regular Strength work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Rogaine. The response to Rogaine cannot be predicted. No one will be able to grow back all their hair.

You may respond better if you have been losing your hair for a short period of time or have little initial hair loss.

In clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, the following response to Rogaine was reported:

### Rogaine Response in Men Percent reporting hair regrowth



3

4



Black

Composition Unit 2566

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# Patent Package insert

26% of men reported moderate to dense hair regrowth after using Rogaine for 4 months (26% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 11% of men reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 4 months (11% had moderate to dense regrowth; 31% had minimal regrowth).

## What Minimal, Moderate and Dense Hair Regrowth Will Mean For You

	Number of Hairs	Hair Density
<b>Minimal</b>	Some new hairs are seen, but not enough to cover thinning areas.	Hairs in thinning areas do not grow as closely together as hairs on the rest of the head.
<b>Moderate</b>	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not as close together as hairs on the rest of the head.
<b>Dense</b>	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of head.

## Can Men's Rogaine Regular Strength be used to prevent hair loss?

We do not know if Rogaine will prevent hair loss.

## How soon can I expect results from using Men's Rogaine Regular Strength?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Rogaine also takes time. Generally new hair growth is slow for a Rogaine user. Continued use 2 times a day for at least 4 months is usually needed before you notice hair regrowth.

If you do not see hair regrowth in 4 months, stop using Rogaine and see your doctor.

When you first begin to use Rogaine, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

## If Men's Rogaine Regular Strength is working, what will the hair look like?

At first, hair growth may be soft, downy, colorless hairs. After further use, the new hair should be the same color and thickness as the other hairs on your scalp.

## How long do I need to use Men's Rogaine Regular Strength?

If you respond to Rogaine, you will need to use it 2 times a day to keep and continue the hair regrowth. Up to 12 months of use may be needed to see your best results from Rogaine.

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Composition Unit 2566

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			TYPESET BY
			AV

# Patient Package Insert

## What happens if I completely stop using Men's Rogaine Regular Strength? Will I keep the new hair?

Continuous use of Rogaine is needed to maintain hair regrowth. If you stop using Rogaine, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

## What is the dosage of Men's Rogaine Regular Strength?

You should apply a dose (1 mL) of Rogaine directly onto the scalp in the hair loss area **TWO TIMES A DAY**; for example, once in the morning and once at night. Each bottle should last about one month, if used as directed. Please refer to the "Directions for Use" section of this booklet.

## What if I miss a dose or forget to use Men's Rogaine Regular Strength?

If you miss one or two daily doses of Rogaine, just continue with your next dose. You should not make up for missed doses.

## Can I use Men's Rogaine Regular Strength more than two times a day? Will it work faster, better?

No. Rogaine will not work faster or better if used more than 2 times a day. Studies have been carefully conducted to determine the correct amount of Rogaine needed to get

the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

## What are the most common side effects with Men's Rogaine Regular Strength?

The most common side effects are itching and other skin irritations of the treated area of the scalp. Rogaine contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Rogaine accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

## What kind of shampoo should I use with Men's Rogaine Regular Strength?

If you wash your scalp before applying Rogaine, use a mild shampoo.

## Can I use hair sprays, mousses, conditioners, gels, etc.?

Yes. There is no need to change your usual hair care routine when using Rogaine. However, you should apply Rogaine first and wait for it to dry before applying your styling aids.

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Composition Unit 2566

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Composition Unit 2566

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		[Signature]	

# Patient Package Insert

**Can I have my hair colored or permed or use hair relaxers while using Men's Rogaine Regular Strength?**

Yes. We have no information that these treatments change the effect of Rogaine. However, to avoid possible scalp irritation, you should make sure all of the Rogaine has been washed out of the hair and scalp before using these chemicals.

**Can I apply Men's Rogaine Regular Strength and wash my hair an hour later?**

No. For Rogaine to work best, you should allow Rogaine to remain on the scalp for about 4 hours before washing.

**Can I go swimming or out in the rain?**

Yes. Avoid washing off the Rogaine. If possible, apply Rogaine to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Rogaine.

**Can Men's Rogaine Regular Strength produce unwanted hair?**

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Rogaine

to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Rogaine.

If you experience unwanted hair, discontinue using Rogaine and see your doctor for recommendations about appropriate treatment. After stopping use of Rogaine, the unwanted hair, if caused by the use of Rogaine, should go away over time.

You can take steps to decrease the chances for unwanted hair growth: 1) limit the application of Rogaine only to the scalp, 2) if you use your hands to apply Rogaine, wash your hands thoroughly afterwards, and 3) allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Rogaine.

**Can I use Men's Rogaine Regular Strength for baldness or hair loss in babies and children?**

No. Rogaine must not be used to treat baldness or hair loss in babies or children.

**Are there any special warnings about the use of Men's Rogaine Regular Strength?**

For external use only

**Flammable: Keep away from fire or flame**

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Composition Unit 2566

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23431		Men's Rogaine RS 2% Orig Formula	
COPY CODE #		CCS #	NDC #
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DRAWING #	REV. #	ADDITIONAL INFO	DATE
			6-10-04
			TYPESET BY
			lh

# Patient Package Insert

## Do not use if

- your degree of hair loss is more than that shown on page 2 and 3 of this booklet, because this product may not work for you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

**Ask a doctor before use if you have heart disease.**

## When using this product

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture
- it takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for everyone.

## Stop use and ask a doctor if

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs
- you do not see hair regrowth in 4 months

**May be harmful if used when pregnant or breast-feeding.**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## What factors may increase the risk of serious side effects with Men's Rogaine Regular Strength?

Rogaine should be applied only to the scalp. The risk of side effects may be greater when it is applied to other parts of the body.

## Directions for Use

1. Remove the overcap. To remove, line up arrows on bottle and overcap and pull off the overcap.
2. Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
3. Part your hair in the area of hair thinning/loss. Follow the instructions below for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not

11

12



Black

Composition Unit 2566

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EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			6-10-04
		TYPESET BY	
		[Signature]	



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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23431		Men's Rogaine RS 2% Orig Formula	
COPY CODE #		CCS #	NDC #
816 713 107		3779-70	0009-3779-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			6-10-04
		TYPESET BY	
		[Signature]	

# Patient Package Insert

use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Rogaine.

**Store at Controlled Room Temperature 20° to 25° C (68° to 77° F).**

*Save this booklet for future reference.*



### Using the Dropper Applicator

1. Squeeze the rubber bulb and insert the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze the extra amount back into the bottle.
2. Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
3. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.

If you have any other questions, ask your health care professional or call us at **1-800-ROGAINE (1-800-764-2463)**. You can also visit our website at **rogaine.com**.

Pfizer Consumer Healthcare  
Morris Plains, NJ 07950 U.S.A.  
Revised June 2004  
816 713 107

691717

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14



Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23431		Men's Rogaine RS 2% Orig Formula	
COPY CODE #		CCS #	NDC #
816 713 107		3779-70	0009-3779-01
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691717	Booklet	2 x 5.5"	
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			6-10-04
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			TYPESET BY

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Composition Unit 2566

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691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
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			TYPESET BY
			TSV

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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23431		Men's Rogaine RS 2% Orig Formula	
COPY CODE #		CCS #	NDC #
816 713 107		3779-70	0009-3779-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			6-10-04
			TYPESET BY
			TSV



Inner Carton Label - Women's Rogaine  
(Unscented)

12/20/2004

See inside for applicator  
and important  
consumer information.  
**Make Sure to Apply Rogaine  
Directly on Scalp**

**Directions for use**

1. Remove the overcap. To remove, line up arrows on bottle and overcap and pull off the overcap.
2. Remove the inner cap by pushing and turning in the direction of the arrows on the cap.
3. Part your hair in the area of hair thinning/loss. Follow the instructions on the side panel for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Rogaine.

**Using the Dropper Applicator**

- squeeze the rubber bulb and insert the dropper into the bottle
- release the bulb, allowing the dropper to fill to the 1 mL line
- if the level of solution is above the 1 mL line, squeeze the extra amount back into the bottle
- place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution
- to prevent the solution from running off the scalp, apply a small amount at a time
- after each use, attach the dropper to the bottle to make child-resistant by turning it clockwise until tightly closed



2% Minoxidil Topical Solution  
Hair Regrowth Treatment

- Use Twice a Day - Every Day
- Directly on the Scalp

Want Your Best Results?  
Enroll in Rogaine Results at [rogaie.com](http://rogaie.com)

Rogaine Results is a free personalized e-mail support program designed to help you get your best results using Rogaine. The e-mails have useful information about hair loss, including:

- Advice from hair loss experts
- Valuable offers
- The tips you need to succeed
- How Rogaine works



Please Recycle

[rogaie.com](http://rogaie.com)

Pfizer Consumer Healthcare  
Morris Plains, NJ 07950 U.S.A.  
© 2004 Pfizer Inc.

818 376 206

773402

See inside for applicator and important consumer information.

**Unscented**

7393C Rog Wom Drp InnrPckC Uns3 (Unscented)  
2:30:36 PM 2/24/04

AUGUST VERSION

7361 Rog Wom Drp InnrPck 3A2  
4:50:38 PM 9/8/03

7398 Rog Wom Innr Pack 3A1  
11:03:05 AM 8/4/03

ROGAINE INNER PACKS  
6/1/03 X 143 1

Starting Date	Product	CCSI#	EDP#	Copy Code	NDC#
8/7/02	Women's Rogaine Inner Pack w/ dropper Unscented	3780-93-000	773402	818 376 206	0009-3780-01



Black VARNISH

Immediate Container label - (Women's Rogaine associated)

12/20/2004

2.125"

Type: Hevlicia 4.34  
Condensed 13%  
10/21/03

**Directions**

- apply one mL 2 times a day directly onto the scalp in the hair loss area
- see inner carton and enclosed booklet for complete directions
- using more or more often will not improve results
- continued use is necessary or hair loss will begin again

**Inactive ingredients:** alcohol (60% v/v), propylene glycol (20% v/v), purified water

**Questions?**  
Call toll free 1-800-ROGAINE (1-800-764-2463) or visit us on the internet at [rogaine.com](http://rogaine.com)

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

LOT: S18070603

EXP:

Pfizer Consumer Healthcare  
Morris Plains, NJ 07950 U.S.A.  
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**2% Minoxidil Topical Solution**

**Hair Regrowth Treatment**

*Clinically Proven to Help Regrow Hair*

Revitalizes Hair Follicles

One Month Supply  
60mL (2 fl oz)

**Read and keep carton and booklet for full product information**

**Active ingredient:** Minoxidil 2% w/v

**Warnings**

**For external use only**

**Flammable:** Keep away from fire or flame

**Do not use if**

- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

**Ask a doctor before use if you have heart disease**

**When using this product:**

- do not apply to other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture

**Stop use and ask a doctor if:**

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs

**May be harmful if used when pregnant or breast-feeding.**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

NOTE: IMPRINT AREA  
NO VARNISH

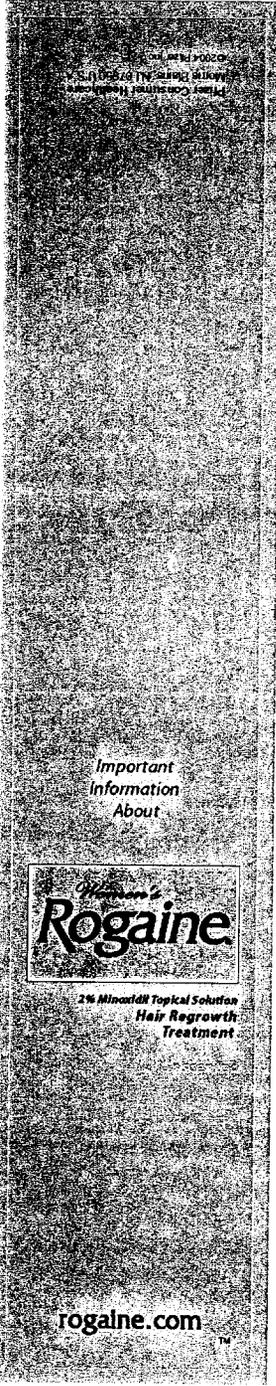
S1846950/RogWmUnsc  
12-14-04 AM 9/26/04

Pfizer CONSUMER HEALTHCARE PACKAGING APPROVAL				APPROVED (WHICH USE)	
NAME	DATE	INITIALS	AS IS	WITH CHANGES	
PACKAGING SPECIALIST					
PROOFREADER					
PRODUCT MANAGEMENT					
CONSUMER PROMOTIONS					
REGULATORY					
TRADEMARK/PATENT					
LEGAL					
MEDICAL					
CONSUMER AFFAIRS					

FAST TRACK APPROVAL  MINOR CHANGE APPROVAL  DATE \_\_\_\_\_ INITIAL \_\_\_\_\_

(b)(4)

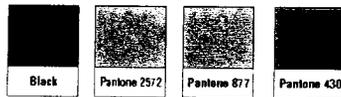
PFIZER CONSUMER HEALTHCARE				
Spec #	Date	Rev #	Artist	Nature of Revisions
818 373 609	08.26.04	0	(b)(4)	New Mechanical, Update to latest Drug Facts



Patient package insert  
 Women's Rogaine  
 (unscented)  
 12/20/2004



Composition Unit 2566



7498B RoWomInsr816714309 Cv Uns  
 8:40:13 AM 6/30/04



COMPOSITION CODES*	PRODUCT		COPY CODE*
23420	Women's Rogaine 2% Original Formula		816 714 XXX
CSA*	UNCA*	QSP*	TEM*
3780-93-000	0009-3780-01	691717	Booklet Insert Cover
BOTTLE*	SIZE	PRINTING AREA	DESCRIPTION*
	2 x 5.5"		
ADDITIONAL INFORMATION			DATE
Approved Printing Method: 2% Minoxidil Topical Solution Hair Regrowth Treatment (C) 2004			06/30/04

Was 816 714 309

Pantone® colors used in this proof may not match the Pantone® solid color standards; use current Pantone® swatch guide for most accurate color

# Patent Package Insert

## Women's Rogaine®

2% Minoxidil Topical Solution  
Unscented

Save booklet for future reference.

- Hair regrowth treatment
- Previously available only by prescription

Over 30 million American women experience hair thinning or hair loss, so you're not alone. Women's Rogaine contains the only ingredient that is medically proven effective to help regrow hair in women.

Please read this booklet carefully. It will help you understand how to use Rogaine and what to expect from its use. If you have any questions after reading this booklet, or anytime while using Women's Rogaine, you should ask your health care professional or call us at **1-800-ROGAINE (1-800-764-2463)**. You can also visit our website at [rogaine.com](http://rogaine.com).

### What is Women's Rogaine?

Rogaine is a colorless liquid medication for use only on the top of the scalp to help regrow hair.

### Who may use Women's Rogaine?

Women's Rogaine may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Women's Rogaine is for general thinning of hair on the top of the scalp as shown on the next page. Rogaine has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Rogaine may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. **If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.**

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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23420		Women's Rogaine 2% Original Formula	
COPY CODE #		CCS #	NDC #
816 714 309		3780-93-000	0009-3780-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	x
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			06/30/04
		TYPESET BY	
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DRAWING #	REV. #	ADDITIONAL INFO	DATE
			02/24/04
		TYPESET BY	
		(b)(4)	

# Patient Package Insert



## Who should NOT use Women's Rogaine?

Rogaine will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Rogaine will not improve hair loss due to:

- damage from the use of hair care products which cause scarring or deep burns of the scalp.
- hair grooming methods such as cornrowing or ponytails which require pulling the hair tightly back from the scalp.

Do not use Rogaine if hair loss is patchy as shown below.



You should ask your doctor if you are unsure of the cause of your hair loss.

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Composition Unit 2566

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			02/24/04
		TYPESET BY	
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# Patient Package Insert

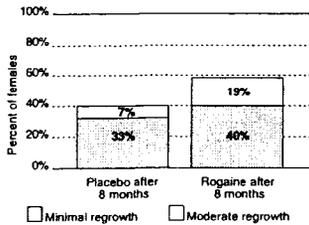
## Will Women's Rogaine work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Rogaine. The response to Rogaine cannot be predicted. No one will be able to grow back all their hair.

In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to Rogaine was reported:

### Female Response to Rogaine

Percent reporting hair regrowth



19% of women reported moderate hair regrowth after using Rogaine for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).

5

## What Minimal, Moderate and Dense Hair Regrowth Will Mean For You

	Number of Hairs	Hair Density
<b>Minimal</b>	Some new hairs are seen, but not enough to cover thinning areas.	Hairs in thinning areas do not grow as closely together as hairs on the rest of the head.
<b>Moderate</b>	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not as close together as hairs on the rest of the head.
<b>Dense</b>	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of head.

## Can Women's Rogaine be used to prevent hair loss?

We do not know if Rogaine will prevent hair loss.

## How soon can I expect results from using Women's Rogaine?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Rogaine also takes time. Generally new hair growth is slow for a Rogaine user. Continued use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth.

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Composition Unit 2566

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EDP #	ITEM	SIZE	FOLDED SIZE		
691717	Booklet	2 x 5.5"	X		
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# Patient Package Insert

If you do not see hair regrowth in 4 months, stop using Rogaine and see your doctor.

When you first begin to use Rogaine, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

**If Women's Rogaine is working, what will the hair look like?**

At first, hair growth may be soft, downy, colorless hairs. After further use, the new hairs should be the same color and thickness as the other hairs on your scalp.

**How long do I need to use Women's Rogaine?**

If you respond to Rogaine, you need to use it 2 times a day to keep and continue the hair regrowth. Up to 8 months of usage may be needed to see your best results from Rogaine.

**What happens if I completely stop using Women's Rogaine? Will I keep the new hair?**

Continuous use of Rogaine is needed to maintain hair regrowth. If you stop using Rogaine, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

**What is the dosage of Women's Rogaine?**

You should apply a dose (1 mL) of Rogaine directly onto the scalp in the hair loss area **TWO TIMES A DAY**; for example, once in the morning and once at night. Each bottle should last about one month, if used as directed. Please refer to the "Directions for Use" section of this booklet.

**What if I miss a dose or forget to use Women's Rogaine?**

If you miss one or two daily doses of Rogaine, just continue with your next dose. You should not make up for missed doses.

**Can I use Women's Rogaine more than two times a day? Will it work faster, better?**

No. Rogaine will not work faster or better if used more than two times a day. Studies by Pharmacia have been carefully conducted to determine the correct amount of Rogaine needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chances of side effects.

**What are the most common side effects with Women's Rogaine?**

The most common side effects are itching and other skin irritations of the treated area of the scalp.

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Composition Unit 2566

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23420		Women's Rogaine 2% Original Formula			
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			02/24/04	[Signature]	

# Patient Package Insert

Rogaine contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Rogaine accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

**What kind of shampoo should I use with Women's Rogaine?**

If you wash your scalp before applying Rogaine, use a mild shampoo.

**Can I use hair sprays, mousses, conditioners, gels, etc.?**

Yes. There is no reason to change your usual hair care routine when using Rogaine. However, you should apply Rogaine first and wait for it to dry before applying your styling aids.

**Can I have my hair colored or permed or use hair relaxers while using Women's Rogaine?**

Yes. We have no information that these treatments change the effect of Rogaine. However, to avoid possible scalp irritation, you should make sure all of the Rogaine has been washed off the hair and scalp before using these chemicals.

**Can I apply Women's Rogaine and wash my hair an hour later?**

No. For Rogaine to work best, you should allow Rogaine to

remain on the scalp for about 4 hours before washing.

**Can I go swimming or out in the rain?**

Yes. Avoid washing off the Rogaine. If possible, apply Rogaine to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Rogaine.

**Can Women's Rogaine produce unwanted hair?**

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Rogaine to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Rogaine.

If you experience unwanted hair, discontinue using Rogaine and see your doctor for recommendations about appropriate treatment. After stopping use of Rogaine, the unwanted hair, if caused by the use of Rogaine, should go away over time.



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		TYPESET BY	
		(b)(4)	

# Patient Package Insert

You can take steps to decrease the chances for unwanted hair growth: 1) limit the application of Rogaine only to the scalp, 2) if you use your hands to apply Rogaine, wash your hands thoroughly afterwards, and 3) allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Rogaine.

**Can I use Women's Rogaine for baldness or hair loss in babies and children?**

No. Rogaine must not be used to treat baldness or hair loss in babies or children.

**Are there any special warnings about the use of Women's Rogaine?**

**For external use only**

**Flammable: Keep away from fire or flame**

**Do not use if**

- your degree of hair loss is more than that shown on page 3 of this booklet, because this product may not work for you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- you do not know the reason for your hair loss

- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

**Ask a doctor before use if you have heart disease.**

**When using this product**

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture
- it takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for everyone.

**Stop use and ask a doctor if**

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs

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Composition Unit 2566

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		TYPESET BY	
		(b)(4)	

# Patent Package Insert

- you do not see hair regrowth in 4 months

**May be harmful if used when pregnant or breast-feeding. Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**What factors may increase the risk of serious side effects with Women's Rogaine?**

Rogaine should be applied only to the scalp. The risk of side effects may be greater when Rogaine is applied to other parts of the body.

**Directions for Use**

1. Remove the overcap. To remove, line up arrows on bottle and overcap and pull off the overcap.
2. Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
3. Part your hair in the area of hair thinning/loss. Follow the instructions below for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a

mild shampoo if you wash your scalp before applying Rogaine.



**Using the Dropper Applicator**

1. Squeeze the rubber bulb and insert the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze the extra amount back into the bottle.
2. Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
3. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.

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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23420		Women's Rogaine 2% Original Formula	
COPY CODE #		CCS #	NDC #
816 714 309		3780-93-000	0009-3780-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	X
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			06/30/04
		TYPESET BY	
		(b)(4)	



Black

Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23420		Women's Rogaine 2% Original Formula	
COPY CODE #		CCS #	NDC #
816 714 309		3780-93-000	0009-3780-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	X
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			02/24/04
		TYPESET BY	
		(b)(4)	

# Patient Package Insert

If you have any other questions, ask your health care professional or call us at **1-800-ROGAINE (1-800-764-2463)**. You can also visit our website at **rogaine.com**.

**Store at Controlled Room Temperature 20° to 25° C (68° to 77° F).**

*Save this booklet for future reference.*

**Pfizer Consumer Healthcare**  
Morris Plains, NJ 07950 U.S.A.

Revised June 2004  
816 714 XXX

691717

15

16



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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23420		Women's Rogaine 2% Original Formula	
COPY CODE #		CCS #	NDC #
816 714 309		3780-93-000	0009-3780-01
EOP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	X
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			02/24/04
			(b)(4)



Black

Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23420		Women's Rogaine 2% Original Formula	
COPY CODE #		CCS #	NDC #
816 714 309		3780-93-000	0009-3780-01
EOP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	X
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			02/24/04
			(b)(4)



PROOFHEADER		
PRODUCT MANAGEMENT		
CONSUMER PROMOTIONS		
REGULATORY		
TRADEMARK/PATENT		
LEGAL		
MEDICAL		
CONSUMER AFFAIRS		
FAST TRACK APPROVAL <input type="checkbox"/>	MINOR CHANGE APPROVAL <input type="checkbox"/>	DATE _____

See inside for applicator  
and important  
consumer information.

**Make Sure to Apply Rogaine  
Directly on Scalp**

*Inner Carton Label  
Women's Rogaine  
(scanned)  
12/20/2004*

**Directions for use**

1. Remove the overcap. To remove, line up arrows on bottle and overcap and pull off the overcap.
2. Remove the inner cap by pushing and turning in the direction of the arrows on the cap.
3. Part your hair in the area of hair thinning/loss. Follow the instructions on the side panel for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Rogaine.

**Using the Dropper Applicator**

- squeeze the rubber bulb and insert the dropper into the bottle
- release the bulb, allowing the dropper to fill to the 1 mL line
- if the level of solution is above the 1 mL line, squeeze the extra amount back into the bottle
- place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution
- to prevent the solution from running off the scalp, apply a small amount at a time
- after each use, attach the dropper to the bottle to make child-resistant by turning it clockwise until tightly closed



*2% Minoxidil Topical Solution  
Hair Regrowth  
Treatment*

Want Your Best Results?  
Enroll in Rogaine Results at [rogaine.com](http://rogaine.com)

Rogaine Results is a free personalized e-mail support program designed to help you get your best results using Rogaine. The e-mails have useful information about hair loss, including:

- Advice from hair loss experts
- Valuable offers
- The tips you need to succeed
- How Rogaine works

- **Use Twice a Day – Every Day**
- **Directly on the Scalp**

820 014 000



Please Recycle

773402

[rogaine.com](http://rogaine.com)

Pfizer Consumer Healthcare  
Morris Plains, NJ 07950 U.S.A.  
© 2004 Pfizer Inc.

See inside for applicator and important consumer information.

**Cyrano**



Medicine Container Label  
 Women's Rogaine (scented)  
 12/20/2004

Subheadings: Helvetica Bold 4.5 pt.  
 Body: Helvetica Regular 4.5 pt.  
 Bullets/Squares: 4.5 pt.  
 Hairline: 0.5 pt.

**Women's Rogaine®**  
 2% Minoxidil Topical Solution  
 Hair Regrowth Treatment

**Directions:**  
 • Apply one mL, 2 times a day directly onto the scalp in the hair loss area.  
 • See inner carton and enclosed booklet for complete directions.  
 • Using the enclosed applicator will not improve results.  
 • Continued use is necessary or hair loss will begin again.  
 • Inactive ingredients: alcohol (80% v/v), fragrance, propylene glycol (20% w/v).

**Warnings:**  
 • Do not use if:  
 • you have no family history of hair loss  
 • your hair loss is sudden and/or patchy  
 • you are under 18 years of age  
 • you use other medicines on the scalp  
 • you use other medicines on the body  
 • you have had a heart attack, stroke, or chest pain  
 • you are pregnant or breastfeeding  
 • you are taking medicine for high blood pressure  
 • you are taking medicine for heart disease  
 • you are taking medicine for diabetes  
 • you are taking medicine for thyroid disease  
 • you are taking medicine for depression  
 • you are taking medicine for anxiety  
 • you are taking medicine for asthma  
 • you are taking medicine for allergies  
 • you are taking medicine for colds or flu  
 • you are taking medicine for pain  
 • you are taking medicine for infection  
 • you are taking medicine for skin conditions  
 • you are taking medicine for eye conditions  
 • you are taking medicine for ear conditions  
 • you are taking medicine for nose conditions  
 • you are taking medicine for throat conditions  
 • you are taking medicine for mouth conditions  
 • you are taking medicine for skin conditions  
 • you are taking medicine for eye conditions  
 • you are taking medicine for ear conditions  
 • you are taking medicine for nose conditions  
 • you are taking medicine for throat conditions  
 • you are taking medicine for mouth conditions

**When using this product:**  
 • do not apply to other parts of the body  
 • avoid contact with eyes, nose, mouth, or throat  
 • avoid contact with cool tap water  
 • stop use and ask a doctor if:  
 • you experience dizziness, lightheadedness, or fainting  
 • you experience chest pain, shortness of breath, or rapid heartbeat  
 • you experience swelling of the face, lips, or tongue  
 • you experience difficulty breathing  
 • you experience changes in voice  
 • you experience changes in taste  
 • you experience changes in vision  
 • you experience changes in hearing  
 • you experience changes in smell  
 • you experience changes in touch  
 • you experience changes in pain  
 • you experience changes in temperature  
 • you experience changes in sweating  
 • you experience changes in skin conditions  
 • you experience changes in eye conditions  
 • you experience changes in ear conditions  
 • you experience changes in nose conditions  
 • you experience changes in throat conditions  
 • you experience changes in mouth conditions

**One Month Supply**  
 60 mL (2 fl oz)

**LOT:** 820013101  
**EXP:** 11/2004

**Prater Consumer Healthcare**  
 Morris Plains, NJ 07950, U.S.A.  
 © 2004 Pfizer, Inc.

**Read and keep carton and booklet for full product information.**  
**Active ingredient:** Minoxidil 2% w/v  
**Warnings:** For external use only  
**Flammable:** Keep away from fire or flame  
**Do not use if:**  
 • you have no family history of hair loss  
 • your hair loss is sudden and/or patchy  
 • you are under 18 years of age  
 • you use other medicines on the scalp  
 • you use other medicines on the body  
 • you have had a heart attack, stroke, or chest pain  
 • you are pregnant or breastfeeding  
 • you are taking medicine for high blood pressure  
 • you are taking medicine for heart disease  
 • you are taking medicine for diabetes  
 • you are taking medicine for thyroid disease  
 • you are taking medicine for depression  
 • you are taking medicine for anxiety  
 • you are taking medicine for asthma  
 • you are taking medicine for allergies  
 • you are taking medicine for colds or flu  
 • you are taking medicine for pain  
 • you are taking medicine for infection  
 • you are taking medicine for skin conditions  
 • you are taking medicine for eye conditions  
 • you are taking medicine for ear conditions  
 • you are taking medicine for nose conditions  
 • you are taking medicine for throat conditions  
 • you are taking medicine for mouth conditions

**When using this product:**  
 • do not apply to other parts of the body  
 • avoid contact with eyes, nose, mouth, or throat  
 • avoid contact with cool tap water  
 • stop use and ask a doctor if:  
 • you experience dizziness, lightheadedness, or fainting  
 • you experience chest pain, shortness of breath, or rapid heartbeat  
 • you experience swelling of the face, lips, or tongue  
 • you experience difficulty breathing  
 • you experience changes in voice  
 • you experience changes in taste  
 • you experience changes in vision  
 • you experience changes in hearing  
 • you experience changes in smell  
 • you experience changes in touch  
 • you experience changes in pain  
 • you experience changes in temperature  
 • you experience changes in sweating  
 • you experience changes in skin conditions  
 • you experience changes in eye conditions  
 • you experience changes in ear conditions  
 • you experience changes in nose conditions  
 • you experience changes in throat conditions  
 • you experience changes in mouth conditions

EDP 693668

NOTE: IMPRINT AREA  
 NO VARNISH

1.0

0.1250

Cyrano

820013101-RoWmSc\_L\_7635.ai  
 2/4/21 PM 11/2/04

(b)(6)

- 7563 Reg Wom PS Lbl DppCy Op3b 9:45:16 AM 7/6/04
- 7498 Reg Wom PS Lbl DppCy Op3 10:49:54 AM 6/14/04
- 7498 Reg Wom PS Lbl DppCy Op3 9:40:39 AM 2/18/04
- Was 7393C Reg Wom PS Lbl DppCy3 9:40:39 AM 2/18/04
- 7361 Reg Wom PS Label Dbr/Dpp2 2:59:54 PM 9/9/03
- 7236 Rogaine Women PS Lbl B3 10:32:51 AM 7/18/03

Color: GRAY 7, BLACK, WHITE, PMS 877, PANTONE 2572, PANTONE 2572, PANTONE Black, VARNISH

Product	CCS#	EDP#	Copy Code	NDC
Women Rogaine PS Bottle Label Fragrance	4768-00	693668	820013101	0501-4002-60

Option 3:

- A) New pregnancy warning may be harmful if used without treatment or breast-feeding
- B) Removed the space between Minoxidil and Hair Regrowth Treatment

7.1.04

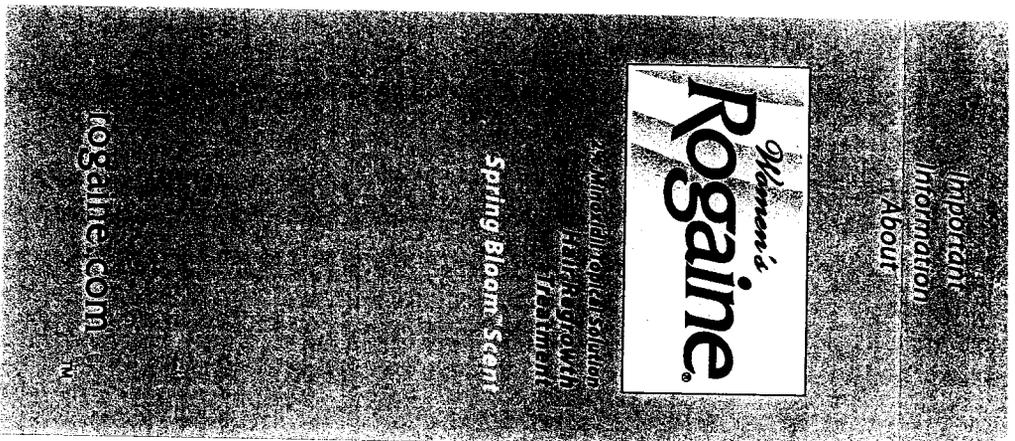
Option 3b:  
 Updated EDP & Copy code (New label Material)

7.6.04

Updated NDC in info box per MAT: 0501-4002-60

11.2.04

Myriad MM to Reg Myriad  
 Cleaned up Swatch & Type Usage



*Patient Package Insert  
 Women's Rogaine (oxertis)  
 12/20/2004*

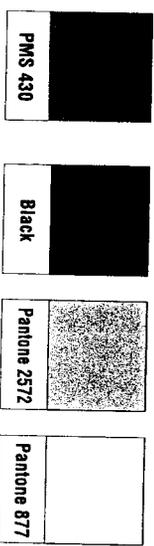
**X**

Signature  
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Digitally signed  
 by Kathy Lowe  
 DN: cn=Kathy  
 Lowe,  
 o=Pharmacia,  
 ou=Composition,  
 c=US  
 Date: 2004.04.06  
 11:03:58 -0400  
 Reason:  
 Document is  
 released



Composition Unit 2566



COMPOSITION ORDER #	23444	PRODUCT	Women's Rogaine 2% (Fragrance w/dropper)		COPY CODE #	820 011 001		
CCS #	4768-00-000	NDC #	0009-5292-01	EDP #	691717	ITEM	Booklet Insert Cover	
BOTTLE #		SIZE	2 X 5.5"	IMPRINT AREA		DRAWING #		
ADDITIONAL INFORMATION							DESIGNED BY	
							DATE	4-6-04

Pantone® colors used in this proof may not match the Pantone® solid color standards. Use current Pantone® swatch guide for most accurate color.

# Patient Package Insert

## Women's Rogaine®

2% Minoxidil Topical Solution  
Spring Bloom™ Scent

Save booklet for future reference.

- Women's Rogaine with Spring Bloom™ Scent, the only treatment proven to regrow hair in women, with a soft floral fragrance.
- Hair regrowth treatment
- Previously available only by prescription

Over 30 million American women experience hair thinning or hair loss, so you're not alone. Women's Rogaine contains the only ingredient that is medically proven effective to help regrow hair in women.

Please read this booklet carefully. It will help you understand how to use Rogaine and what to expect from its use. If you have any questions after reading this booklet, or anytime while using Women's Rogaine, you should ask your health care professional or call us at **1-800-ROGAINE (1-800-764-2463)**. You can also visit our website at **rogaïne.com**.

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### What is Women's Rogaine?

Rogaine is a colorless liquid medication for use only on the top of the scalp to help regrow hair.

### Who may use Women's Rogaine?

Women's Rogaine may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Women's Rogaine is for general thinning of hair on the top of the scalp as shown on the next page. Rogaine has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Rogaine may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. **If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.**

1

2



Black

Composition Unit 2566

COMPOSITION ORDER # 23444		PRODUCT Women's 2% Fragr w/dropper	
COPY CODE # 820 011 001		CCS # 4768-00	NDC # 0009-5292-01
EDP # 691717	ITEM Booklet	SIZE 2 x 5.5"	FOLDED SIZE
DRAWING #	REV #	ADDITIONAL INFO	DATE 4-6-04
			TYPESET BY



Black

Composition Unit 2566

COMPOSITION ORDER # 23444		PRODUCT Women's 2% Fragr w/dropper	
COPY CODE # 820 011 001		CCS # 4768-00	NDC # 0009-5292-01
EDP # 691717	ITEM Booklet	SIZE 2 x 5.5"	FOLDED SIZE
DRAWING #	REV #	ADDITIONAL INFO	DATE 4-6-04
			TYPESET BY (b)(4)

# Patient Package Insert



3

**Who should NOT use Women's Rogaine?**

Rogaine will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Rogaine will not improve hair loss due to:

- damage from the use of hair care products which cause scarring or deep burns of the scalp.
- hair grooming methods such as crowning or ponytails which require pulling the hair tightly back from the scalp.

Do not use Rogaine if hair loss is patchy as shown below.

**You should ask your doctor if you are unsure of the cause of your hair loss.**

4



Black

Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		b14	



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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		b14	

# Patent Package insert

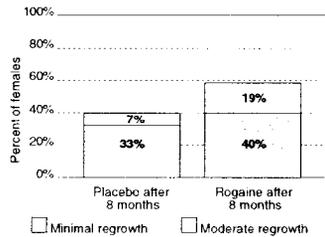
## Will Women's Rogaine work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Rogaine. The response to Rogaine cannot be predicted. No one will be able to grow back all their hair.

In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to Rogaine was reported:

### Female Response to Rogaine

Percent reporting hair regrowth



19% of women reported moderate hair regrowth after using Rogaine for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).

5

## What Minimal, Moderate and Dense Hair Regrowth Will Mean For You

	Number of Hairs	Hair Density
Minimal	Some new hairs are seen, but not enough to cover thinning areas.	Hairs in thinning areas do not grow as closely together as hairs on the rest of the head.
Moderate	New hairs cover some or all of thinning areas.	Hairs in the thinning areas grow more closely together, but are not as close together as hairs on the rest of the head.
Dense	New hairs cover, or almost completely cover, thinning areas.	Hairs in thinning areas grow as closely together as hairs on the rest of head.

### Can Women's Rogaine be used to prevent hair loss?

We do not know if Rogaine will prevent hair loss.

### How soon can I expect results from using Women's Rogaine?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Rogaine also takes time. Generally new hair growth is slow for a Rogaine user. Continued use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth.

6



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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			4-6-04
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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		[Signature]	

# Patient Package Insert

If you do not see hair regrowth in 4 months, stop using Rogaine and see your doctor.

When you first begin to use Rogaine, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

**If Women's Rogaine is working, what will the hair look like?**

At first, hair growth may be soft, downy, colorless hairs. After further use, the new hairs should be the same color and thickness as the other hairs on your scalp.

**How long do I need to use Women's Rogaine?**

If you respond to Rogaine, you need to use it 2 times a day to keep and continue the hair regrowth. Up to 8 months of usage may be needed to see your best results from Rogaine.

**What happens if I completely stop using Women's Rogaine? Will I keep the new hair?**

Continuous use of Rogaine is needed to maintain hair regrowth. If you stop using Rogaine, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

**What is the dosage of Women's Rogaine?**

You should apply a dose (1 mL) of Rogaine directly onto the scalp in the hair loss area **TWO TIMES A DAY**; for example, once in the morning and once at night. Each bottle should last about one month, if used as directed. Please refer to the "Directions for Use" section of this booklet.

**What if I miss a dose or forget to use Women's Rogaine?**

If you miss one or two daily doses of Rogaine, just continue with your next dose. You should not make up for missed doses.

**Can I use Women's Rogaine more than two times a day? Will it work faster, better?**

No. Rogaine will not work faster or better if used more than two times a day. Studies by Pharmacia have been carefully conducted to determine the correct amount of Rogaine needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chances of side effects.

**What are the most common side effects with Women's Rogaine?**

The most common side effects are itching and other skin irritations of the treated area of the scalp.

7

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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		b7c	

# Patient Package Insert

Rogaine contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Rogaine accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

**What kind of shampoo should I use with Women's Rogaine?**

If you wash your scalp before applying Rogaine, use a mild shampoo.

**Can I use hair sprays, mousses, conditioners, gels, etc.?**

Yes. There is no reason to change your usual hair care routine when using Rogaine. However, you should apply Rogaine first and wait for it to dry before applying your styling aids.

**Can I have my hair colored or permed or use hair relaxers while using Women's Rogaine?**

Yes. We have no information that these treatments change the effect of Rogaine. However, to avoid possible scalp irritation, you should make sure all of the Rogaine has been washed off the hair and scalp before using these chemicals.

**Can I apply Women's Rogaine and wash my hair an hour later?**

No. For Rogaine to work best, you should allow Rogaine to

remain on the scalp for about 4 hours before washing.

**Can I go swimming or out in the rain?**

Yes. Avoid washing off the Rogaine. If possible, apply Rogaine to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Rogaine.

**Can Women's Rogaine produce unwanted hair?**

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Rogaine to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Rogaine.

If you experience unwanted hair, discontinue using Rogaine and see your doctor for recommendations about appropriate treatment. After stopping use of Rogaine, the unwanted hair, if caused by the use of Rogaine, should go away over time.



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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
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EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
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820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		[Signature]	

# Patient Package Insert

You can take steps to decrease the chances for unwanted hair growth: 1) limit the application of Rogaine only to the scalp, 2) if you use your hands to apply Rogaine, wash your hands thoroughly afterwards, and 3) allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Rogaine.

**Can I use Women's Rogaine for baldness or hair loss in babies and children?**

No. Rogaine must not be used to treat baldness or hair loss in babies or children.

**Are there any special warnings about the use of Women's Rogaine?**

**For external use only**

**Flammable: Keep away from fire or flame**

**Do not use if**

- your degree of hair loss is more than that shown on page 3 of this booklet, because this product may not work for you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- you do not know the reason for your hair loss

11

- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

**Ask a doctor before use if you have heart disease.**

**When using this product**

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture
- it takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for everyone.

**Stop use and ask a doctor if**

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs

12



Black

Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		b1/4	



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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		b1/4	

# Patient Package Insert

- you do not see hair regrowth in 4 months

**May be harmful if used when pregnant or breast-feeding. Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**What factors may increase the risk of serious side effects with Women's Rogaine?**

Rogaine should be applied only to the scalp. The risk of side effects may be greater when Rogaine is applied to other parts of the body.

**Directions for Use**

1. Remove the overcap. To remove, line up arrows on bottle and overcap and pull off the overcap.
2. Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
3. Part your hair in the area of hair thinning/loss. Follow the instructions below for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a

mild shampoo if you wash your scalp before applying Rogaine.

**Using the Dropper Applicator**



1. Squeeze the rubber bulb and insert the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze

the extra amount back into the bottle.

2. Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
3. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.



Black

Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		[Signature]	



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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
EDP #	ITEM	SIZE	FOLDED SIZE
691717	Booklet	2 x 5.5"	
DRAWING #	REV. #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	
		[Signature]	

# Patient Package Insert

If you have any other questions, ask your health care professional or call us at **1-800-ROGAINE (1-800-764-2463)**. You can also visit our website at **rogaine.com**.

**Store at Controlled Room Temperature 20° to 25° C (68° to 77° F).**

*Save this booklet for future reference.*

**Pfizer Consumer Healthcare**  
Morris Plains, NJ 07950 U.S.A.

March 2004  
820 011 001

691717

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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
23444		Women's 2% Fragr w/dropper	
COPY CODE #		CCS #	NDC #
820 011 001		4768-00	0009-5292-01
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691717	Booklet	2 x 5.5"	
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			4-6-04
		TYPESET BY	

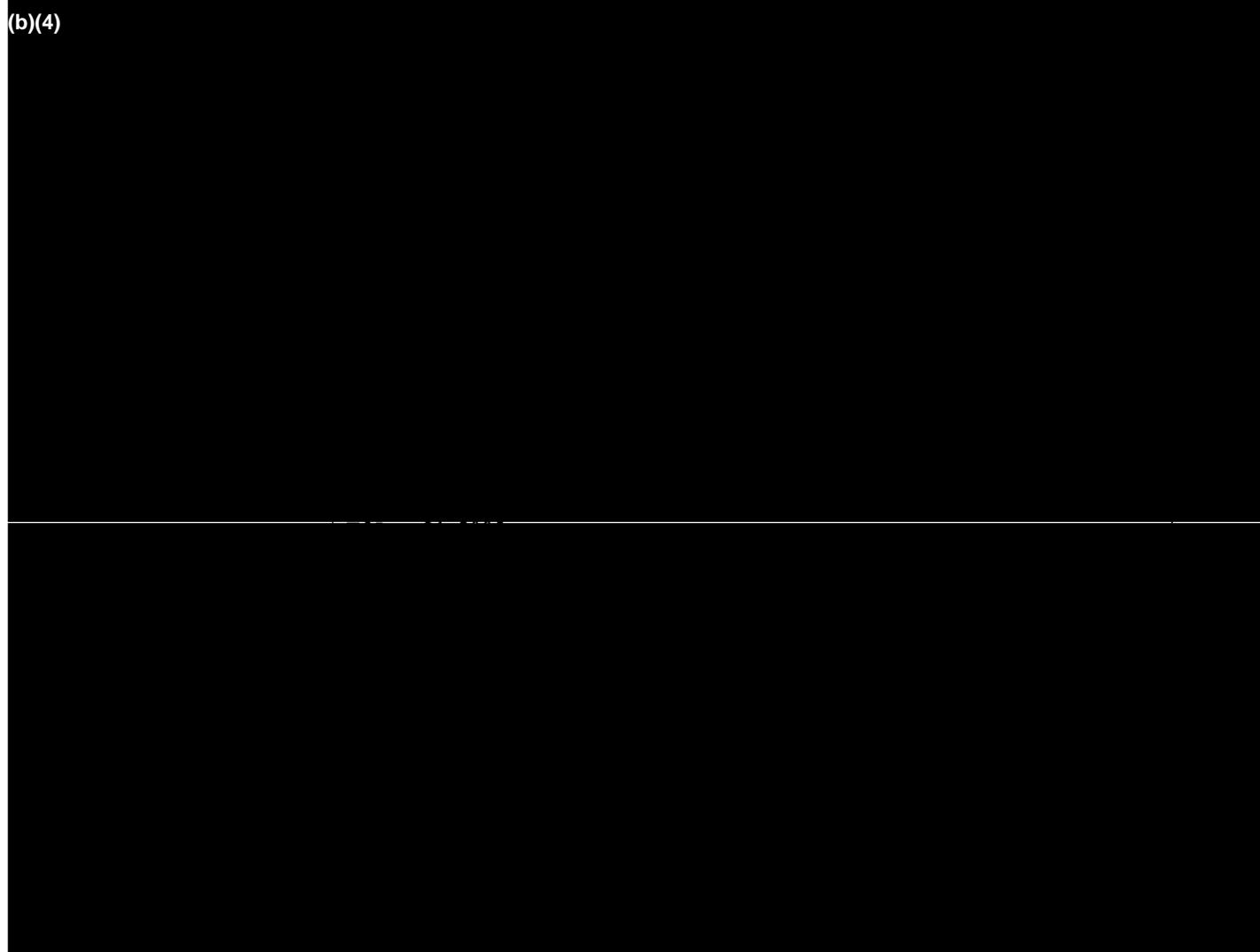


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Composition Unit 2566

COMPOSITION ORDER #		PRODUCT	
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DRAWING #	REV #	ADDITIONAL INFO	DATE
			4-6-04
		TYPESET BY	

(b)(4)



**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**19-501/S025**

**MEDICAL REVIEW(S)**

While (b) (4) can not guarantee that it is the physician who personally responds to the survey, the Sponsor states that (b) (4) attempts to gear the process toward a personal response from the surveyed physician. The survey is personalized and mailed directly to each physician, and the physicians are asked which products and therapies they recommended to their patients. (b) (4) believes that, since such data is usually not charted, other office staff would have little insight as to the physician's verbal recommendations. To offset bogus responses to survey data, (b) (4) employs an editing process to exclude outliers or aberrations. The survey response rates have been consistent over time for each specialty group, indicating stable reporting trends.

The survey respondent receives a \$5 honorarium with the option to donate this \$5 to one of three charities: the American Cancer Society, the American Heart Association, or the Multiple Sclerosis Society. The offer of the small honorarium could probably not be said to rise to the level of influencing a physician's product recommendation, however, the question of whether the survey is really completed by the named dermatologist and not by a member of his office staff is not easily answered, and probably can not be answered definitively.

There are other inherent flaws and weaknesses in the survey process and the survey instrument. The survey instrument does not mention any of the competing store brands or generic products by name. The only OTC products mentioned by brand name are the Rogaine products, and the only other product specifically mentioned by name is the prescription product, Propecia. This may lead the respondent to assign recommendations either more frequently or even exclusively to the three Rogaine products, rather than to unnamed competing OTC products which may not be as easily recalled. Another weakness is that most of the survey responses received each year come from solo or small group physician practices (66.61% in 2003), which does not reflect a broad cross section of the dermatologist population.

Nevertheless, even with the limitations and deficiencies mentioned above, based on the data for 2003 it is not entirely unreasonable for Pfizer to claim that Rogaine hair regrowth products are the "#1 Dermatologist Recommended Brand" using aggregate data. Results collected from 2,655 dermatologists in 2003 show that the dermatologists recommended Rogaine products an average of 9.79 times per week, compared with all non-Rogaine options combined (OTC and Rx) which were recommended an average of 4.20 times per week. When comparing just the OTC options, Rogaine products were recommended an average of 9.79 times per week, compared with store brands or generics that were recommended an average of 1.59 times per week. Note, however, that the claim "#1 Dermatologist Recommended Brand" does not hold true if applied just to the individual Men's Regular Strength Rogaine (2% minoxidil) product, which actually had fewer dermatologist recommendations than Propecia.

**Average Weekly Recommendations Per Physician – National Survey Data from Fourth Quarter 2003**

Responders	Rogaine Women's 2%	Rogaine Men's 2%	Rogaine Men's 5%	All Rogaine Combined	Store Brands/ Generics (Men's)	Store Brands/ Generics (Women's)	Propecia Rx
2,655	3.37	1.75	4.67	9.79	0.93	0.66	2.61

The "#1 Dermatologist Recommended Brand" statement for Rogaine products is based on fairly typical, even though scientifically limited marketing-related survey data. Overall, data for 2003 indicate that Rogaine products received more recommendations, as a brand group, than store

brands or generic products, or the prescription therapy Propecia. On average, the dermatologists who responded to the survey recommended a Rogaine product 69.99% of the time, a generic product 11.35% of the time, and Propecia 18.65% of the time, indicating that those physicians made more\* recommendations for Rogaine products than for Propecia (Rx) or competing OTC store brands/generics. To ensure that the brand claim remains accurate, Pfizer has agreed to examine the quarterly collections of survey data and re-evaluate its claim every 12 months.

**National Survey Data from Fourth Quarter 2003 Brand Share of Hair Growth Therapies**

Responders	Rogaine Women's 2%	Rogaine Men's 2%	Rogaine Men's 5%	All Rogaine Combined	Store Brands/ Generics (Men's)	Store Brands/ Generics (Women's)	Propecia Rx
2,655	24.10	12.51	33.38	69.99	6.62	4.73	18.65

Concerning the use of a seal on the front display panel, the Agency has suggested that the seal is misleading in that it suggests endorsement by a medical society. However, no such statement is made, and with the modified shape of the seal and the removal of the caduceus symbol, it is unlikely that consumers would reach that conclusion. A large number of consumer products on the market today, including many healthcare products, promote themselves with similar seals and statements on the product packaging. Given the proliferation of such seals in the marketplace, it is reasonable to conclude that consumers view these symbols as simply promotional in nature. The modified seal is indicated below.



In its response to FDA's Approvable Letter dated 3/19/04, Pfizer points out that a number of consumer products on the market today promote themselves with brand leadership statements and use seals and emblems on product packaging. Several examples are listed below and are attached to this review (see Appendix). As can be seen, many of the seals and emblems continue to include the caduceus symbol, which Pfizer has actually removed from its own seal.

Phazyme (for gas relief)  
Fleet (glycerin suppositories)  
Efamil (pediatric vitamin drops)  
St. Joseph (aspirin)  
Dulcolax (laxative)  
Feosol (iron supplement)

Alcon (lubricant eye drops)  
Phillips (laxative and antacid)  
Dulcolax (laxative)  
Tylenol (junior strength)  
Tavist (allergy/sinus/headache relief)  
Scalpicin (for seborrheic dermatitis)

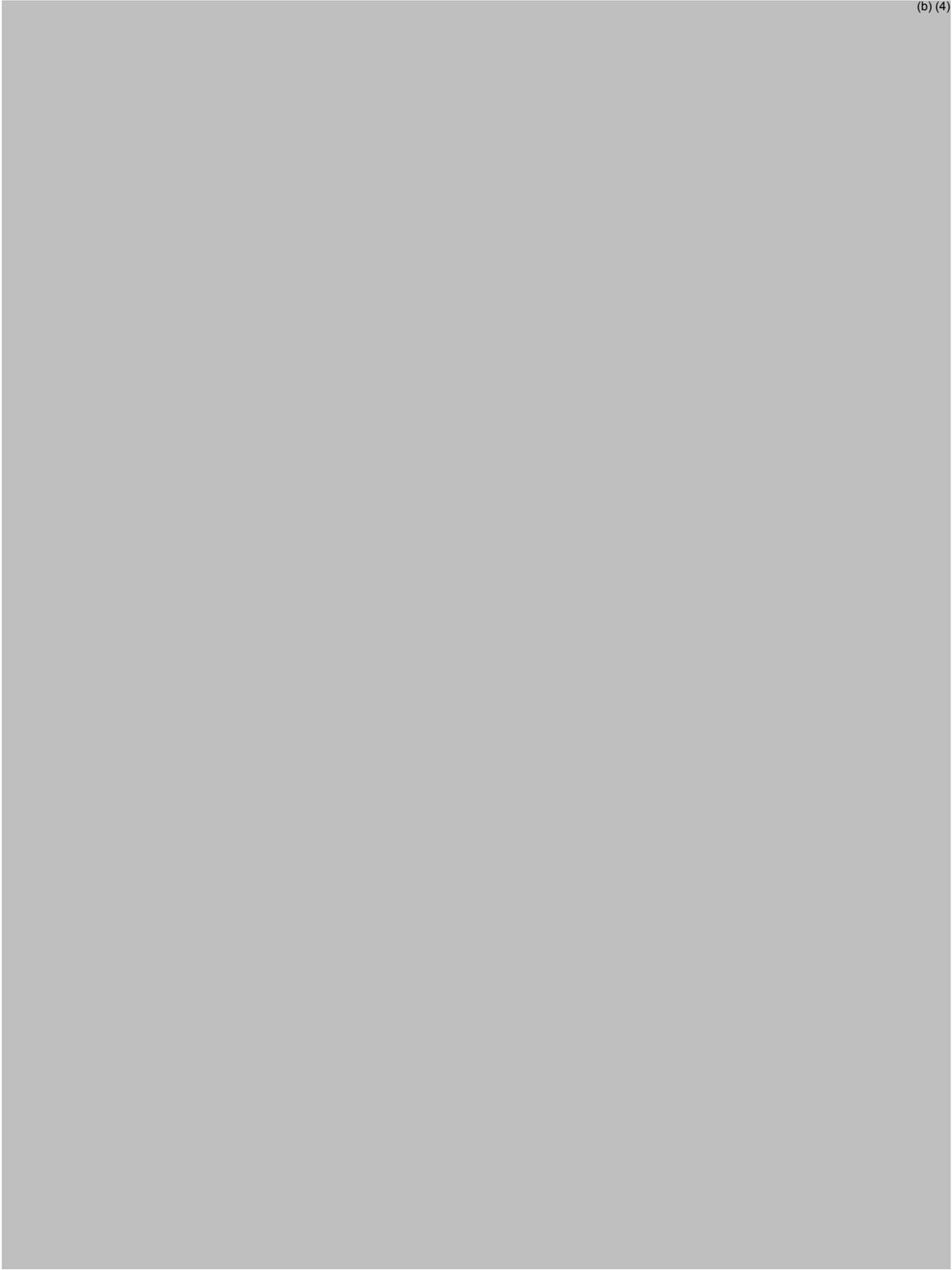
Curel (moisturizing lotion)  
Renu (multipurpose contact lense solution)  
Ecotrin (enteric aspirin)  
Chlortrimeton (antihistemine)  
Dimetapp (nasal decongestant/antihistamine)  
Triaminic (pediatric antihistamine/nasal decongestant)

***Recommendation: Notwithstanding some inherent weaknesses in the marketing data, I would, at this time, approve the claim “#1 Dermatologist Recommended Brand,” and approve the revised seal for the principal display panel on the product packaging.***

\* Sponsor states that these were “statistically significantly more” and needs to supply the P-value to indicate significance.

**Proposed packaging for Rogaine Regular Strength for Men (2% Unscented) and Rogaine 2% for Women (Scented and Unscented) with the revised seal and the "#1 Dermatologist Recommended Brand" claim.**

(b) (4)



## BACKGROUND

Pfizer has submitted this supplement in support of the claim "#1 Dermatologist Recommended Brand" in labeling for Men's Rogaine Regular Strength and Women's Rogaine (2% Minoxidol Topical Solution) products (fragranced and unfragranced) covered by NDA 19-501.

Prior submissions, sNDA S-020, provided labeling for Men's Rogaine Regular Strength and Women's Rogaine (both without fragrance) in the Drug Facts format. That labeling was modified in an August 13, 2002 amendment, and an approvable letter was issued on February 3, 2003.

Supplemental NDA S-021 was submitted on December 2, 2002, which originally provided for (b) (4) a new child-resistant overcap. (b) (4) but the child-resistant overcap was retained. This supplement is at the approvable stage pursuant to the Agency's June 5, 2003 letter.

Supplemental NDA S-024 provided for the addition of a fragrance to Women's Rogaine as an alternate presentation. During the review of supplements S-020, S-021, and S-024, the Agency requested that the claims "#1 Dermatologist Recommended Brand" and "Dermatologist Recommended Brand" (within a "seal" graphic), be deleted from carton labeling pending the submission of satisfactory supporting data. In Pfizer's March 19, 2004 response to the approvable letter for supplement S-024, information was included to support the claim "Dermatologist Recommended Brand".

In a teleconference held with the Agency on June 3, 2004, FDA indicated that both of the above claims have essentially the same meaning (stated or implied), and direction was given to Pfizer as to additional background information that would be needed concerning the survey data submitted in support the claim. In order to facilitate the approval of supplement S-024 (which requested approval of the scented formula), Pfizer agreed to delete the above claim (pending submission of the additional requested data) and the approval letter was issued on June 25, 2004.

With regard to validating the "#1 Dermatologist Recommended Brand" claim, FDA asked Pfizer to submit a description of the survey method, including the following information:

- How were dermatologists selected and sampled?
- What was the response rate for dermatologists?
- Who completed the survey (e.g., physician, nurse, receptionist) and what assurance can be provided to prove that the dermatologists themselves completed the surveys?
- What monetary or other compensation did physicians receive for completing the survey?
- What questions were asked and in what order (i.e., what did the questionnaire look like)?
- What are the demographics (e.g., geographical location, academic/private/public institution, years in practice) of the survey participants?

FDA also told Pfizer to be aware that any data supporting the statement will have to be verified periodically in order to continue including the statement on the label. (*See FDA "Minutes of a Teleconference" June 3, 2004*).

**RESPONSE TO FDA QUESTIONS ON THE SURVEY SUPPORTING THE  
#1 DERMATOLOGIST RECOMMENDED CLAIM**

**1. How were dermatologists selected and sampled?**

The data used to support the claim “#1 Dermatologist Recommended Brand” is collected and processed by (b) (4) (b) (4) which provides marketing data to numerous companies about dozens of product recommendations made by healthcare providers, and collects demographic data from a large number of potential prescribers/recommenders. (b) (4) uses self-administered surveys circulated to more than 455,000 healthcare providers, in 55 healthcare specialties, in 30 therapeutic categories. The healthcare providers include 300,000 physicians, 150,000 dental healthcare providers and 20,000 physician assistants. Each physician receives the survey twice a year and the data is processed on a quarterly basis with a response rate of about 10-20%.

From this universe of prescribers, (b) (4) surveys sub-populations by physician specialty. The basis of survey selection is to ensure that the response universe is similar to the real universe in terms of specialty and state. In other words, if Internal Medicine physicians represent 20% of all doctors in Arizona, the response universe should contain about 20% of Internal Medicine doctors. Within each specialty and state, the physicians with higher response probability are selected using a Logistic Regression model. In the model, all demographic data are used (location, gender, age, type of practice, historical response activity and so on).

**2. What was the response rate for dermatologists?**

The response rates for dermatologists in the last six quarters preceding the submission to FDA were:

Q1 2003 - 28%  
Q2 2003 - 22%  
Q3 2003 - 22%  
Q4 2003 - 19%  
Q1 2004 - 22%  
Q2 2004 - 20%

**3. Who completes the survey (eg. physician, nurse, receptionist) and what assurance can be provided to prove that dermatologists themselves complete the survey?**

Although (b) (4) can not guarantee that the physician (dermatologist) is personally responding to the survey, (b) (4) believes that both the nature of its process and the survey encourage a personal response from the surveyed physician. Each (b) (4) Physician Recommendation survey is personalized and mailed directly to each physician. The physician is asked to complete the survey and instructed on the honorarium check cashing and donation. The nature of questions on the (b) (4) Recommendation Audit are related to medical practices exercised by the medical

professional, in this case, dermatologists. Physicians are asked what OTC therapies they recommended to their patients. (b) (4) believes that, since this data is generally not charted, other office staff would have little or no insight as to the physician's verbal recommendations. To offset bogus responses to survey data, (b) (4) employs an editing process to exclude outliers or aberrations. The survey response rates have been consistent over time for each specialty group, also indicating a stable reporting trend of specialty recommendations.

**4. What monetary or other compensation did physicians receive for completing the survey?**

The dermatologists receive a \$5 honorarium with the option to donate this \$5 to one of three charities: the American Cancer Society, the American Heart Association, or the Multiple Sclerosis Society.

The honorarium section of the survey is as follows.

(b) (4)

##### **5. What questions were asked and in what order (what did the questionnaire look like)?**

The questionnaire asked the physicians to indicate the total number of times they recommend products listed in a variety of categories, not just hair growth products. The questionnaire asked the respondents to report any recommendation they make for non-brand-specific products (i.e., generics) under the heading Store Brands/Generics, and to skip products they do not recommend.

(b) (4)



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As mentioned earlier, there are some inherent weaknesses in the survey process and the survey instrument: (1) The survey instrument does not mention any of the competing store brands or generic products by name. This may lead respondents to assign recommendations more frequently or even exclusively to the three named Rogaine products, rather than to unnamed competing OTC products which may not be as easily recalled. (2) Most of the survey responses come from solo or small group physician practices (66.61% in 2003), which does not reflect a broad cross section of the dermatologist population. (3) There is absolutely no guarantee that it is the dermatologist who is completing the questionnaire rather than one of his/her office staff.

Listed on the following page is the Hair Growth Therapy category which included the items that yielded data for the “#1 Dermatologist Recommended” claim. Dermatologists were asked to indicate their weekly average frequency for recommending Rogaine versus generic and/or store brand OTC hair growth products, versus Propecia, which is the prescription hair growth product.



**6. What are the demographics (eg. geographical location, academic/private/public institution, years in practice) of the survey participants?**

(b) (4) receives information on the universe of prescribers/recommenders from various associations including the American Medical Association. The AMA’s master list is used as the basis for the survey and includes all states, zip codes, age groups, medical specialties, and types of practices. The following table indicates the types of physician practices from which survey responses are received. These range from solo physician practices (44.51%), to group practices (22.10%), HMOs (0.42%), medical schools (1.64%), government hospitals and other medical facilities (1.95%), and private hospitals and clinics (7.17%).

**TABLE 1: TYPES OF PRACTICES**

A large rectangular grey box redacts the table content. The text "(b) (4)" is visible in the top right corner of this redacted area.

(b) (4) also attempts to include physicians with a range of years of experience in its population. The number of years in practice ranged from one year or less to 66 years, with the highest percentage of respondents falling in the range of 20-40 years in practice.

**TABLE 2: YEARS IN PRACTICE**

(b) (4)

**The Survey Results**

*Definitions and Categories of Data Collected:* Brand Management Reports have provided Average Weekly Recommendations per Physician and Brand Share data based on dermatologist recommendations for the Hair Growth Therapy category, on a quarterly basis, from 1998 through 2003, including the last 9 quarters.

Average Weekly Recommendations (AWR) per Physician is the value calculated by dividing the total weekly recommendations for a product or a category reported by the responder sample, by the number of physicians in the responder sample.

The Category is the combination of all products listed in the category. The Category Average Weekly Recommendations per Physician is the total of Average Weekly Recommendations of all products in the category.

The Brand Share (or Share Recommendations) is a product's percentage of the total Category's AWRs. It equals the sum of recommendations for a specific product in a category divided by the sum of the recommendations for all products in the category

The Moving Annual Total (MAT) of AWR's/physician or Brand Share is based on the most recent rolling four quarters (i.e. Q403 MAT = Q403, Q303, Q203 and Q103).

*Results from 2003:* The data for 2003, collected from 2,655 dermatologists, shows that the dermatologists recommended a Rogaine product on average 9.79 times per week, a generic topical minoxidil product 1.59 times per week and Propecia (the Rx brand) 2.61 times per week.

**National Survey Data from Fourth Quarter 2003**  
**Average Weekly Recommendations Per Physician**

Responders	Rogaine Women's 2%	Rogaine Men's 2%	Rogaine Men's 5%	All Rogaine Combined	Store Brands/ Generics (Men's)	Store Brands/ Generics (Women's)	Propecia Rx
2,655	3.37	1.75	4.67	9.79	0.93	0.66	2.61

A Brand Share calculation from this data indicates that, on average, dermatologists recommend a Rogaine product 69.99% of the time, a generic product 11.35% of the time, and Propecia 18.65% of the time, revealing that in 2003 there were more \* recommendations made by dermatologists for Rogaine than for Propecia (the prescription brand) which had the second highest number of recommendations in the Hair Growth Therapy category.

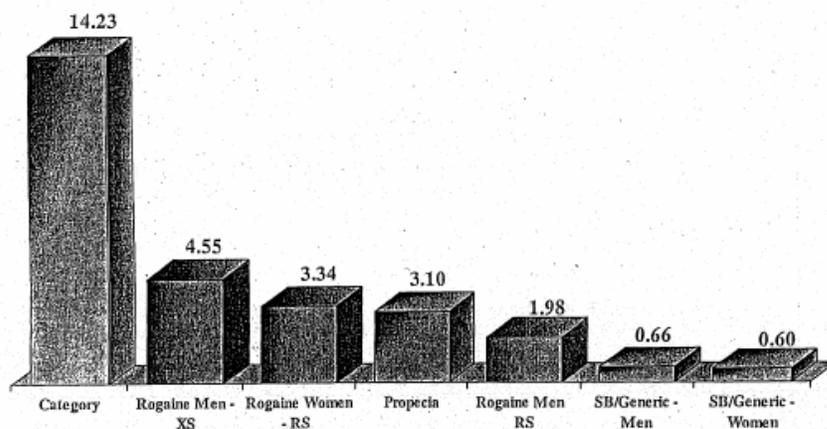
**National Survey Data from Fourth Quarter 2003**  
**Brand Share of Hair Growth Therapies**

Responders	Rogaine Women's 2%	Rogaine Men's 2%	Rogaine Men's 5%	All Rogaine Combined	Store Brands/ Generics (Men's)	Store Brands/ Generics (Women's)	Propecia Rx
2,655	24.10	12.51	33.38	69.99	6.62	4.73	18.65

The Sponsor also included a histogram displaying data collected by (b) (4) showing Average Weekly Recommendations per office-based dermatologist for the year 2001. Although the information in this chart is out-of-date, it may be worth noting that Rogaine has been the most recommended brand among hair regrowth products since its OTC launch in 1996.

Time Frame = Moving Annual Total  
(MAT = Q1'01, Q2'01, Q3'01, Q4'01)

Responders = 2410



\* Sponsor states there were "statistically significantly more" and needs to supply the P-value to indicate significance.

The bar-graph shows that of the 2,410 dermatologists (out of an approximate total of 7,500 office-based dermatologists) who responded to the survey asking for their average weekly recommendations, Rogaine Extra Strength for Men was recommended on average 4.55 times per week; Women's Rogaine (Regular Strength) was recommended 3.34 times on average per week; Men's Regular Strength Rogaine was recommended 1.98 times per week on average, and store/generic brands were recommended 0.66 and 0.60 times per week, on average, for men's and women's hair growth products respectively.

### **CONCLUSIONS**

There are some inherent flaws and weaknesses in the survey process and the survey instrument. The survey instrument does not mention any of the competing store brands or generic products by name. The only OTC products mentioned by brand name are the Rogaine products, and the only other product specifically mentioned by name is the prescription product, Propecia. This may lead respondents to assign recommendations more frequently or even exclusively to the three Rogaine products, rather than to unnamed competing OTC products, which may not be as easily recalled. Another weakness is that most of the survey responses received each year come from solo or small group physician practices (66.61% in 2003), which does not reflect a broad cross section of the dermatologist population. Also, the question of whether the survey is really completed by the named dermatologist and not by a member of his office staff is not easily answered, and probably can not be answered definitively.

Nevertheless, even with the limitations and deficiencies mentioned above, based on the data for 2003 it is not entirely unreasonable for Pfizer to claim that Rogaine hair regrowth products are the "#1 Dermatologist Recommended Brand" using aggregate data. Results collected from 2,655 dermatologists in 2003 show that the dermatologists recommended Rogaine products an average of 9.79 times per week, compared with all non-Rogaine options combined (OTC and Rx) an average of 4.20 times per week. When comparing just the OTC options, Rogaine products were recommended an average of 9.79 times per week, compared with store brands or generics that received an average of 1.59 recommendations per week. Note, however, that the claim "#1 Dermatologist Recommended Brand" does not hold true if applied just to the individual Men's Regular Strength Rogaine (2% minoxidil) product, which actually had fewer dermatologist recommendations, on average, than Propecia.

Concerning the use of a seal on the front display panel, the Agency has suggested that such a seal implies that the product is endorsed by a medical organization. However, no such statement is made, and with the modified shape of the seal and the removal of the caduceus symbol, it is unlikely that consumers would reach that conclusion. A large number of consumer products on the market today, including many healthcare products, promote themselves with similar seals and statements on the product packaging. Given the proliferation of such seals in the marketplace, it is reasonable to conclude that consumers view these seals as merely promotional in nature.

***Recommendation: Notwithstanding some inherent weaknesses in the marketing data, I would, at this time, approve the claim "#1 Dermatologist Recommended Brand," and approve the revised seal for the principal display panel on the product packaging.***

-----  
Susanna Weiss, Ph.D., J.D.  
Social Science Analyst  
Division of Nonprescription Clinical Evaluation  
Office of Nonprescription Products

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Curtis Rosebraugh, M.D., M.P.H.  
Director  
Division of Nonprescription Clinical Evaluation  
Office of Nonprescription Products

Attached Appendix: Examples of healthcare products that use seals, including seals with the caduceus symbol.

Phazyme (for gas relief)  
Curel (moisturizing lotion)  
Phillips (milk of magnesia laxative and antacid)  
Efamil (pediatric vitamin drops)  
Ecotrin (enteric aspirin)  
St. Joseph (aspirin)  
Chlortrimeton (antihistamine)  
Dulcolax (laxative)  
Dimetapp (nasal decongestant & antihistamine)

Alcon (lubricant eye drops)  
Fleet (glycerin suppositories)  
Renu (multipurpose contact lense solution)  
Dulcolax (laxative)  
Scalpicin (seborrheic dermatitis anti-itch liquid)  
Tylenol (junior strength)  
Triaminic (pediatric antihistamine & nasal decongestant)  
Tavist (allergy/sinus/headache relief)  
Feosol (iron supplement)

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Curtis Rosebraugh  
6/3/05 07:19:56 AM  
MEDICAL OFFICER

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**19-501/S025**

**OTHER REVIEW(S)**



# OTC Drug Labeling Review for Men's & Women's Rogaine

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## Office of Nonprescription Products

Center for Drug Evaluation and Research • Food and Drug Administration  
Rockville • MD 20857

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<b>SUBMISSION DATE(S):</b>	December 20, 2004 May 23, 2005	<b>RECEIVED DATE(S):</b>	December 22, 2004 May 23, 2005
<b>REVIEW DATE:</b>	June 7, 2005		
<b>NDA/SUBMISSION TYPE:</b>	NDA 19-501 (SLR025)		
<b>SPONSOR:</b>	Pfizer Consumer Healthcare		
<b>DRUG PRODUCT:</b>	Men's & Women's Rogaine		
<b>ACTIVE INGREDIENT:</b>	2% minoxidil topical solution		
<b>PHARMACOLOGICAL CATEGORY:</b>	Hair regrowth treatment		
<b>STOCK KEEPING UNITS:</b>	submitted carton, bottle, & package insert labeling for 60 mL (2 fl oz) unscented men's product & unscented & scented women's products		
<b>REVIEWER:</b>	Matthew R. Holman, Ph.D.		

**BACKGROUND**

On December 20, 2004, the sponsor submitted supplement SLR-025 to include a new “#1 dermatologist recommended” claim on the carton label for the following products:

- Men's unscented Rogaine
- Women's unscented Rogaine
- Women's scented Rogaine

This submission responds to an approvable letter that FDA sent the sponsor on March 5, 2004, for S-024. The letter outlined the type of information necessary to support the claim.

**REVIEWER'S COMMENTS**

With the exception of adding the new “#1 dermatologist recommended” claim, the proposed labeling is identical to the last approved labeling, which was approved on June 25, 2004 (S-024). Pending the social scientist's review of the information submitted to support this claim, the labeling is acceptable as proposed.

**RECOMMENDATIONS**

If the social scientist finds the submitted data and information sufficient to support the “#1 dermatologist recommended” claim, issue an approval letter for Men's unscented regular strength Rogaine and Women's unscented and scented regular strength Rogaine (2% minoxidil) and request final printing labeling.

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/s/

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Matthew Holman  
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INTERDISCIPLINARY

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**19-501/S025**

**ADMINISTRATIVE and CORRESPONDENCE**  
**DOCUMENTS**

**MEMORANDUM OF TELECONFERENCE MEETING**

DATE: June 20, 2005

APPLICATION NUMBERS: 1) sNDA 19-501/S-021

2) [REDACTED] (b) (4)

**BETWEEN:**

Name: Dina Russello  
Phone: 973-385-4909  
Representing: Pfizer Consumer Healthcare

**AND**

Name: Tia Frazier  
Division of Nonprescription Clinical Evaluation, HFD-560

SUBJECT: Ongoing regulatory issues related to sNDA 19-501/S-021 and sNDA 20-834/S-010

RE: sNDA 19-501/S-021:

Ms. Russello telephoned me at my request. I acknowledged Pfizer's June 7, 2005 correspondence to S-025 requesting that FDA consolidate this supplement with application S-021. I first reviewed the changes proposed in S-021 with Ms. Russello, which are as follows: [REDACTED] ) new bottle and overcap modifications, and 3) changes to the product carton, label, and package insert. We reviewed the fact that Pfizer's June 7, 2005, correspondence to application S-025 requests that we consider the information in that amendment, together with the contents of application S-025, as a complete response to application S-021. I explained that, to close S-021, Pfizer must instead submit a complete response to all of the deficiencies outlined in the June 5, 2003, approvable letter for that supplement in order to allow for a thorough review of the submitted information.

[REDACTED] (b) (4)

Ms. Russello verbalized understanding of the information that was conveyed on the telephone, and the conversation concluded cordially.

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Tia Frazier, R.N., M.S.  
Regulatory Project Manager

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Tia Frazier  
6/22/05 12:49:25 PM  
CSO

SLR-025(SA)  
NDA SUPPL AMENDMENT



## Consumer Healthcare

June 7, 2005

Curtis Rosebraugh, M.D., Acting Director  
Division of Nonprescription Clinical Evaluation (HFD-560)  
Office of Nonprescription Drug Products  
Center for Drug Evaluation and Research  
Food and Drug Administration  
9201 Corporate Blvd.  
Rockville, MD 20850

RECEIVED  
JUN 08 2005  
MEGA / CDER

**Re:** NDA 19-501/Amendment to S-025  
Men's Rogaine® Regular Strength/Women's Rogaine® 2% Minoxidil  
Topical Solution

**Subject:** #1 Dermatologist Recommended Brand Claim  
Consolidation with S-020 (Drug Facts)  
Consolidation with S-021 (b) (6) CR-SF Overcap/Product Name/Labeling  
Changes)

Dear Dr. Rosebraugh:

In response to the telephone request made by Tia Frazier of your Division on May 31, 2005 for clarification regarding our request to consolidate supplements S-020 and S-021 with this supplement (S-025), the following information is provided.

Supplement S-020, dated March 22, 2002, was a CBE labeling supplement providing for adoption of the Drug Facts format for the Rogaine 2% products. Our amendment of August 13, 2002 responded to your approvable letter of July 12, 2002, and a second approvable letter was then issued on February 3, 2003. That letter (see **Attachment #1**) requested that the pregnancy warning read "May be harmful if used when pregnant or breast-feeding." for both men's and women's products. At the time, these products were both unscented formulations. Subsequently, supplement S-024 was filed to add a fragrance to the women's product as an alternate presentation. Labeling for that supplement was approved on June 25, 2004 with the pregnancy warning requested in your February 3, 2003 approvable letter for supplement S-020. Draft labeling implementing the same pregnancy warning in the men's product and the unscented women's product was later included in supplement S-025. Hence, our request for consolidation of supplement S-020 into S-025 would complete the

ORIGINAL

Drug Facts approval for the remaining Rogaine 2% products with the new pregnancy warning.

Supplement S-021, dated December 2, 2002, was a CBE-30 supplement providing for (b) (4) changes in the bottle exterior and overcap configuration to meet child-resistant/senior-friendly (CR/SF) packaging requirements, and labeling changes which are detailed in the attached cover letter for that submission (see **Attachment #2**).

In the Agency's responding approvable letter, dated June 5, 2003 (see **Attachment #3**), several requests were made as follows:

1. (b) (4)
2. (b) (4)
3. Delete the claim, "DERMATOLOGIST RECOMMENDED BRAND" and the associated seal or provide supporting information.

The following point by point response to these items is offered as follows:

1. In the annual report for 2004, we informed the Agency (b) (4)  
(b) (4)
2. (b) (4)
3. Following discussions with the Agency, supplement S-025 was submitted on December 20, 2004 in support of a "#1 Dermatologist Recommended Brand" claim for use in labeling. This supplement is still under review.

**Therefore, we repeat our request that supplements S-020 and S-021 be consolidated into your review of supplement S-025 for the sake of simplicity in resolving all open labeling issues for Rogaine 2% products.**

This submission contains confidential/trade secret information to which all claims of privilege and confidentiality are asserted in both statutory and common law. Further dissemination may only be made with the express written permission of Pfizer Inc.

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If there are any questions regarding this submission, please contact me at the telephone number below.

Sincerely,



Dina Russello  
Director Regulatory Affairs  
973-385-4909

Attachments



## Consumer Healthcare

May 23, 2005

Central Document Room  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5901-B Ammendale Road  
Beltsville, MD 20705

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MAY 24 2005

CDR / CDER

SLR-015-BL

**Attention:** Charles Ganley, M.D., Director  
Division of OTC Drug Products (HFD-560)  
Office of Drug Evaluation V

NDA SUPPL AMENDMENT

**Re:** NDA 19-501/S-025  
Men's Rogaine® Regular Strength and Women's Rogaine 2% Minoxidil Topical Solution

**Subject:** Electronic Regulatory Submission for Archive  
Labeling Supplement – “#1 Dermatologist Recommended Brand”  
Consolidation with Supplement S-020 and S-021

Dear Dr. Ganley:

Reference is made to the above noted labeling supplement (NDA 19-501/S-025) submitted on December 20, 2004 in support of the claim “#1 Dermatologist Recommended Brand” in labeling for Rogaine products (fragranced and unfragranced) covered by NDA 19-501.

Pursuant to Ms. Tia Frazier's your request of May 19, 2005 for electronic copies of selected sections of this submission, enclosed please find the following items.

- Item 1 Cover Letter
- Item 2 PDP Labeling
- Item 3 Pages 1-2 and Appendix 1 of Attachment 3
- Item 4 Attachment 4 (excluding the cover letter)
- Item 5 Attachment 5

ORIGINAL

These files were scanned with McAfee Virus Scan, Version 4.5.1 SP1, Virus Definition 4.0.4497, Scan Engine 4.4.00 and are virus free.

This submission contains confidential/trade secret information to which all claims of privilege and confidentiality are asserted in both statutory and common law. Further dissemination may only be made with the express written permission of Pfizer Inc.

Please call me at the number below should you have any questions concerning this submission.

Sincerely,



Dina R. Russello  
Director Regulatory Affairs  
(973) 385-4909

**Frazier, Tia**

---

**To:** Dina Russello (dina.rusello@pfizer.com)  
**Subject:** Request for electronic copies of sNDA submissions  
**Contacts:** Dina Russello

**RECEIVED**  
**MAY 19 2005**  
**HFD-560/CDER**

Dina,

I write to request electronic copies of the selected sections of the NDAs below:

NDA 20-834 Supplement 009 dated 11/29/04

Cover letter, PDP, pages 1-2 and Appendix 1 of Attachment 3, contents of Attachment 4 excluding your company's 8/13/2002 letter, and the entire contents of attachment 5.

NDA 19-501 Supplement 025 dated 12/20/04

Cover letter, PDP, pages 1-2 and Appendix 1 of Attachment 3, Contents of Attachment 4 excluding your 8/13/2002 cover letter and the entire contents of attachment 5.

Receiving these items electronically (in editable format such as Word, if possible) will help us expedite our review of these applications. If you are not able to send every item, simply send what you can. You may send these items in a CD or via e-mail directly to me as a review aid as long as you send an identical copy to the EDR.

Thank-you very much.

Tia Frazier, R.N., M.S.

Regulatory Project Manager

Division of Over-the-Counter Drug Products

Office of Drug Evaluation V

Telephone: 301-827-2271

Fax: 301-827-2315

E-mail: frazier1@cder.fda.gov

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

-----  
Tia Frazier  
5/20/05 09:13:36 AM  
CSO



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## Consumer Healthcare

December 20, 2004

Charles Ganley, M.D., Director  
Division of OTC Drug Products (HFD-560)  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research  
Food and Drug Administration  
9201 Corporate Blvd.  
Rockville, MD 20850

**Re: NDA 19-501**  
**Men's Rogaine® Regular Strength and Women's Rogaine®**  
2% Minoxidil Topical Solution  
**Labeling Supplement**

**Subject: “#1 Dermatologist Recommended Brand” Claim**  
Consolidation with Supplements S-020 and S-021

Dear Dr. Ganley:

This supplemental NDA is submitted in support of the claim “#1 Dermatologist Recommended Brand” in labeling for Rogaine products (fragranced and unfragranced) covered by NDA 19-501.

Please refer to sNDA S-020, which provided labeling for Men's Rogaine Regular Strength and Women's Rogaine (both without fragrance) in the Drug Facts format. That labeling was modified in our August 13, 2002 amendment, and an approvable letter was issued on February 3, 2003. Representative carton labels from this supplement are included in **Attachment #1**.

Supplemental NDA S-021 was submitted on December 2, 2002, which originally provided for (b) (4)  
a new child-resistant overcap. (b) (4)

(b) (4) but the child-resistant overcap was retained. This supplement is at the approvable stage pursuant to the Agency's June 5, 2003 letter.

Also, please refer to supplemental NDA S-024, which provided for the addition of a fragrance to Women's Rogaine as an alternate presentation. During the review of supplements S-020, S-021, and S-024, the Agency requested that the claims “#1 Dermatologist Recommended Brand” and “Dermatologist Recommended Brand” (within a “seal” graphic), be deleted from carton labeling pending the submission of satisfactory supporting data. In Pfizer's March 19, 2004 response to the approvable letter for supplement S-024, information was included to support the claim “Dermatologist Recommended Brand”. In a teleconference held with the Agency on June 3, 2004, FDA indicated that both of the above claims have essentially the same meaning (stated or implied), and direction was given as to the needed additional background information concerning the supporting survey (see FDA minutes

in **Attachment #2**). In order to facilitate the approval of supplement S-024, Pfizer agreed to delete the above claim and the approval letter was issued on June 25, 2004.

Background information for the “#1 Dermatologist Recommended Brand” claim requested by the Agency is contained in **Attachment #3**. For your convenience, survey results that were submitted in the August 13, 2002 correspondence and previously in March 19, 2004 correspondence are provided in **Attachments #4** and **#5**, respectively. They were conducted in 2001 and 2003, respectively, and are consistent over time. To ensure the claim remains valid, however, we agree to revalidate it on an ongoing basis every 12 months.

Concerning the appearance of the “#1 Dermatologist Recommended Brand” claim and the Agency's belief that the seal is misleading in that it suggests endorsement by a medical society, we agree to modify the shape of the seal and to delete the caduceus symbol.

Proposed draft artwork for representative cartons with the revised “#1 Dermatologist Recommended Brand” claim is enclosed in **Attachment #6** for Men's Rogaine Regular Strength (only available without fragrance), in **Attachment #7** for Women's Rogaine without fragrance, and in **Attachment #8** for Women's Rogaine with fragrance. These three attachments also contain all associated labeling components (bottle label, inner carton, and insert).

Currently, Men's Rogaine Regular Strength and the unscented form of Women's Rogaine are labeled in accordance with the approvable CBE sNDA S-021, and Women's Rogaine with fragrance is labeled per the approved supplement S-024. The labeling in Attachments #6 through 8 is consistent with that covered by S-024 and incorporates all changes requested by the Agency in its review of supplements S-020 and S-021.

We request that the approvable supplements S-020 and S-021 be consolidated into this new supplemental NDA, which will then provide final approval for (1) Rogaine 2% products in Drug Facts format, (2) use of the new child-resistant overcap, and (3) the #1 Dermatologist Recommended Brand claim. The approval of this new supplement, together with the consolidation of supplements S-020 and S-021, will then close out all outstanding labeling issues for Rogaine 2% products.

Please contact me at the number below should you have any questions about this information.

Sincerely,

Dina Russello  
Director, Regulatory Affairs  
(973) 385-4909

Attachments