



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

USI 7393 Rog RS Dropper Unscented 34-3  
12/20/04

2.6 0.11 1.9 AS Inner Pack 341  
12/13/04

0.2 3.1 1.1 A MER PACKS  
5.04 X 40.03 X 143.1

15/14



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, itchy, oozing, 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

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11-16:00 AM 8/26/04

Pfizer CONSUMER HEALTHCARE PACKAGING APPROVAL				APPROVED (REV. IN RED)	
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  
 23431  
 3779-70

Patient Package Insert  
 12/20/2004

Important  
 Information  
 About



REGULAR STRENGTH

2% Minoxidil Topical Solution

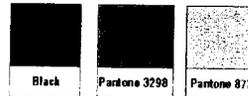
Hair Regrowth  
 Treatment

Unscented

rogaine.com



Composition Unit: 2566



Hair art is 40% black  
 over Pantone 872

COMPOSITION 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 solid 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.

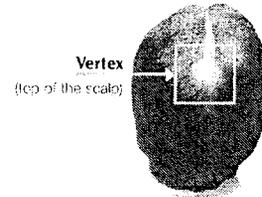
© 2004 Pfizer Inc.

### 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.**



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Composition Unit 2566

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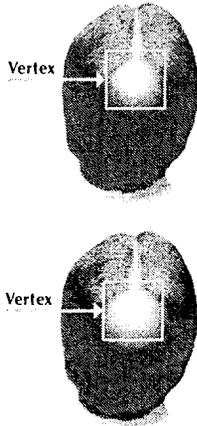
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			(b)

# 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.**

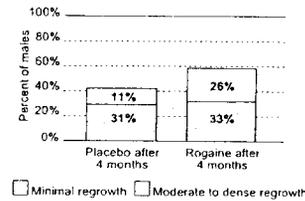
### Will Men's Rogaine Regular Strength work for me?

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



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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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# 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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# 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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# 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

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# 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

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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.
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**Using the Dropper Applicator**

- squeeze the rubber bulb and insert the dropper into the bottle
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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



Please Recycle

[rogaine.com](http://rogaine.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  
11:00:05 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  
 Contoured 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)**

818373609

LOT:  
 EXP:

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

**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

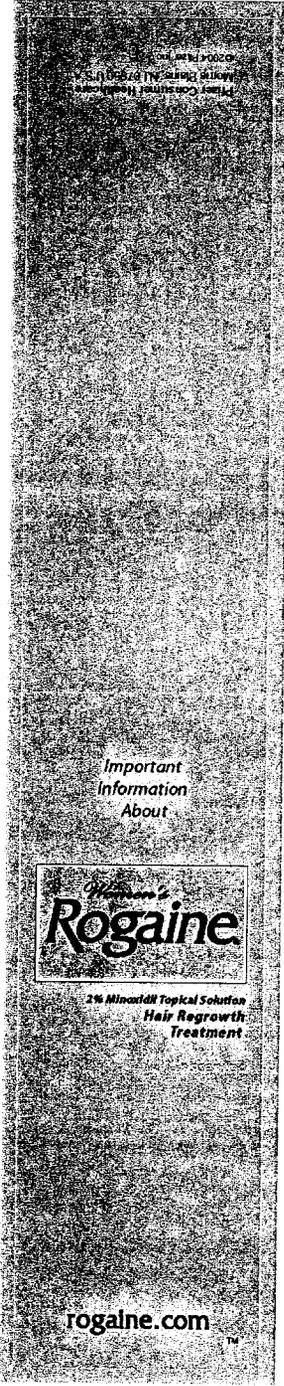
81846950/RogWmUnsc  
 12-14-04 AM 9/26/04

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)

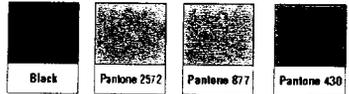
PFIZER CONSUMER HEALTHCARE				
Spec #	Date	Rev #	Artist	Nature of Revisions
818 373 609	08.26.04	0	(b)(4)	New Mechanical, Update to latest Drug Facts



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
CS#	UNCS#	QSP#	ITEM
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 01/04			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 color and rate 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
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			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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# Patient Package Insert

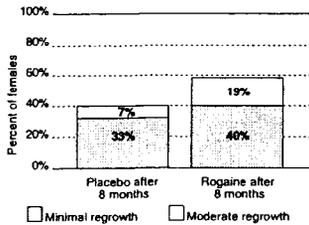
## Will Women's Rogaine work for me?

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).

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## 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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# 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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DRAWING #	REV. #	ADDITIONAL INFO	DATE	TYPESET BY	
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# 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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# 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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		(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

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23420		Women's Rogaine 2% Original Formula	
COPY CODE #		CCS #	NDC #
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# 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](http://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  
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Composition Unit 2566

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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

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

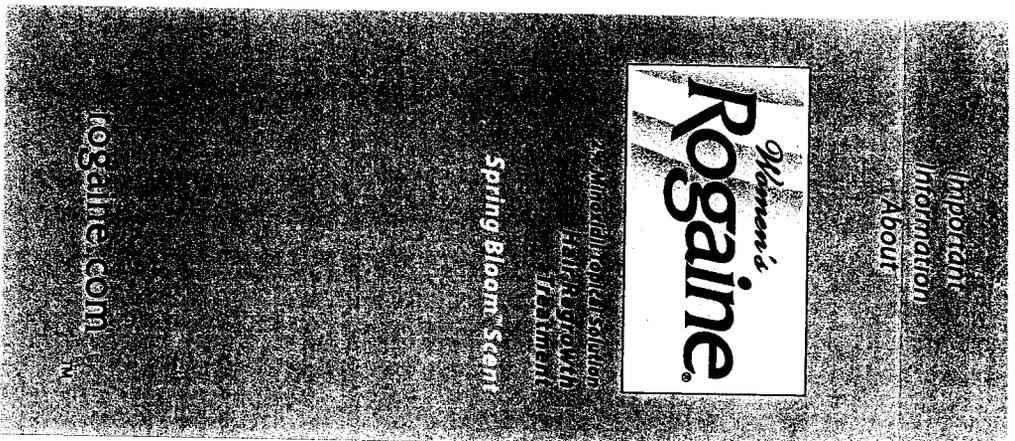
Pfizer Consumer Healthcare  
Morris Plains, NJ 07950 U.S.A.  
© 2004 Pfizer Inc.

773402

See inside for applicator and important consumer information.

**Cyrano**





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

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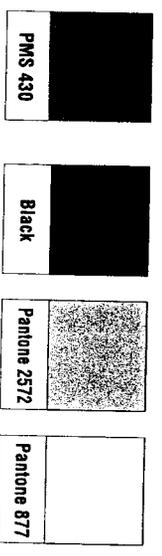
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Composition Unit 2566

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							DATE	4-6-04
							APPROVED BY	



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.**

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**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.**

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# Patent Package insert

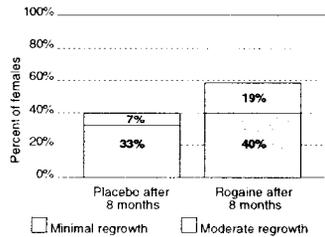
## Will Women's Rogaine work for me?

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).

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## 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.

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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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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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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

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- 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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- 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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# 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  
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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
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