

**DR. BOSLEY MINOXIDIL (FOR MEN) HAIR REGROWTH TREATMENT-  
minoxidil solution  
Scientific Hair Research, LLC**

-----

**Dr. Bosley Minoxidil Topical Solution 5% (For Men) Hair Regrowth Treatment**

***Drug Facts***

***Active Ingredient***

Minoxidil 5.0%w/v

***Purpose***

Hair regrowth treatment for men

***Use***

to regrow hair on the top of the scalp (vertex only, see picture on side of box)

***Warnings***

**For external use only. For men only.**

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

**Do not use if:**

- you are a woman
- your amount of hair loss is different than that shown on the side of this box or your hair loss is on the front of the scalp. 5% Minoxidil Topical Solution is not intended for frontal baldness or receding hairline.
- 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 medications 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. Results may occur at 2 months with twice a day usage.

For some men, you may need to use this product for at least 4 months before seeing results.

- the amount of hair regrowth is different for each person. This product will not work for all men.

**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 breastfeeding.**

**Keep out of reach of children.**

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

***Directions***

- apply one ml. (6 sprays) 2 times a day directly onto the scalp in the hair loss area
- using more or more often will not improve results
- continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

***Other information***

- see hair loss picture on side of this box
- before use, read all information on carton and enclosed insert
- keep carton, it contains important information
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with Minoxidil Topical Solution 5 % for men
- in clinical studies with mostly white men aged 18-45 years with moderate degrees of hair loss, Minoxidil Topical Solution 5% for men provided more hair regrowth than Minoxidil Topical Solution 2 %
- **store at controlled room temperature 20° to 25°C (68° to 77°F)**

***Inactive Ingredients***

alcohol, propylene glycol, purified water

***Question or comments?***

Call us at 1-800-267-5391 or visit website at [www.bosleymd.com](http://www.bosleymd.com)

**Package Labeling:**



### Drug Facts

**Active Ingredient**  
Minoxidil 5%w/v

**Purpose**  
Hair regrowth treatment for men

**Use** to regrow hair on the top of the scalp (vertex only, see picture on side of box)

#### Warnings

For external use only. For men only.

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

#### Do not use if:

- you are a woman
- your amount of hair loss is different than that shown on the side of this box or your hair loss is on the front of the scalp. 5% Minoxidil Topical Solution is not intended for frontal baldness or receding hairline.
- 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 medications 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. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before seeing results.
- the amount of hair regrowth is different for each person. This product will not work for all men.

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

- chest pain, rapid heartbeat, faintness.

### Drug Facts (continued)

- 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 breastfeeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.**

#### Directions

- apply one mL (6 sprays) 2 times a day directly onto the scalp in the hair loss area
- using more or more often will not improve results
- continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

#### Other information

- see hair loss pictures on side of this box
- before use, read all information on carton and enclosed insert
- keep carton, it contains important information
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with Minoxidil Topical Solution 5% for men
- in clinical studies with mostly white men aged 18-45 years with moderate degrees of hair loss, Minoxidil Topical Solution 5% for men provided more hair regrowth than Minoxidil Topical Solution 2% store at controlled room temperature 20° to 25°C (68° to 77°F)

#### Inactive Ingredients

alcohol, propylene glycol, purified water

#### Questions or comments?

Call us at 1-800-267-5391 or visit website at [www.bosleymd.com](http://www.bosleymd.com)

SKINUS 7700 Menage Belgium / London WC2H 9JQ UK  
© 2025 Bosley, Inc. All rights reserved.  
Manufactured for Scientific Hair Research LLC,  
Los Angeles, CA 90045 Made in USA.  
\*BOSLEY'S DOCTORS RECOMMEND BOSLEY PRODUCTS IN BOSLEY OFFICES.

BP-SGF0090N



DR BOSLEY

## Minoxidil

Topical Solution, 5% (For Men)

HAIR REGROWTH TREATMENT

NDC XXXXX-XXX-XX



## Minoxidil

Topical Solution, 5% (For Men)

HAIR REGROWTH TREATMENT

## Minoxidil

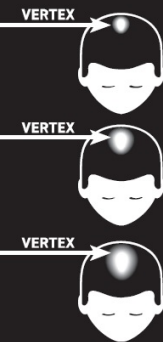
5% Minoxidil Topical Solution, USP

HAIR REGROWTH TREATMENT

Minoxidil topical solution 5% is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below).

Not intended for frontal baldness or a receding hairline. Minoxidil topical solution 5% has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.

If men have more hair loss or hair loss in a place different than shown below, Dr. Bosley Extra Strength for Men may not work.



For Best Results: Apply Directly to Scalp. Use Twice Daily



FDA APPROVED

NO-MESS  
PRECISION  
SPRAYER

CLINICALLY  
PROVEN TO  
HELP REGROW  
HAIR

UNSCENTED

NOT FOR USE  
BY WOMEN

One Month Supply  
One 60 mL (2 FL. OZ.) Bottle

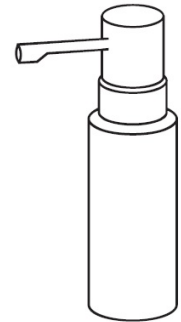


## Minoxidil

Topical Solution,  
5% (For Men)

HAIR REGROWTH  
TREATMENT

THIS PACKAGE CONTAINS



One 60 mL (2 fl. oz.) Bottle of Men's Dr. Bosley Extra Strength (one-month supply).

With child-resistant Sprayer pump applicator

Information leaflet with complete directions on how to use and obtain best results

(Read enclosed leaflet before use)

Made in USA  
Distributed by: Scientific Hair Research LLC,  
Los Angeles, CA 90045 Made in USA.  
Label part #  
Rev.

**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.

**Directions**

• **apply one mL with sprayer (6 sprays) 2 times a day** directly onto the scalp in the hair loss area • see enclosed leaflet for complete Directions for Use • using more or more often will not improve result • continued use is necessary, or hair loss will begin again

**Inactive Ingredients**

Alcohol, Propylene Glycol, Purified Water

**Questions?** Call BosleyMD at (800)-BOSLEY1 or reach us on the internet at [www.bosleyemd.com](http://www.bosleyemd.com)

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

LOT#	Label part#
EXP:	Rev. date

Made in USA  
Distributed by:  
Scientific Hair Research LLC, Los Angeles, CA 90066 Made in U.S.A.

NDC XXXXX-XXX-XX

**DR. BOSLEY**  
EST 1974

**MEN'S**  
**Minoxidil**  
**EXTRA STRENGTH**

**5% MINOXIDIL TOPICAL SOLUTION, USP**

**HAIR REGROWTH TREATMENT**

Reactivates Hair Follicles to Stimulate Regrowth  
Clinically Proven to Help Regrow Hair  
Topical Solution  
Unscented

**FOR BEST RESULTS:**

Apply Directly to Scalp.  
Use Twice Daily

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

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

**Active Ingredient:** Minoxidil 5% w/v

**Warnings**

**For external use only. For use by men only.**

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

**Do not use if** • you are a woman • 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

**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 ➡



## (5% Minoxidil Topical Solution USP) Hair Regrowth Treatment Extra Strength For Men

Save booklet for future reference

Unscented

It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.

Please read this insert carefully. It will help you understand how to use Dr. Bosley Extra Strength for Men and what to expect from its use. If you have any questions after reading this insert, or any time while using Dr. Bosley Extra Strength for Men, you should ask your health care professional or contact Dr. Bosley at 1-800-BOSLEY1. Monday-Friday, 9:00 AM – 5:00 PM (EST). You can also contact us at our website at [www.bosleymd.com](http://www.bosleymd.com).

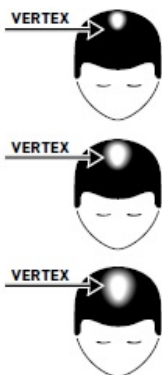
### What is Dr. Bosley Extra Strength for Men

Dr. Bosley Extra Strength for Men is a colorless liquid medication containing 5% minoxidil for use only on the scalp to help regrow hair in men.

### Who may use Dr. Bosley Extra Strength for Men?

Dr. Bosley Extra Strength for Men is for use only by men. Dr. Bosley Extra Strength for Men may be appropriate for you if you are a male at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the scalp (vertex only as shown in the illustration below). It is not intended for frontal baldness or a receding hairline. The common inherited thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Dr. Bosley Extra Strength for Men is for men with hair loss or thinning hair that begins on the vertex of the scalp. Dr. Bosley Extra Strength for Men is more likely to regrow hair in men with hair loss in the range shown. If men have more hair loss than shown, Dr. Bosley Extra Strength for Men may not work.



Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. If you have no family history of gradual thinning hair or of gradual hair loss or your hair loss is patchy, see your doctor.

### Who should NOT use Dr. Bosley Extra Strength for Men?

Women should not use Dr. Bosley Extra Strength for Men because studies have shown it works no better in women than Minoxidil Topical Solution for Women. Some women may also grow facial hair. In addition, Dr. Bosley Extra Strength for Men may be harmful if used during pregnancy or breastfeeding.

Dr. Bosley Extra Strength for Men should not be used on babies or for children under 18 years old.

Dr. Bosley Extra Strength for Men 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; too much vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Dr. Bosley Extra Strength for Men 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 if you are unsure of the reason for your hair loss.

### 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 the 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 the thinning areas grow as closely together as hairs on the rest of the head.

### Will Dr. Bosley Extra Strength for Men work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Dr. Bosley Extra Strength for Men. The response to the amount of hair regrowth for Dr. Bosley Extra Strength for Men cannot be predicted. It is unlikely anyone will be able to grow back all their hair.

However, to see your best results with Dr. Bosley Extra Strength for Men, make sure you get the medicine directly to the scalp and apply it twice a day, every day.

You may get better results if you have been losing your hair for a short period of time or have little hair loss. However, for some men Dr. Bosley Extra Strength for Men may not work.

### How soon can I expect results from using Dr. Bosley Extra Strength for Men?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Dr. Bosley Extra Strength for Men also takes time.

Results may be seen as early as 2 months with twice daily use. For some men, it may take at least 4 months for results to be seen. If you do not see any results after 4 months, stop using Dr. Bosley Extra Strength for Men.

When you first begin to use Dr. Bosley Extra Strength for Men, your hair loss may increase temporarily for up to 2 weeks. This is likely a sign that you are getting rid of old hair in order to regrow more new hairs. This temporary increase in hair loss is expected and is a part of the process for how Dr. Bosley Extra Strength for Men regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

### If Dr. Bosley Extra Strength for Men is working, what will the hair look like?

At first, hair growth is usually soft, downy, colorless hairs (like peach fuzz). 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 Dr. Bosley Extra Strength for Men?

If you respond to Dr. Bosley Extra Strength for Men, continued use of Dr. Bosley Extra Strength for Men is necessary or the hair loss will begin again. In studies with Minoxidil Topical Solution 5% (Extra Strength), hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials.

### What happens if I completely stop using Dr. Bosley Extra Strength for Men? Will I keep the new hair?

Continuous use of Dr. Bosley Extra Strength for Men is needed to maintain hair regrowth. If you stop using Dr. Bosley Extra Strength for Men, you will lose your newly regrown hair in 3 or 4 months.

### How do I use Dr. Bosley Extra Strength for Men?

For best results, apply 1 mL with sprayer 2 times a day directly onto the scalp in the hair loss area. Using more or using more often will not improve results. Each bottle should last one month if used as directed.

Allow time for Dr. Bosley Extra Strength for Men to dry completely before wearing a hat or lying on a pillow, etc. Dr. Bosley Extra Strength for Men may cause staining of clothing or linens if damp on the scalp. When applying Dr. Bosley Extra Strength for Men at night, be sure to allow 2 to 4 hours to dry completely. Never take this product by mouth or apply to other parts of the body.

### When do I use Dr. Bosley Extra Strength for Men?

Apply Dr. Bosley Extra Strength for Men once in the morning and once at night.

The nighttime application should occur 2 to 4 hours before going to bed to allow for drying. Each bottle should last one month, if used as directed.

### What if I miss a dose or forget to use Dr. Bosley Extra Strength for Men?

If you miss one or two daily doses of **Dr. Bosley Extra Strength for Men**, just continue with your next dose. You should not make up for missed doses.

### Can I use Dr. Bosley Extra Strength for Men more than twice a day? Will it work faster or better?

No. **Dr. Bosley Extra Strength for Men** will not work faster or better if used more than two times a day. Studies were carefully conducted to determine the correct amount of **Dr. Bosley Extra Strength for Men** 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 kind of shampoo should I use with Dr. Bosley Extra Strength for Men?

If you wash your scalp before applying **Dr. Bosley Extra Strength for Men**, use a mild shampoo.

### Can I use hairspray, mousse, conditioner, gel, etc.?

Yes. Hairsprays, spritz, or styling aids may be used on your hair while using **Dr. Bosley Extra Strength for Men**. For best results, **Dr. Bosley Extra Strength for Men** should be allowed to soak into the scalp before using any styling products. First, try to develop a good routine of applying **Dr. Bosley Extra Strength for Men** and then start applying styling products and style as usual. Keep in mind that your best results will be seen with proper application.

### Can I have my hair colored, permed or use hair relaxers while using Dr. Bosley Extra Strength for Men?

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of **Dr. Bosley Extra Strength for Men**. However, because the use of a permanent wave and hair color can cause scalp irritation on certain people, we recommend the following precautions:

- To avoid possible scalp irritation, you should make sure all of the **Dr. Bosley Extra Strength for Men** has been washed off the hair and scalp before using color or perm chemicals.
- For best results, do not apply **Dr. Bosley Extra Strength for Men** on the same day that you use a chemical treatment on your hair.
- Do not use **Dr. Bosley Extra Strength for Men** for 24 hours after using any chemicals to make sure your scalp has not been irritated by the perm or color treatment. If no irritation occurs, continue use of **Dr. Bosley Extra Strength for Men** as usual.
- Simply restart your normal **Dr. Bosley Extra Strength for Men** routine. There is no need to use more **Dr. Bosley Extra Strength for Men** to make up for missed applications. Missing one day of **Dr. Bosley Extra Strength for Men** will not affect your hair regrowth results.

### Can I apply Dr. Bosley Extra Strength for Men and wash my hair an hour later?

No. For **Dr. Bosley Extra Strength for Men** to work best, you should allow it to stay on the scalp for about 4 hours before washing.

### Directions for Use

When applying **Dr. Bosley Hair Regrowth Treatment**, make sure the medicine comes in direct contact with the scalp. The medicine will not work if it is sprayed only on your hair and does not reach your scalp.

Carefully follow the instructions below to use the child-resistant sprayer pump to apply **Dr. Bosley Hair Regrowth Treatment**.

- Remove the bottle of **Dr. Bosley Hair Regrowth Treatment** from the carton.
- Firmly hold the bottle upright with the turning wheel on the back of the bottle facing you. Push in the small tab located to the bottom right of the turning wheel.
- While holding the tab in, press down on the top of the sprayer and turn the upper part of the sprayer with the turning wheel to the left until the spray nozzle is centered between the beveled grooves on the front of the bottle.
- Then prime the sprayer by holding the bottle upright and pumping the sprayer 5 times to ensure delivery of a full spray. Be careful not to inhale the mist.
- Aim the sprayer at your area of thinning hair or hair loss and pump the sprayer 6 times to **apply a 1 mL dose twice a day**.
- After applying **Dr. Bosley Hair Regrowth Treatment**, use the turning wheel to turn the sprayer cap back to the right to release the tab which places the sprayer nozzle behind the sprayer cap wall. Make sure the sprayer cannot be pushed or pumped before putting the bottle away.

### Warnings

#### For external use only

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

#### Do not use if

- You are a woman. **For use by men only.**
- Your amount of hair loss is different than that shown on the diagrams included in this insert or your hair loss is on the front of the scalp.
- Dr. Bosley Extra Strength for Men** is not intended for frontal baldness or receding hairline.
- 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 apply to babies or children.
- Your scalp is red, inflamed, infected, irritated, or painful
- You use other medications 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. Results may occur at 2 months with twice a day usage. For some men you may need to use this product for at least 4 months before you see results.
- The amount of hair regrowth is different for each person. This product will not work on all men.



### 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 during pregnancy or breastfeeding.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

### What are the most common side effects with Dr. Bosley Extra Strength for Men?

The most common side effects are itching and skin irritation of the treated area of the scalp. If scalp irritation continues, stop use and see a doctor. **Dr. Bosley Extra Strength for Men** contains alcohol, which will cause burning or irritation of the eyes. If **Dr. Bosley Extra Strength for Men** accidentally gets into eyes, rinse with large amounts of cool tap water.

### Can Dr. Bosley Extra Strength for Men produce unwanted hair growth?

Unwanted hair growth on the face and other parts of the body has been reported in women. But it is rare and reversible. If you develop unwanted hair, stop using **Dr. Bosley Extra Strength for Men**. Over time, the unwanted hair, if caused by **Dr. Bosley Extra Strength for Men** will go away. You can take the following steps to decrease the chances of unwanted hair growth:

- Limit the application of **Dr. Bosley Extra Strength for Men** only to the scalp.
- If you use your hands to apply **Dr. Bosley Extra Strength for Men**, wash your hands well immediately afterwards.
- After your nighttime application of **Dr. Bosley Extra Strength for Men**, allow enough drying time before going to bed (usually 2 to 4 hours).

### Can I use Dr. Bosley Extra Strength for Men for baldness or hair loss in babies or children?

No. **Dr. Bosley Extra Strength for Men** must not be used to treat baldness or hair loss in babies and children.

If you have any other questions, ask your health care professional or call **Dr. Bosley** at 1-800-BOSLEY1

**Store at controlled room temperature 20° to 25°C (68° to 77°F).**

You can also visit our website at [www.bosleymd.com](http://www.bosleymd.com)

Save this leaflet for future reference.  
BosleyMD  
Scientific Hair Research LLC D.B.A. BosleyMD, Los Angeles, CA 90045 U.S.A.

MMS-01  
03/23/23

Label part#

Rev. date

## DR. BOSLEY MINOXIDIL (FOR MEN) HAIR REGROWTH TREATMENT

minoxidil solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69113-913
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MINOXIDIL</b> (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69113-913-00	1 in 1 BOX	10/16/2025	
1		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	10/16/2025	

**Labeler -** Scientific Hair Research, LLC (961897647)

**Registrant -** Pure Source, LLC (080354456)

Revised: 12/2025

Scientific Hair Research, LLC