

**DS LABS SPECTRAL UHP MEN S EXTRA STRENGTH HAIR REGROWTH
TREATMENT- minoxidil solution
DS Healthcare Group**

DS Labs Spectral UHP Men's Extra Strength Hair Regrowth Treatment

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 pictures on side of carton)

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
- your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. Minoxidil topical solution 5% is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- 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.
- 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.
- 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 for all men.
- some people have experienced changes in hair color and/or texture

Stop use and ask a doctor if

- chest pain, rapid heart beat, 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.

Directions

- prime the sprayer by holding the bottle upright and pump the sprayer 5 times to ensure delivery of full spray. Do not inhale mist.
- apply 1 mL with sprayer (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 carton
- before use, read all information on carton and enclosed leaflet
- keep the 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 5% minoxidil topical solution for men in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- store at controlled room temperature 20° to 25°C (68° to 77°F)

Inactive ingredients

alcohol, propylene glycol, purified water

Questions or comments?

call toll free (888) 829-4212 or visit website at www.dslaboratories.com

Package Labeling:

Drug Facts

Active ingredient Minoxidil 5% w/v.....**Purpose** Hair regrowth treatment for men

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- you are under 18 years of age. Do not use on babies and children.
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- you use other medicines on the scalp

Ask a doctor before use if you have heart disease

When using this product

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Other information

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- before use, read all information on carton and enclosed leaflet
- keep the 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 5% minoxidil topical solution for men
- in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- store at controlled room temperature 20° to 25°C (68° to 77°F)

Inactive ingredients alcohol, propylene glycol, purified water

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NDC 69188-001-01



SPECTRAL[®]

UHP TOPICAL SOLUTION

MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

TRAITEMENT DE REPOUSSE DES CHEVEUX

Minoxidil topical solution USP 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 USP 5% has been shown to regrow hair. On 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 above, Minoxidil Topical Solution 5% may not work.

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

NOT FOR USE BY WOMEN

SPECTRAL[®]

UHP TOPICAL SOLUTION

MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

TRAITEMENT DE REPOUSSE DES CHEVEUX

MINOXIDIL TOPICAL SOLUTION, USP 5%

Reactivate Hair Follicles to Stimulate Regrowth
Clinically Proven To Help Regrow Hair

1 MONTH SUPPLY
UNSCENTED

60 mL / 2 FL OZ e

DS LABORATORIES

WHO WE ARE

We are a leading dermatological brand, specialized in science-backed haircare and skincare, offering future forward, clinical-grade products formulated and recommended by top dermatologists around the world. We focus on creating products of the highest quality and proven efficacy that drive real results.

THIS PACKAGE CONTAINS



- One 60 mL (2 fl oz) Bottle of Men's SpectralUHP[®] Extra Strength Hair Regrowth Treatment (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)

WWW.DSLABORATORIES.COM

PRODUCIDO POR/PRODUCCION PARA: DS Healthcare Group Inc. 1395 Brickell Ave Suite 800, Miami, FL 33131 contacto@dslaboratories.com

MADE IN/HECHO EN: United States of America / Estados Unidos de Norteamérica.

IMPORTADO POR: Divine Skin Laboratories, S.A. de C.V., Av. Cafetalera, No. 1747, Col. Haciendas de Copacación, C.P. 04970, Copacación, Ciudad de México, México. contacto@dslaboratories.com

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Stop use and ask a doctor if

- chest pain, rapid heart beat, 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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Directions

- apply 1 mL with sprayer (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, or hair loss will begin again
- see enclosed leaflet for complete Directions for Use

Inactive ingredients alcohol, propylene glycol, purified water

Questions? call toll free (888) 829-4212 or visit dslaboratories.com

Other Information store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

LOT# Label Part# UHPUSALB-002

EXP: Rev.date 10/24

Made In USA

Distributed By: **DS Healthcare Group, Inc.**
1395 Brickell Ave Suite 800, Miami, FL 33131 LB0222



SPECTRAL[®]

UHP

TOPICAL SOLUTION

MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

TRAITEMENT DE REPOUSSE DES CHEVEUX

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

MINOXIDIL TOPICAL SOLUTION, USP 5%

Reactivate Hair Follicles to Stimulate Regrowth
Clinically Proven To Help Regrow Hair

1 MONTH SUPPLY

UNSCENTED

60 mL / 2 FL OZ e

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

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- you have no family history of hair loss
- 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 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 for all men.▶



SPECTRAL[®]

UHP

TOPICAL SOLUTION

MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

MINOXIDIL TOPICAL SOLUTION, USP 5%

Save this leaflet for future reference.

• 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 leaflet carefully. It will help you understand how to use Spectral.UHP Extra Strength for Men and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Spectral.UHP Extra Strength for Men, you should ask your health care professional or contact us at DS Healthcare Group Inc. at (888) 829-4212. Monday - Friday; 9:00 AM - 5:00 PM (EST).

What is Men's Spectral.UHP Extra Strength?

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

Who may use Men's Spectral.UHP Extra Strength?

Spectral.UHP Extra Strength is for use only by men. Spectral.UHP Extra Strength 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 on 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.

Spectral.UHP Extra Strength is for men with hair loss or thinning hair that begins on the vertex of the scalp. Spectral.UHP Extra Strength is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength for Men?

- Women should not use Spectral.UHP Extra Strength for Men because studies have shown it works no better in women than Women's 2% Minoxidil Topical Solution for Women. Some women may also grow facial hair. In addition, Spectral.UHP Extra Strength may be harmful if used during pregnancy or breast-feeding.
- Spectral.UHP Extra Strength for Men should not be used on babies or for children under 18 years old.
- Spectral.UHP 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, Spectral.UHP 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 crowning or ponytails which require pulling the hair tightly back from the scalp.

Do not use if you are not sure of the reason for your hair loss.

Will Men's Spectral.UHP Extra Strength work for me?

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

However, to see your best results with Spectral.UHP Extra Strength, 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 Spectral.UHP Extra Strength may not work.

How soon can I expect results from using Men's Spectral.UHP Extra Strength?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength.

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

If Men's Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength for Men?

If you experience hair regrowth, continued use of Spectral.UHP 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 Spectral.UHP Extra Strength for Men? Will I keep the new hair?

Continuous use of Spectral.UHP Extra Strength is needed to maintain hair regrowth. If you stop using Spectral.UHP Extra Strength, you will lose your newly regrown hair in 3 to 4 months.

How do I use Spectral.UHP Extra Strength for Men?

For best results, **apply 1 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. Each bottle should last one month, if used as directed. Allow time for Spectral.UHP Extra Strength for Men to dry completely before wearing a hat, or lying on a pillow, etc. Spectral.UHP Extra Strength for Men may cause staining of clothing or linens if damp on the scalp. When applying Your Spectral.UHP 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 Men's Spectral.UHP Extra Strength?

Apply Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength for Men?

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

Can I use Spectral.UHP Extra Strength for Men more than twice a day? Will it work faster, better?

No. Spectral.UHP Extra Strength will not work faster or better if used more than two times a day. Studies have been carefully conducted to determine the correct amount of Spectral.UHP Extra Strength 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 Men's Spectral.UHP Extra Strength?

If you wash your scalp before applying Spectral.UHP Extra Strength, use a mild shampoo.

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

Yes. Hair sprays, spritz, or styling aids may be used on your hair while using Spectral.UHP Extra Strength. For best results, Spectral.UHP Extra Strength should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying Spectral.UHP Extra Strength first, and then 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 or permed or use hair relaxers while using Men's Spectral.UHP Extra Strength?

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

- 1.To avoid possible scalp irritation, you should make sure all of the Spectral.UHP Extra Strength has been washed off the hair and scalp before using color or perm chemicals.
- 2.For best results, do not apply Spectral.UHP Extra Strength on the same day that you use a chemical treatment on your hair.
- 3.Do not use Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength as usual.
- 4.Simply restart your normal Spectral.UHP Extra Strength for Men routine. There is no need to use more Spectral.UHP Extra Strength for Men to make up missed applications. Missing 1 day of Spectral.UHP Extra Strength for Men will not affect your hair regrowth results.

Can I apply Spectral.UHP Extra Strength for Men and wash my hair an hour later?

No. For Spectral.UHP Extra Strength to work best, you should allow it to stay on the scalp for about 4 hours before washing.

Directions for Use

When applying Spectral.UHP Extra Strength for Men, 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 Spectral.UHP Extra Strength for Men



- 1.Remove the bottle of Spectral.UHP Extra Strength for Men from the carton.
- 2.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.
- 3.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.
- 4.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.

5.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.**

6.After applying Spectral.UHP Extra Strength for Men, 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

For use by 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 in the illustration on page 1 of this leaflet 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.
- 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. 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 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 breast-feeding. 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 Spectral.UHP 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. Spectral.UHP Extra Strength contains alcohol, which will cause burning or irritation of the eyes. If Spectral.UHP Extra Strength accidentally gets into eyes, rinse with large amounts of cool tap water.

Can Men's Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength. Over time, the unwanted hair, if caused by Spectral.UHP Extra Strength, will go away.

You can take the following steps to decrease the chances of unwanted hair growth:

- 1.limit the application of Spectral.UHP Extra Strength only to the scalp;
- 2.if you use your hands to apply Spectral.UHP Extra Strength, wash your hands well immediately afterwards; and
- 3.after your nighttime application of Spectral.UHP Extra Strength, allow enough drying time before going to bed (usually 2 to 4 hours).

Can I use Spectral.UHP Extra Strength for Men for baldness or hair loss in babies or children?

No. Spectral.UHP Extra Strength 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 DS Healthcare Group Inc. at +1 (888) 829-4212

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

DS Healthcare Group Inc.
1395 Brickell Ave Suite 800, Miami, FL 33131 U.S.A.

Label Part# UHPUSAIN-001
Rev.date 11/24

Package Labeling:



NDC 65188-001-02

Drug Facts

Active ingredient: Minoxidil 5% w/v. **Purpose:** Hair regrowth treatment for men.

Use: Apply hair on the top of the scalp (crown only, see picture on side of carton).

Warnings: For external use only. For use by men only. Flammable: Keep away from fire or flame.

Do not use if: you have a serious scalp infection; you have had a heart attack or stroke; you have a family history of heart loss; you have a sudden weight gain; you are under 18 years of age. Do not use on babies and children. It may be red, inflamed, infected, irritated or painful.

Ask doctor before use if you have heart disease.

When using this product: Avoid contact with the eyes of the scalp; avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water. For some men, you may need to use this product for at least 4 months before you see results. Your amount of hair regrowth is different for each person. This product will not work for all men. Some people have experienced changes in hair color and/or texture.

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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: Shake the sprayer by holding the bottle upright and pump the sprayer 5 times to reach delivery of full dose. Do not shake bottle. Apply 1 mL with sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area. Continuing use is necessary to increase and keep your hair regrowth, or hair loss will begin again.

Drug Facts (continued)

Other information: Keep hair loss on side of this carton. Do not use if you have a heart attack or stroke. Do not use if you have a family history of heart loss. Do not use on babies and children. It may be red, inflamed, infected, irritated or painful.

Inactive ingredients: alcohol, propylene glycol, purified water.

Questions or comments? Call toll free (888) 829-4212. Visit us at www.dslaboratories.com.

Label Part# UHPUSALB-001
NDC 65188-001-02
Distributed by: DS Laboratories, Inc.
1395 Brickell Ave Suite 800, Miami, FL 33131

SPECTRAL[®]

UHP
MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

TRAITEMENT DE REPOUSSE DES CHEVEUX

Minoxidil topical solution USP 5% is for men who have a general thinning of hair on the top of the scalp (crown only, as shown below). Not intended for frontal baldness or a receding hairline. Minoxidil topical solution USP 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 above, Minoxidil Topical Solution 5% may not work.

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

NOT FOR USE BY WOMEN



SPECTRAL[®]

UHP
MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

TOPICAL SOLUTION

MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

TRAITEMENT DE REPOUSSE DES CHEVEUX

MINOXIDIL TOPICAL SOLUTION, USP 5%

Reactivate Hair Follicles to Stimulate Regrowth Clinically Proven To Help Regrow Hair

3 MONTH SUPPLY

THREE 60mL (2 FL OZ) BOTTLES, TOTAL 180mL (6 FL OZ)

DS LABORATORIES

WHO WE ARE

We are a leading dermatological brand dedicated to science-backed hair care and skincare, offering future-forward, clinic-grade products formulated and recommended by top dermatologists around the world. We focus on creating products of the highest quality and proven efficacy that drive real results.

THIS PACKAGE CONTAINS



- Three 60 mL (2 fl oz) bottles of Men's Spectral UHP Extra Strength Hair Regrowth Treatment (three month supply) with clinical-grade propylene glycol application information sheet with complete directions on how to use and obtain best results (see enclosed leaflet for use)

www.dslaboratories.com

www.dslaboratories.com | #DSLABS | contact@dslaboratories.com

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- Directions**
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 - continued use is necessary, or hair loss will begin again
 - see enclosed leaflet for complete Directions for Use

Inactive ingredients alcohol, propylene glycol, purified water

Questions? call toll free (888) 829-4212 or visit dslaboratories.com

Other information store at Controlled Room Temperature 20° to 25°C (68° to 77°F)

LOT# _____ Label Part# UHPUSALB-002
EXP: _____ Rev.date 10/24

Made in USA
Distributed By: DS Healthcare Group, Inc.
1395 Brickell Ave Suite 800, Miami, FL 33131 LB0222



SPECTRAL[®]

UHP TOPICAL SOLUTION

MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

TRAITEMENT DE REPOUSSE DES CHEVEUX

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

MINOXIDIL TOPICAL SOLUTION, USP 5%

Reactivate Hair Follicles to Stimulate Regrowth Clinically Proven To Help Regrow Hair

1 MONTH SUPPLY

UNSCENTED

60 mL / 2 FL OZ e

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
 - your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. Minoxidil topical solution 5% is not intended for frontal baldness or receding hairline.
 - you have no family history of hair loss
 - 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 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 for all men. ▶



SPECTRAL®

UHP

TOPICAL SOLUTION

MEN'S EXTRA STRENGTH HAIR REGROWTH TREATMENT

MINOXIDIL TOPICAL SOLUTION, USP 5%

Save this leaflet for future reference.

• 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 leaflet carefully. It will help you understand how to use Spectral.UHP Extra Strength for Men and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Spectral.UHP Extra Strength for Men, you should ask your health care professional or contact us at DS Healthcare Group Inc. at (888) 829-4212. Monday - Friday; 9:00 AM - 5:00 PM (EST).

What is Men's Spectral.UHP Extra Strength?

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

Who may use Men's Spectral.UHP Extra Strength?

Spectral.UHP Extra Strength is for use only by men. Spectral.UHP Extra Strength 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 on 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. Spectral.UHP Extra Strength is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength for Men?

- Women should not use Spectral.UHP Extra Strength for Men because studies have shown it works no better in women than Women's 2% Minoxidil Topical Solution for Women. Some women may also grow facial hair. In addition, Spectral.UHP Extra Strength may be harmful if used during pregnancy or breast-feeding.
- Spectral.UHP Extra Strength for Men should not be used on babies or for children under 18 years old.
- Spectral.UHP 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, Spectral.UHP 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 not sure of the reason for your hair loss.

Will Men's Spectral.UHP Extra Strength work for me?

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

However, to see your best results with Spectral.UHP Extra Strength, 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 Spectral.UHP Extra Strength may not work.

How soon can I expect results from using Men's Spectral.UHP Extra Strength?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength. When you first begin to use Spectral.UHP Extra Strength, your hair loss may increase temporarily for up to 2 weeks. This is likely a sign that you are getting rid of old hairs in order to regrow more new hairs. This temporary increase in hair loss is expected and is a part of the process for how Spectral.UHP Extra Strength regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

If Men's Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength for Men?

If you experience hair regrowth, continued use of Spectral.UHP 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 Spectral.UHP Extra Strength for Men? Will I keep the new hair?

Continuous use of Spectral.UHP Extra Strength is needed to maintain hair regrowth. If you stop using Spectral.UHP Extra Strength, you will lose your newly regrown hair in 3 to 4 months.

How do I use Spectral.UHP Extra Strength for Men?

For best results, **apply 1 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. Each bottle should last one month, if used as directed. Allow time for Spectral.UHP Extra Strength for Men to dry completely before wearing a hat, or lying on a pillow, etc. Spectral.UHP Extra Strength for Men may cause staining of clothing or linens if damp on the scalp. When applying Your Spectral.UHP 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 Men's Spectral.UHP Extra Strength?

Apply Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength for Men?

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

Can I use Spectral.UHP Extra Strength for Men more than twice a day? Will it work faster, better?

No. Spectral.UHP Extra Strength will not work faster or better if used more than two times a day. Studies have been carefully conducted to determine the correct amount of Spectral.UHP Extra Strength 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 Men's Spectral.UHP Extra Strength?

If you wash your scalp before applying Spectral.UHP Extra Strength, use a mild shampoo.

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

Yes. Hair sprays, spritz, or styling aids may be used on your hair while using Spectral.UHP Extra Strength. For best results, Spectral.UHP Extra Strength should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying Spectral.UHP Extra Strength first, and then 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 or permed or use hair relaxers while using Men's Spectral.UHP Extra Strength?

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

- 1.To avoid possible scalp irritation, you should make sure all of the Spectral.UHP Extra Strength has been washed off the hair and scalp before using color or perm chemicals.
- 2.For best results, do not apply Spectral.UHP Extra Strength on the same day that you use a chemical treatment on your hair.
- 3.Do not use Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength as usual.
- 4.Simply restart your normal Spectral.UHP Extra Strength for Men routine. There is no need to use more Spectral.UHP Extra Strength for Men to make up missed applications. Missing 1 day of Spectral.UHP Extra Strength for Men will not affect your hair regrowth results.

Can I apply Spectral.UHP Extra Strength for Men and wash my hair an hour later?

No. For Spectral.UHP Extra Strength to work best, you should allow it to stay on the scalp for about 4 hours before washing.

Directions for Use

When applying Spectral.UHP Extra Strength for Men, 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 Spectral.UHP Extra Strength for Men



- 1.Remove the bottle of Spectral.UHP Extra Strength for Men from the carton.
- 2.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.
- 3.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.
- 4.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.

5.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.**

6.After applying Spectral.UHP Extra Strength for Men, 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

For use by 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 in the illustration on page 1 of this leaflet 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.
- 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. 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 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 breast-feeding. 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 Spectral.UHP 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. Spectral.UHP Extra Strength contains alcohol, which will cause burning or irritation of the eyes. If Spectral.UHP Extra Strength accidentally gets into eyes, rinse with large amounts of cool tap water.

Can Men's Spectral.UHP Extra Strength 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 Spectral.UHP Extra Strength. Over time, the unwanted hair, if caused by Spectral.UHP Extra Strength, will go away.

You can take the following steps to decrease the chances of unwanted hair growth:

- 1.limit the application of Spectral.UHP Extra Strength only to the scalp;
- 2.if you use your hands to apply Spectral.UHP Extra Strength, wash your hands well immediately afterwards; and
- 3.after your nighttime application of Spectral.UHP Extra Strength, allow enough drying time before going to bed (usually 2 to 4 hours).

Can I use Spectral.UHP Extra Strength for Men for baldness or hair loss in babies or children?

No. Spectral.UHP Extra Strength 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 DS Healthcare Group Inc. at +1 (888) 829-4212

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

DS Healthcare Group Inc.
1395 Brickell Ave Suite 800, Miami, FL 33131 U.S.A.

Label Part# UHPUSAIN-001
Rev.date 11/24

DS LABS SPECTRAL UHP MEN S EXTRA STRENGTH HAIR REGROWTH TREATMENT

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69188-593
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69188-593-00	1 in 1 BOX	02/26/2025	
1		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:69188-593-03	3 in 1 BOX	02/26/2025	
2		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	02/26/2025	

Labeler - DS Healthcare Group (015504134)**Registrant** - Pure Source, LLC (080354456)

Revised: 5/2025

DS Healthcare Group