HAIR REGROWTH TREATMENT- minoxidil aerosol, foam
Meijer Distribution Inc

Meijer Distribution, Inc. Hair Regrowth Treatment For Men Drug Facts

Active ingredient

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the top of the scalp (vertex only, see pictures on side of this carton)

Warnings

For external use only. For use by men only.

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on side of this carton or your hair loss is on the front of the scalp. Minoxidil Topical Aerosol, 5% (Foam) 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 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. (1-800-222-1222)

Directions

- apply half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- 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

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- see hair loss pictures on side of this carton
- before use, read all information on package and enclosed leaflet
- keep the package. It contains important information.
- store at 20-25°C (68-77°F)
- contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Inactive ingredients

butane, butylated hydroxytoluene, cetyl alcohol, citric acid, dehydrated alcohol, isobutane, lactic acid, polysorbate 60, propane, purified water, stearyl alcohol

Questions or comments?

1-800-719-9260

Consumer Information

IMPORTANT INFORMATION ABOUT

Minoxidil Topical Aerosol, 5% (Foam)

Hair Regrowth Treatment

UNSCENTED

For Men

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.

Clinically Proven to Help Regrow Hair

Not For Use By Women

SAVE THIS LEAFLET FOR FUTURE REFERENCE

Please read this leaflet carefully. It will help you understand how to use Minoxidil Topical Aerosol, 5% and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Minoxidil Topical Aerosol, 5% you should ask your healthcare professional or call us at 1-800-719-9260.

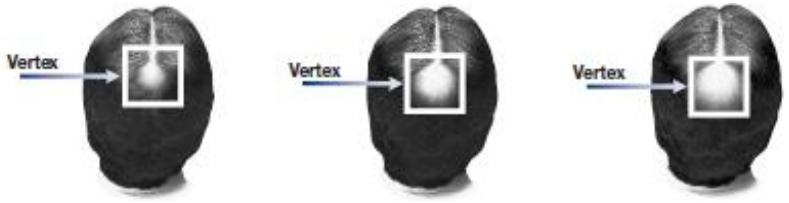
What is Minoxidil Topical Aerosol, 5%?

Minoxidil Topical Aerosol, 5% is a white foam containing 5% minoxidil for use only on the scalp to help regrow hair in men.

Who may use Minoxidil Topical Aerosol, 5%?

Minoxidil Topical Aerosol, 5% is for use only by men. Minoxidil Topical Aerosol, 5% 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 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.

Minoxidil Topical Aerosol, 5% is for men with hair loss or thinning hair that begins on the vertex of the scalp. Minoxidil Topical Aerosol, 5% is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, Minoxidil Topical Aerosol, 5% may not work.



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

Who should NOT use Minoxidil Topical Aerosol, 5%?

• Women should not use Minoxidil Topical Aerosol, 5%.

• Minoxidil Topical Aerosol, 5% should not be used on babies or children under 18 years old.

• Minoxidil Topical Aerosol, 5% 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, Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5% work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Minoxidil Topical Aerosol, 5%. The response to Minoxidil Topical Aerosol, 5% cannot be predicted. It is unlikely anyone will be able to grow back all their hair.

However, to see your best results with Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5% may not work.

How soon can I expect results from using Minoxidil Topical Aerosol, 5%?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5% and seek the advice of your physician.

When you **first** begin to use Minoxidil Topical Aerosol, 5%, 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 part of the process for how Minoxidil Topical Aerosol, 5% regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your physician.

If Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5%?

If you experience hair regrowth, continued use of Minoxidil Topical Aerosol, 5% is necessary or the hair loss will begin again.

What happens if I completely stop using Minoxidil Topical Aerosol, 5%?

Continuous use of Minoxidil Topical Aerosol, 5% is needed to maintain hair regrowth. If you stop using Minoxidil Topical Aerosol, 5%, you will lose your newly regrown hair in 3 to 4 months.

How do I use Minoxidil Topical Aerosol, 5%?

For best results, apply half a capful **2 times a day directly** to the scalp in the hair loss area. Using more than the recommended amount will not improve results. Each can should last one month, if used as directed.

Never take this product by mouth or apply to other parts of the body.

When do I use Minoxidil Topical Aerosol, 5%?

Apply Minoxidil Topical Aerosol, 5% once in the morning and once at night. Allow the nighttime application to dry completely before going to bed. Each can should last one month, if used as directed.

What if I miss a dose or forget to use Minoxidil Topical Aerosol, 5%?

If you miss one or two daily doses of Minoxidil Topical Aerosol, 5% just continue with your next dose. You should not make up for missed doses.

Can I use Minoxidil Topical Aerosol, 5% more than twice a day?

Will it work faster, better?

No. Minoxidil Topical Aerosol, 5% will not work faster or better if used more than two times a day. 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 Minoxidil Topical Aerosol, 5%?

If you wash your scalp before applying Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5%. For best results, Minoxidil Topical Aerosol, 5% should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5%?

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of Minoxidil Topical Aerosol, 5%. 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 Minoxidil Topical Aerosol, 5% has been washed off the hair and scalp before using color or perm chemicals.

2) For best results, do not apply Minoxidil Topical Aerosol, 5% on the same day that you use a chemical treatment on your hair.

3) Do not use Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5% as usual.

4) Simply restart your normal Minoxidil Topical Aerosol, 5% routine. There is no need to use more Minoxidil Topical Aerosol, 5% to make up for missed applications.

Missing one day of Minoxidil Topical Aerosol, 5% will not affect your hair regrowth results.

Can I apply Minoxidil Topical Aerosol, 5% and wash my hair an hour later?

No. For Minoxidil Topical Aerosol, 5% to work best, you should allow it to stay on the scalp for about 4 hours before washing.

Using the product:

To Open:

1. Hold **RING** (See diagram)

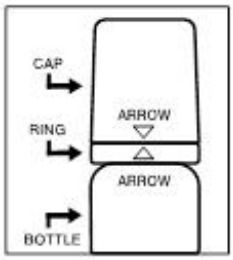
2. While holding **RING** twist **CAP** to line up arrow on **RING** with arrow on **CAP**.

3. Tilt **CAP** back and pull

To Close:

1. Place **CAP** on container and snap into place.

2. Be sure arrows ***DO NOT*** line up so **CAP** remains child resistant.



• Within the hair thinning area, part the hair into one or more rows to maximize scalp exposure.

• Minoxidil Topical Aerosol, 5% may begin to melt right away on contact with your warm skin. If your fingers are warm, rinse them in cold water first. (Be sure to dry them thoroughly before handling Minoxidil Topical Aerosol, 5%.)

• Hold the can upside down and press nozzle to dispense Minoxidil Topical Aerosol, 5% onto your fingers. The total amount of Minoxidil Topical Aerosol, 5% applied should not exceed half a capful.

• Using your fingers, spread Minoxidil Topical Aerosol, 5% over the hair loss area and gently massage into scalp and then wash your hands well.

• After each use, close the container to make child resistant by snapping the cap back on to the can.

Warnings

For external use only

For use by men only

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

• you are a woman

• your amount of hair loss is different than that shown on the other side of this leaflet or your hair loss is on the front of the scalp. Minoxidil Topical Aerosol, 5% 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 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 may experience 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

Not for use by women

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. (1-800-222-1222)

What are the most common side effects with Minoxidil Topical Aerosol, 5%?

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. Minoxidil Topical Aerosol, 5% contains alcohol, which will cause burning or irritation of the eyes. If Minoxidil Topical Aerosol, 5% accidentally gets into eyes, rinse with large amounts of cool tap water.

Can Minoxidil Topical Aerosol, 5% 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 Minoxidil Topical Aerosol, 5%. Over time, the unwanted hair growth caused by Minoxidil Topical Aerosol, 5% will go away. You can take the following steps to decrease the chances of unwanted hair growth:

1) limit the application of Minoxidil Topical Aerosol, 5% only to the scalp

2) if you use your hands to apply Minoxidil Topical Aerosol, 5%, wash your hands well immediately afterwards

Can I use Minoxidil Topical Aerosol, 5% for baldness or hair loss in babies or children?

No. Minoxidil Topical Aerosol, 5% must not be used to treat baldness or hair loss in babies and children.

If you have any other questions, ask your healthcare professional or call us at 1-800-719-9260.

Store at 20-25°C (68-77°F).

Save this leaflet for future reference

Made in Israel

Manufactured by Perrigo

Yeruham, Israel 80500

Distributed By
Perrigo®
Allegan, MI 49010 • www.perrigo.com

Rev. 10/11
:29400 00 J2

Package/Label Principal Display Panel

MINOXIDIL TOPICAL AEROSOL, 5% (FOAM)
HAIR REGROWTH TREATMENT FOR MEN
clinically proven to help regrow hair
EASY-TO-USE UNSCENTED FOAM
NOT FOR USE BY WOMEN
COMPARE TO THE ACTIVE INGREDIENT OF MEN'S ROGAINE®
FOAM

meijer™

MINOXIDIL TOPICAL AEROSOL, 5% (FOAM)

HAIR REGROWTH TREATMENT

FOR MEN

NDC 41250-294-01

meijer™

MINOXIDIL TOPICAL AEROSOL, 5% (FOAM)

HAIR REGROWTH TREATMENT

FOR MEN

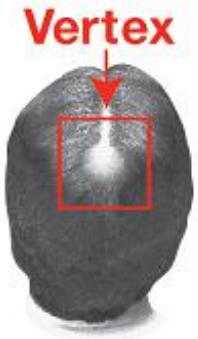
clinically proven to help regrow hair

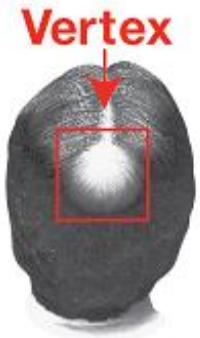
EASY-TO-USE UNSCENTED FOAM

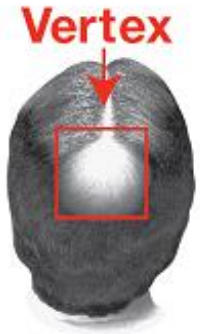
One Month Supply

NOT FOR USE BY WOMEN

Minoxidil Topical Aerosol, 5% (Foam) 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 aerosol, 5% (foam) 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 Aerosol, 5% (Foam) may not work.

COMPARE TO THE
ACTIVE INGREDIENT
OF MEN'S ROGAINE®*

FOAM

1-60 g (2.11 oz) CAN

7 13733 64341 2

LOT NO.

EXP.

: 294D3 6E C2

Drug Facts

Active ingredient	Purpose
Minoxidil 5% w/w (without propellant).....	Hair regrowth treatment for men

Use to regrow hair on the top of the scalp (vertex only, see pictures on side of this carton)

Warnings

For external use only. For use by men only.

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on side of this carton or your hair loss is on the front of the scalp. Minoxidil Topical Aerosol, 5% (Foam) 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 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. (1-800-222-1222)

Directions

- apply half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- 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

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- see hair loss pictures on side of this carton
- before use, read all information on package and enclosed leaflet
- keep the package. It contains important information.
- store at 20-25°C (68-77°F)
- contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Using the Product:

- To open container: Match arrow on can ring with arrow on cap. Pull off cap.
- Within the hair thinning area, part the hair into one or more rows to maximize scalp exposure.
- The foam may begin to melt right away on contact with your warm skin. If your fingers are warm, rinse them in cold water first. (Be sure to dry them thoroughly before handling the foam.)
- Hold the can upside down and press nozzle to dispense the topical foam product onto your fingers. The total amount of foam applied should not exceed half a capful.
- Using your fingers, spread the foam over the hair loss area and gently massage into scalp and then wash your hands well.
- After each use, close the container to make child resistant by snapping the cap back on the can.

REMOVE CAP

PART THE HAIR

HOLD CAN UPSIDE DOWN

MASSAGE WITH FINGERS

Made in Israel

DIST. BY MEIJER DISTRIBUTION, INC.
2929 WALKER AVE NW
GRAND RAPIDS, MI 49544
www.meijer.com

PHARMACIST RECOMMENDED
meijer
MONEY BACK GUARANTEE

Inactive ingredients butane, butylated hydroxytoluene, cetyl alcohol, citric acid, dehydrated alcohol, isobutane, lactic acid, polysorbate 60, propane, purified water, stearyl alcohol

Questions or comments? 1-800-719-9260

This Package Contains:
- 1 - 60 g (2.11 oz) Can of Minoxidil Topical Aerosol, 5% (Foam) (1 month supply)
- Information leaflet with complete directions on how to use and obtain best results

*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Rogaine®.

HAIR REGROWTH TREATMENT

minoxidil aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41250-294
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTANE (UNII: 6LV4FOR43R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
ISOBUTANE (UNII: BXR49TP611)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPANE (UNII: T75W9911L6)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:41250-294-01	1 in 1 CARTON		
1		60 g in 1 CAN		
2	NDC:41250-294-03	3 in 1 CARTON		
2		60 g in 1 CAN		
3	NDC:41250-294-04	4 in 1 CARTON		
3		60 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091344	03/19/2012	

Labeler - Meijer Distribution Inc (006959555)

Revised: 1/2013 Meijer Distribution Inc