

HAIR REGROWTH TREATMENT- minoxidil aerosol, foam
Kroger Company

Kroger Co. Hair Regrowth Treatment Drug Facts

Active ingredient

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for women

Use

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

Warnings

For external use only.

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

Do not use if

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

Ask a doctor before use if you have

heart disease

When using this product

- do not use more than directed
- 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 3 months with **once daily** use. For some women, you may need to use this product **once a day** for at least 6 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for all

women.

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 6 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

- see enclosed leaflet for complete directions on how to use
- apply half a capful once daily directly to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- 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.
- 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?

1-800-632-6900

Consumer information

#1 DERMATOLOGIST RECOMMENDED ACTIVE INGREDIENT†

IMPORTANT INFORMATION ABOUT

Minoxidil Topical Aerosol, 5% (Foam)

Hair Regrowth Treatment

For Women

- **Reactivates Hair Follicles To Stimulate Regrowth**
- **Clinically Proven to Regrow Hair**
- **Once-a-Day Foam For Women**

UNSCENTED

SAVE THIS LEAFLET FOR FUTURE REFERENCE

Please read this leaflet carefully. It will help you understand how to use Minoxidil Topical Aerosol, 5% (For Women) and what to expect from its use. It takes time to regrow hair. Results may occur at 3 months with **once daily** usage. For some women, you may need to use this product for at least 6 months before you see results. If you have any questions after reading this leaflet, or anytime while using Minoxidil Topical Aerosol, 5% (For Women), you should ask your health care professional or call us at 1-800-719-9260.

WHAT IS MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

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

WHO MAY USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

Minoxidil Topical Aerosol, 5% (For Women) may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of your scalp. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Minoxidil Topical Aerosol, 5% (For Women) is for general thinning of hair on the top of the scalp as shown below. Minoxidil Topical Aerosol, 5% (For Women) has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Minoxidil Topical Aerosol, 5% (For Women) may not work.

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



WHO SHOULD NOT USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

Minoxidil Topical Aerosol, 5% (For Women) will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth

control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Minoxidil Topical Aerosol, 5% (For Women) 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% (FOR WOMEN) WORK FOR ME?

The amount of hair regrowth is different for each person. Not everyone will respond to Minoxidil Topical Aerosol, 5% (For Women). The response to Minoxidil Topical Aerosol, 5% (For Women) cannot be predicted. No one will be able to grow back all their hair.

To see your best results with Minoxidil Topical Aerosol, 5% (For Women), make sure you apply the product directly to the scalp **once daily**. For some women, Minoxidil Topical Aerosol, 5% (For Women) may not work.

HOW SOON CAN I EXPECT RESULTS FROM USING MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Minoxidil Topical Aerosol, 5% (For Women) also takes time. Generally, new hair growth is slow for a Minoxidil Topical Aerosol, 5% (For Women) user. Results may be seen as early as 3 months with **once daily** use. For some women, it may take at least 6 months for results to be seen. If you do not see any results after 6 months, stop using Minoxidil Topical Aerosol, 5% (For Women) and seek the advice of your doctor.

When you first begin to use Minoxidil Topical Aerosol, 5% (For Women), your hair loss may continue for up to 2 weeks. This increase in hair loss is expected and is temporary. However, if it continues after two weeks, see your physician.

IF MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN) IS WORKING, WHAT WILL THE HAIR LOOK LIKE?

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

HOW LONG DO I NEED TO USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

If you respond to Minoxidil Topical Aerosol, 5% (For Women), you need to use it **once daily** to keep and continue the hair regrowth. Up to 3 months of usage may be needed to see your best results from Minoxidil Topical Aerosol, 5% (For Women).

WHAT HAPPENS IF I COMPLETELY STOP USING MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)? WILL I KEEP THE NEW HAIR?

Continuous use of Minoxidil Topical Aerosol, 5% (For Women) is needed to maintain hair regrowth. If you stop using Minoxidil Topical Aerosol, 5% (For Women), the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

HOW DO I USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

For best results, apply half a capful **once 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 two months, if used as directed. Never take this product by mouth or apply to other parts of the body. Please refer to the "Directions for Use" section of this leaflet.

WHEN DO I USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

Apply Minoxidil Topical Aerosol, 5% (For Women) **once daily**. If you apply at night, allow application to dry completely before going to bed.

WHAT IF I FORGET TO USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN) OR MISS A DOSE?

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

CAN I USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN) MORE THAN ONCE A DAY? WILL IT WORK FASTER, BETTER?

No. Minoxidil Topical Aerosol, 5% (For Women) will not work faster or better if used more than **once a day**. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chances of side effects.

WHAT KIND OF SHAMPOO SHOULD I USE WITH MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

If you wash your scalp before applying Minoxidil Topical Aerosol, 5% (For Women), use a mild shampoo.

CAN I USE HAIR SPRAYS, MOUSSES, CONDITIONERS, GELS, ETC.?

Yes. There is no reason to change your usual hair care routine when using Minoxidil Topical Aerosol, 5% (For Women). However, you should apply Minoxidil Topical Aerosol, 5% (For Women) first and wait for it to dry before applying your styling aids.

CAN I HAVE MY HAIR COLORED OR PERMED OR USE HAIR RELAXERS WHILE USING MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

Yes. We have no evidence that coloring, perming, or using relaxers on your hair change the effect of Minoxidil Topical Aerosol, 5% (For Women). 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% (For Women) 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% (For Women) on the same day that you use a chemical treatment on your hair.
3. Do not use Minoxidil Topical Aerosol, 5% (For Women) 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% (For Women) as usual.
4. Simply restart your normal Minoxidil Topical Aerosol, 5% (For Women) routine. There is no need to use more Minoxidil Topical Aerosol, 5% (For Women) to make up for missed applications.

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

CAN I APPLY MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN) AND WASH MY HAIR AN HOUR LATER?

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

DIRECTIONS FOR USE

- Please familiarize yourself with the instructions below in order to help make your product application a success.
- This product should be used **ONCE DAILY, EVERY DAY**.
- To be effective, it is important to apply the product **DIRECTLY TO YOUR SCALP** and **NOT TO**

YOUR HAIR so that it can easily get to your hair follicles to help regrow your hair.

- There is no need to shampoo your hair before using the product. If you wish to shampoo your hair before applying Minoxidil Topical Aerosol, 5% (For Women), towel dry your hair so that the skin on the scalp is dry.
- **TO OPEN** the container: Hold ring. While holding ring, twist cap to line up the arrow on the ring with the arrow on the cap. (Figure 1 below) Tilt cap back and pull off cap.
- **The foam may begin to melt on contact if your fingers are warm. Rinse your fingers in cold water first before dispensing. Be sure to dry them thoroughly before handling the foam.**
- Hold the can straight upside down, press nozzle to dispense half a capful of the foam onto a non-absorbent surface (Figure 2 below). The total amount of foam applied should not exceed half a capful.
- Within your hair thinning areas, make a center part to help maximize scalp exposure. Part your hair at least 2 more times on each side of the center part (Figure 3 below).
- Using your fingertips, spread just enough foam over the hair loss areas and gently massage the foam into the scalp starting from the back to front (forehead) direction (Figure 4 below). Use until all the foam is gone.
- After each use, thoroughly clean and dry the dish or saucer if used.
- Wash your hands well with soap and water after applying.
- **TO CLOSE** the container: place cap on container and snap into place. Be sure arrows do not line up so cap remains child resistant.



ARE THERE ANY SPECIAL WARNINGS ABOUT THE USE OF MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

For external use only.

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

DO NOT USE IF

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

Ask a doctor before use if you have heart disease.

WHEN USING THIS PRODUCT

- do not use more than directed
- 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 in 3 months with **once daily** use. For some women you may need to use this product **once daily** for at least 6 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for everyone.

STOP USE AND ASK A DOCTOR IF

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs
- you do not see hair regrowth in 6 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)

WHAT ARE THE MOST COMMON SIDE EFFECTS WITH MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

The most common side effects are itching and other skin irritations of the treated area of the scalp. Minoxidil Topical Aerosol, 5% (For Women) contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Minoxidil Topical Aerosol, 5% (For Women) accidentally gets into these areas, rinse with large amounts of cool tap water. Stop using Minoxidil Topical Aerosol, 5% (For Women) and contact your doctor if irritation persists.

CAN MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN) PRODUCE UNWANTED HAIR?

Unwanted hair growth has been reported on the face and on other parts of the body with Minoxidil Topical Aerosol, 5% (For Women) use. The unwanted hair growth may be caused by the transfer of Minoxidil Topical Aerosol, 5% (For Women) to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not relate to the use of Minoxidil Topical Aerosol, 5% (For Women).

If you experience unwanted hair, discontinue using Minoxidil Topical Aerosol, 5% (For Women) and see your doctor for recommendations about appropriate treatment. After stopping use of Minoxidil Topical Aerosol, 5% (For Women), the unwanted hair, if caused by the use of Minoxidil Topical Aerosol, 5% (For Women), should go away over time. You can take steps to decrease the chances for unwanted hair growth:

1. Limit the application of Minoxidil Topical Aerosol, 5% (For Women) only to the scalp,
2. If you use the hands to apply Minoxidil Topical Aerosol, 5% (For Women), wash your hands thoroughly afterwards, and

3. Allow sufficient drying time before going to bed (usually 2 to 4 hours before going to bed after applying Minoxidil Topical Aerosol, 5% (For Women)).

CAN I USE MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN) FOR BALDNESS OR HAIR LOSS IN BABIES AND CHILDREN?

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

WHAT FACTORS MAY INCREASE THE RISK OF SERIOUS SIDE EFFECTS WITH MINOXIDIL TOPICAL AEROSOL, 5% (FOR WOMEN)?

Minoxidil Topical Aerosol, 5% (For Women) should be applied only to the scalp. The risk of side effects may be greater when Minoxidil Topical Aerosol, 5% (For Women) is applied to other parts of the body.

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

Store at 20° to 25°C (68° to 77°F).

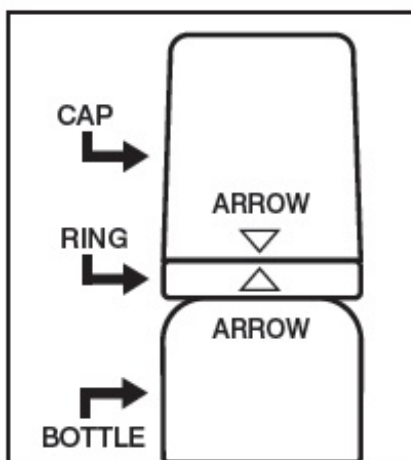
Save this leaflet for future reference.

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.



†In the U.S.

Source: AlphaImpactRx

Made in Israel

Distributed By

Perrigo®

Allegan, MI 49010

Rev 01-17

: 12900 00 J2

Package/Label Principal Display Panel

COMPARE TO the active ingredient of WOMEN'S ROGAINE® See bottom panel

FOAM

MINOXIDIL TOPICAL AEROSOL, 5% (FOAM)

Hair Regrowth Treatment for Women

#1 Dermatologist Recommended

Active Ingredient

Clinically Proven To Regrow Hair

Unscented

Foam For Women

Four Month Supply

Reactivates Hair Follicles To Stimulate Regrowth

One-a-Day

TWO-60 g (2.11 OZ) CANS

TOTAL 120 g (4.22 OZ)



HAIR REGROWTH TREATMENT

minoxidil aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-719
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 g

Inactive Ingredients	
Ingredient Name	Strength
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)	
WATER (UNII: 059QF0K00R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics			
Color	WHITE (off-white, clear)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-719-02	2 in 1 CARTON	05/22/2018	
1		60 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091344	05/22/2018	

Labeler - Kroger Company (006999528)

Revised: 5/2018

Kroger Company