

TOPPIK WOMENS HAIR REGROWTH TREATMENT- minoxidil solution
Spencer Forrest, Inc.

Toppik Women's Hair Regrowth Treatment

Drug Facts

Active ingredient

Minoxidil 2% w/v

Purpose

Hair regrowth treatment

Use

to regrow hair on the scalp

Warnings

For external use only.

Flammable: Keep away from fire or flame.

Do not use if:

- Your degree of hair loss is different than that shown on the inside of this package, 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, irritated or painful
- You use other medicines on the scalp

Ask a doctor before use if you have heart disease.

When using this product:

- Do not apply on other parts of the body
- Avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water
- Some people have experienced changes in hair color and/or texture
- It takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results.
- The amount of hair regrowth is different for each person. This product will not work for everyone.

Stop use and ask a doctor if:

- Side effects occur: You may report side effects to FDA at 1-800-FDA-1088 or to Toppik Inc. at 1-800-THICKEN (844-2536).
- 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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 to increase and keep your hair regrowth, or hair loss will begin again

Other information

- See hair loss pictures on inside of this package
- Before use, read all information on package and enclosed leaflet
- Keep the package. It contains important information.
- In clinical studies with mostly white women age 18-45 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 19% of women reported moderate hair regrowth after using women's minoxidil topical solution 2% for 8 months; 19% had moderate regrowth; 40% had minimal regrowth. This compares with 7% of women reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth, 33% had minimal regrowth).
- Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

Inactive ingredients

Alcohol 60% v/v, Propylene Glycol 20% v/v, Purified Water

Questions or comments?

Call your health professional or Toppik Inc. at 1-800-THICKEN (844-2536)

DIST. BY:

TOPPIK INC.

11777 San Vicente Blvd, Suite 650

Los Angeles, CA 90049

Toppik

Hair Regrowth Treatment

WOMEN'S

2% Minoxidil Topical Solution

Unscented

Important information about Toppik Women's Hair Regrowth Treatment Minoxidil Topical Solution USP 2%

Save this leaflet for future reference.

- Hair regrowth treatment
- Previously available only by prescription

Over 30 million American women experience hair thinning or hair loss, so you're not alone. Toppik Women's Hair Regrowth Treatment contains the only ingredient that is medically proven effective to

help regrow hair in women.

Please read this leaflet carefully. It will help you understand how to use Toppik Women's Hair Regrowth Treatment and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Toppik Women's Hair Regrowth Treatment, you should ask your health care professional or call us at 1-800-THICKEN (844-2536). You can also contact us via email at support@toppik.com or on our website at TOPPIK.com.

What is Toppik Women's Hair Regrowth Treatment?

Toppik Women's Hair Regrowth Treatment is a colorless liquid medication for use only on the scalp to help regrow hair.

Who may use Toppik Women's Hair Regrowth Treatment ?

Toppik Women's Hair Regrowth Treatment may be appropriate for you if you are an adult at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss. Toppik Women's Hair Regrowth Treatment is for general thinning of hair on the top of the scalp as shown in the illustration. Toppik Women's Hair Regrowth Treatment



has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Toppik Women's Hair Regrowth Treatment may not work. Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. If there is no family history of gradual thinning hair or gradual hair loss, or your hair loss is patchy, see your doctor.

Who should NOT use Toppik Women's Hair Regrowth Treatment?

Toppik Women's Hair Regrowth Treatment 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, Toppik Women's Hair Regrowth Treatment 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 Toppik Women's Hair Regrowth Treatment if hair loss is patchy as shown below.

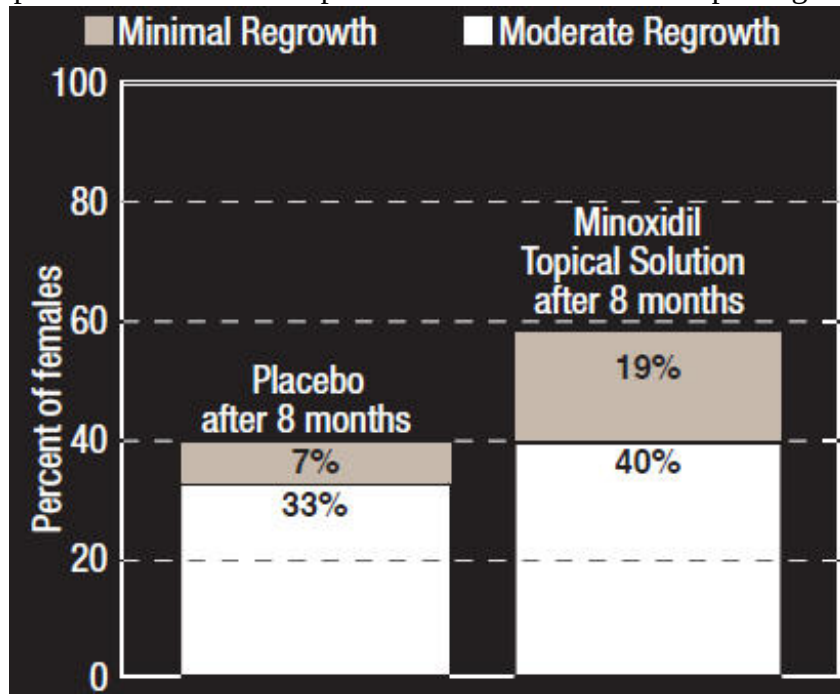


You should ask your doctor if you are unsure of the cause of your hair loss

Will Toppik Women's Hair Regrowth Treatment work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Toppik Women's Hair Regrowth Treatment. The response to Toppik Women's Hair Regrowth Treatment cannot be predicted. No one will be able to grow back all their hair. In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to Minoxidil Topical Solution 2% was reported:

Female Response to Minoxidil Topical Solution 2% Percent reporting hair regrowth



19% of women reported moderate hair regrowth after using Minoxidil Topical Solution 2% for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).

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 hair on the rest of the head.

Can Toppik Women's Hair Regrowth Treatment be used to prevent hair loss?

We do not know if Toppik Women's Hair Regrowth Treatment will prevent hair loss.

How soon can I expect results from using Toppik Women's Hair Regrowth Treatment?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Toppik Women's Hair

Regrowth Treatment also takes time. Generally new hair growth is slow for a Toppik Women's Hair Regrowth Treatment user. Continued use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth. If you do not see hair regrowth in 4 months, stop using Toppik Women's Hair Regrowth Treatment and see your doctor.

When you first begin to use Toppik Women's Hair Regrowth Treatment, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

If Toppik Women's Hair Regrowth Treatment 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 Toppik Women's Hair Regrowth Treatment?

If you respond to Toppik Women's Hair Regrowth Treatment, you need to use it 2 times a day to keep and continue the hair regrowth. Up to 8 months of usage may be needed to see your best results from Toppik Women's Hair Regrowth Treatment.

What happens if I completely stop using Toppik Women's Hair Regrowth Treatment? Will I keep the new hair?

Continuous use of Toppik Women's Hair Regrowth Treatment is needed to maintain hair regrowth. If you stop using Toppik Women's Hair Regrowth Treatment, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

What is the dosage of Toppik Women's Hair Regrowth Treatment?

You should apply a dose (1mL) of Toppik Women's Hair Regrowth Treatment directly onto scalp in the hair loss area TWO TIMES A DAY; for example, once in the morning and once at the night. Each bottle should last about one month, if used as directed. Please refer to the "Directions for Use" section of the leaflet.

What if I miss a dose or forget to use Toppik Women's Hair Regrowth Treatment?

If you miss one or two daily doses of Toppik Women's Hair Regrowth Treatment, just continue with your next dose. You should not make up for missed doses.

Can I use Toppik Women's Hair Regrowth Treatment more than twice a day? Will it work faster, better?

No. Toppik Women's Hair Regrowth Treatment 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 Toppik Women's Hair Regrowth Treatment needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

What are most common side effects with Toppik Women's Hair Regrowth Treatment?

The most common side effects are itching and other skin irritations of the treated area of the scalp. Toppik Women's Hair Regrowth Treatment contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Toppik Women's Hair Regrowth Treatment accidentally gets into these areas, rinse with large amounts of cool tap water. Consult your doctor if irritation persists.

What kind of shampoo should I use with Toppik Women's Hair Regrowth Treatment?

If you wash your scalp before applying Toppik Women's Hair Regrowth Treatment, 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 Toppik Women's Hair Regrowth Treatment. However, you should apply Toppik Women's Hair Regrowth Treatment first and

wait for it to dry before using your styling aids.

Can I have my hair colored or permed or use hair relaxers while using Toppik Women's Hair Regrowth Treatment?

Yes. We have no information that these treatments change the effect of Toppik Women's Hair Regrowth Treatment. However, to avoid possible scalp irritation, you should make sure all of the Toppik Women's Hair Regrowth Treatment has been washed off the hair and scalp before using color or perm chemicals.

Can I apply Toppik Women's Hair Regrowth Treatment and wash my hair an hour later?

No. For Toppik Women's Hair Regrowth Treatment to work best, you should allow it to remain on the scalp for about 4 hours before washing.

Can I go swimming or out in the rain?

Yes. Avoid washing off the Toppik Women's Hair Regrowth Treatment. If possible, apply Toppik Women's Hair Regrowth Treatment to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Toppik Women's Hair Regrowth Treatment.

Can Toppik Women's Hair Regrowth Treatment produce unwanted hair?

Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Toppik Women's Hair Regrowth Treatment to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Toppik Women's Hair Regrowth Treatment. If you experience unwanted hair, discontinue using Toppik Women's Hair Regrowth Treatment and see your doctor for recommendations about appropriate treatment. After stopping use of Toppik Women's Hair Regrowth Treatment, the unwanted hair, if caused by the use of Toppik Women's Hair Regrowth Treatment, should go away over time.

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

1. Limit the application of Toppik Women's Hair Regrowth Treatment only to the scalp,
2. If you use your hands to apply Toppik Women's Hair Regrowth Treatment, wash your hands thoroughly afterwards, and
3. Allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Toppik Women's Hair Regrowth Treatment.

Can I use Toppik Women's Hair Regrowth Treatment for baldness or hair loss in babies and children?

No. Toppik Women's Hair Regrowth Treatment must not be used to treat baldness or hair loss in babies or children.

Are there special warnings about the use of Toppik Women's Hair Regrowth Treatment?

For external use only.

Flammable: Keep away from fire or flame.

Do not use if:

- Your degree of hair loss is more than that shown in the illustration on page 1 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 apply on other parts of the body.
- Avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- Some people have experienced changes in hair color and/or texture.
- It takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results.
- The amount of hair regrowth is different for each person. This product will not work for everyone.

Stop use and ask a doctor if:

- Chest pain, rapid heartbeat, faintness, or dizziness occurs.
- Sudden, unexplained weight gain occurs.
- Your hands or feet swell.
- Scalp irritation or redness occurs.
- Unwanted facial hair growth occurs.
- You do not see hair regrowth in 4 months.

May be harmful if used when pregnant or breast-feeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What factors may increase the risk of serious side effects with Toppik Women's Hair Regrowth Treatment?

Toppik Women's Hair Regrowth Treatment should be applied only to the scalp. The risk of side effects may be greater when Toppik Women's Hair Regrowth Treatment is applied to other parts of the body.

Directions for Use:

When applying Toppik Women's 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 Toppik Women's Hair Regrowth Treatment.

1. Remove the bottle of Toppik Women's Hair Regrowth Treatment from the package.
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 Toppik Women's 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.

If you have any other questions, ask your health care professional or call us at 1-800-THICKEN (844-2536). You can also email us at support@toppik.com or visit our website at TOPPIK.com.

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

Save this leaflet for future reference.

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Canister Label

NDC# 61355-569-60

WOMEN'S

Clinically proven to help regrow
hair. Reactivates hair follicles
to stimulate regrowth.

Toppik

Hair Regrowth Treatment
2% MINOXIDIL TOPICAL SOLUTION

Easy-To-Use

Spray

Unscented

TOPPIK INC.

60mL (2 fl oz) Bottle/ 30-Day Supply



front

NDC# 61355-569-60

548166

WOMEN'S

Clinically proven to help regrow hair. Reactivates hair follicles to stimulate regrowth.

TOPPIK

Hair Regrowth Treatment

2% MINOXIDIL TOPICAL SOLUTION



Easy-To-Use
Spray
Unscented

TOPPIK INC.

60mL (2 fl oz) Bottle/ 30-Day Supply

Drug Facts

Active ingredient

Minoxidil 2% w/v.....Hair regrowth treatment

Purpose

Use to regrow hair on the scalp

Warnings

For external use only.

Flammable: Keep away from fire or flame.

Do not use if: • Your degree of hair loss is different than that shown on the inside of this package, 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, irritated or painful • You use other medicines on the scalp

Ask a doctor before use if you have heart disease.

When using this product:

• Do not apply on other parts of the body • Avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water • Some people have experienced changes in hair color and/or texture • It takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results. • The amount of hair regrowth is different for each person. This product will not work for everyone.

Stop use and ask a doctor if:

• Side effects occur: You may report side effects to FDA at 1-800-FDA-1088 or to Topplik Inc. at 1-800-THICKEN (844-2536). • 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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 to increase and keep your hair regrowth, or hair loss will begin again

Other information • See hair loss pictures on inside of this package • Before use, read all information on package and enclosed leaflet • Keep the package. It contains important information. • In clinical studies with mostly white women age 18-45 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 19% of women reported moderate hair regrowth after using women's minoxidil topical solution 2% for 8 months; 19% had moderate regrowth; 40% had minimal regrowth. This compares with 7% of women reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth, 33% had minimal regrowth). • Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

DRUG FACTS CONT'D INSIDE

back



Topplik Women's Hair Regrowth Treatment (Minoxidil Topical Solution 2%) is for women who have general thinning of hair on the top of the scalp (vertex only, as shown below). Topplik Women's Hair Regrowth Treatment (Minoxidil Topical Solution, 2%) has been shown to regrow hair in women with the following degrees of thinning hair or hair loss:



This Package Contains:





If women have more hair loss than shown above, Toppik Women's Hair Regrowth Treatment may not work.

Do not use if you have patchy hair loss as shown below.



- One 60mL (2 fl oz) Spray Bottle of Toppik Women's Hair Regrowth Treatment (one month supply).
 - Information leaflet with complete directions on how to use and obtain best results
- (Read enclosed leaflet before use)

outside

Drug Facts (continued)

Inactive ingredients

Alcohol 60% w/v, Propylene Glycol 20% w/v, Purified Water

Questions or comments?

Call your health professional or Toppik Inc. at 1-800-THICKEN (844-2536)

DIRECTIONS FOR USE (CONTINUED)

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 Toppik Women's 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.

If you have any other questions, ask your health care professional or call us at 1-800-THICKEN (844-2536). You can also email us at support@toppik.com or visit our website at TOPPIK.com.

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

Save this leaflet for future reference.

Save this label for future reference.

DIST. BY:
TOPPIK INC.
11777 San Vicente Blvd, Suite 650
Los Angeles, CA 90049
Made in USA
TOPPIK.com 1-800-THICKEN (844-2536) 23-MND2

TOPPIK WOMENS HAIR REGROWTH TREATMENT

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61355-569
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Minoxidil (UNII: 5965120SH1) (Minoxidil - UNII:5965120SH1)	Minoxidil	20 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:61355-569-60	1 in 1 CANISTER		
1		60 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	01/01/2014	

Labeler - Spencer Forrest, Inc. (191988237)

Revised: 5/2014

Spencer Forrest, Inc.