MINOXIDIL - minoxidil aerosol, foam
Actavis Pharma, Inc.
-------
Women’s Minoxidil Topical Aerosol, 5% (Foam)

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)

Warning
For external use only.
Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use
- your degree of hair loss is different than that shown on the 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.

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 controlled room temperature 20° to 25° C (68° to 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, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, SD alcohol 40-B, stearyl alcohol

Questions?
1-800-432-8534 between 9 am and 4 pm EST, Monday – Friday.
[use of Actavis 800 number is preferred for Adverse Event reporting purposes, ensure entire statement is bold]

Consumer Information
PATIENT INFORMATION
Women’s Minoxidil(min-OX-i-dil)Topical Aerosol, 5% (Foam)
Hair Regrowth Treatment

UNSCENTED
Clinically Proven to Regrow Hair
Save this leaflet for future reference.
Please read this leaflet carefully. It will help you understand how to use Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam), you should ask your health care professional or call Actavis at 1-800-432-8534.

What is Women’s Minoxidil Topical Aerosol, 5% (Foam)?

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

Who may use Women’s Minoxidil Topical Aerosol, 5% (Foam)?

Women’s Minoxidil Topical Aerosol, 5% (Foam) 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.

Women’s Minoxidil Topical Aerosol, 5% (Foam) is for general thinning of hair on the top of the scalp as shown below. Women’s Minoxidil Topical Aerosol, 5% (Foam) has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

Women’s Minoxidil Topical Aerosol, 5% (Foam) 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, Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam) work for me?

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

To see your best results with Women’s Minoxidil Topical Aerosol, 5% (Foam), make sure you apply the product directly to the scalp once daily. For some women, Women’s Minoxidil Topical Aerosol, 5% (Foam) may not work.
How soon can I expect results from using Women’s Minoxidil Topical Aerosol, 5% (Foam)?

Since normal hair usually grows only ½ to 1 inch per month, hair regrowth with Women’s Minoxidil Topical Aerosol, 5% (Foam) also takes time. Generally, new hair growth is slow for an Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam) and seek the advice of your doctor.

When you first begin to use Women’s Minoxidil Topical Aerosol, 5% (Foam), 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 Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

If you respond to Women’s Minoxidil Topical Aerosol, 5% (Foam), 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 Women’s Minoxidil Topical Aerosol, 5% (Foam).

What happens if I completely stop using Women’s Minoxidil Topical Aerosol, 5% (Foam)? Will I keep the new hair?

Continuous use of Women’s Minoxidil Topical Aerosol, 5% (Foam) is needed to maintain hair regrowth. If you stop using Women’s Minoxidil Topical Aerosol, 5% (Foam), 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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

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

What if I forget to use Women’s Minoxidil Topical Aerosol, 5% (Foam) or miss a dose?

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

Can I use Women’s Minoxidil Topical Aerosol, 5% (Foam) more than once a day? Will it work faster, better?

No. Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

If you wash your scalp before applying Women’s Minoxidil Topical Aerosol, 5% (Foam), 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 Women’s Minoxidil Topical Aerosol, 5% (Foam). However, you should apply Women’s Minoxidil Topical Aerosol, 5% (Foam)
Can I have my hair colored or permed or use hair relaxers while using Women’s Minoxidil Topical Aerosol, 5% (Foam)?

Yes. We have no evidence that coloring, perming, or using relaxers on your hair change the effect of Women’s Minoxidil Topical Aerosol, 5% (Foam). 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 Women’s Minoxidil Topical Aerosol, 5% (Foam) has been washed off the hair and scalp before using color or perm chemicals.
2. For best results, do not apply Women’s Minoxidil Topical Aerosol, 5% (Foam) on the same day that you use a chemical treatment on your hair.
3. Do not use Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam) as usual.
4. Simply restart your normal Women’s Minoxidil Topical Aerosol, 5% (Foam) routine. There is no need to use more Women’s Minoxidil Topical Aerosol, 5% (Foam) to make up for missed applications.

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

Can I apply Women’s Minoxidil Topical Aerosol, 5% (Foam) and wash my hair an hour later?

No. For Women’s Minoxidil Topical Aerosol, 5% (Foam) to work best, you should allow Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam), towel dry your hair so that the skin on the scalp is dry.

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.

- 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-absorbant 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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

**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 more than that shown above on 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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

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

Can Women’s Minoxidil Topical Aerosol, 5% (Foam) produce unwanted hair?

Unwanted hair growth has been reported on the face and on other parts of the body with minoxidil use. The unwanted hair growth may be caused by the transfer of Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam).

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

Can I use Women’s Minoxidil Topical Aerosol, 5% (Foam) for baldness or hair loss in babies and children?

No. Women’s Minoxidil Topical Aerosol, 5% (Foam) 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 Women’s Minoxidil Topical Aerosol, 5% (Foam)?

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

If you have any other questions, ask your health care professional or call Actavis at 1-800-432-8534.

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

Save this leaflet for future reference

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Made in USA

Distributed by:

Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

Revised – October 2015

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Women’s Rogaine®*

Women's Hair Regrowth Treatment
Minoxidil Topical Aerosol, 5% (Foam)
Clinically Proven to Regrow Hair
Revitalizes Hair Follicles To Stimulate Regrowth
UNSCENTED
Once-a-Day [foam picture]
Foam For Women
TWO MONTH SUPPLY - One 60 g (2.11 oz) Can
MINOXIDIL
minoxidil aerosol, foam

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: TOPICAL

WARNING
For external use only. Do not use on children. Allow hair to dry fully before using. If scalp irritation occurs, discontinue use and consult a doctor. If used during pregnancy, it is unknown whether this product will harm an unborn baby. It is not known whether this product is excreted in breast milk. Avoid contact with eyes. Hair loss may occur in some people.
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)</td>
<td>MINOXIDIL</td>
<td>5 g in 100 g</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUTANE (UNII: 6LV4FOR43R)</td>
<td></td>
</tr>
<tr>
<td>BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)</td>
<td></td>
</tr>
<tr>
<td>CETYL ALCOHOL (UNII: 936JST6JCN)</td>
<td></td>
</tr>
<tr>
<td>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)</td>
<td></td>
</tr>
<tr>
<td>ALCOHOL (UNII: 3K958V90M)</td>
<td></td>
</tr>
<tr>
<td>ISOBUTANE (UNII: BXR49TP611)</td>
<td></td>
</tr>
<tr>
<td>LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)</td>
<td></td>
</tr>
<tr>
<td>POLYSORBATE 60 (UNII: CAL22UVI4M)</td>
<td></td>
</tr>
<tr>
<td>PROPANE (UNII: T75W9911L6)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>STEARYL ALCOHOL (UNII: 2KR894H1Y)</td>
<td></td>
</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0472-1665-85</td>
<td>1 in 1 CAPSULE</td>
<td>12/29/2017</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:0472-1665-85</td>
<td>60 g in 1 CAN; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0472-1665-87</td>
<td>2 in 1 CARTON</td>
<td>12/29/2017</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:0472-1665-87</td>
<td>60 g in 1 CAN; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDA</td>
<td>ANDA208092</td>
<td>12/29/2017</td>
<td></td>
</tr>
</tbody>
</table>

**Labeler** - Actavis Pharma, Inc. (119723554)

Revised: 12/2019  
Actavis Pharma, Inc.