

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-839

APPROVAL LETTER

OCT 1 2001

Apotex Corp.
Attention: Marcy Macdonald
U.S. Agent for Novex Pharma
50 Lakeview Parkway, Suite 127
Vernon Hills, IL 60061

Dear Madam:

This is in reference to your abbreviated new drug application dated April 3, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Minoxidil Topical Solution USP, 5% (For Men).

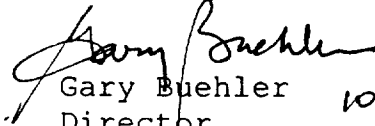
Reference is also made to your amendment dated July 6, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted over-the-counter (OTC) labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Minoxidil Topical Solution USP, 5% (For Men) to be bioequivalent to the listed drug (Rogaine® Extra Strength, 5% (For Men) of Pharmacia & Upjohn Co.).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,


Gary Buehler 10/1/01
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-839

Apotex Corp.
U.S. Agent for: Novex Pharma
Attention: Marcy Macdonald
50 Lakeview Parkway
Suite 127
Vernon Hills, IL 60061
|||||

MAY 2 2000

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Minoxidil Topical Solution USP, 5%

DATE OF APPLICATION: April 3, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: April 6, 2000

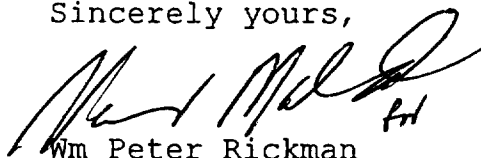
We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Elaine Hu
Project Manager
(301) 827-5848

Sincerely yours,



Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-839

APPROVED DRAFT LABELING

Each mL contains: Minoxidil 5% w/v, alcohol 30% v/v, propylene glycol 50% v/v and purified water.

NDC 60505-7102-1

Not for Use by Women: May grow facial hair. May be harmful if used during pregnancy or breast-feeding.

Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

Questions?

Please ask your health care professional or write to:
Apotex Corp. Consumer Affairs
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Manufactured by:
Novex Pharma
Richmond Hill, Ontario
Canada L4C 5H2
Manufactured for:
Apotex Corp.
Weston, FL 33326



MINOXIDIL
TOPICAL SOLUTION USP 5%
EXTRA STRENGTH FOR MEN.

HAIR REGROWTH TREATMENT

FOR EXTERNAL USE ONLY

DO NOT USE IF YOU ARE UNDER 18 YEARS OF AGE

60 mL (2 FL OZ)

35808

APOTEX CORP.

Directions: For external use only. For use by men only. Apply 1 mL with dropper or sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area. Using more, or using more often will not improve results. Do not apply on other parts of the body.

Warnings:

Do not use if you are:
• a woman • not sure of the reason for your hair loss
• under 18 years of age. Not for babies or children
• using other medicines on the scalp

Do not use if you have:
• no family history of hair loss • sudden and/or patchy hair loss • a red, inflamed, infected, irritated or painful scalp

Stop use and see a doctor if you get:

• chest pain, a rapid heartbeat, faintness or dizziness • sudden, unexplained weight gain
• swollen hands or feet • scalp irritation that continues or worsens

For external use only.
Avoid contact with eyes. In case of accidental contact, rinse with large amounts of cool tap water.

Keep this and all drugs out of the reach of children. Do not use on babies or children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

See carton or information leaflet for additional information.

VW MINOXIDIL MEN'S 5% SINGLE PACK
MAGENTA BLACK

NDC 60505-7102-1

Inactive ingredients: Alcohol 30% v/v, propylene glycol 50% v/v and purified water.

This Package Contains:

- One 60 mL (2 FL OZ) bottle of minoxidil topical solution 5% (one month supply).
- One child-resistant dropper applicator.
- One sprayer applicator (not child-resistant).
- An information leaflet.

Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

Questions?

Please ask your health care professional or write to:
Apotex Corp.
 Consumer Affairs
 2400 N. Commerce Pkwy.,
 Suite 400
 Weston, FL 33326

Manufactured by:
Novex Pharma
Richmond Hill, Ontario
Canada L4C 5H2

Manufactured for:
Apotex Corp.
Weston, FL 33326



OCT - 1 2001



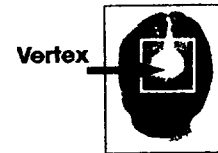
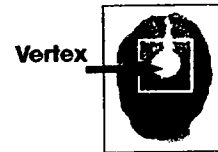
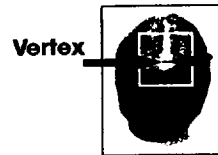
MINOXIDIL
TOPICAL SOLUTION USP 5%
EXTRA STRENGTH FOR MEN

HAIR REGROWTH TREATMENT

NOT FOR USE BY WOMEN

**REGROWS MORE HAIR
RESULTS MAY OCCUR
AT 2 MONTHS**

Minoxidil topical solution 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 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.

60 mL (2 FL OZ)



(L) UNVARNISHED AREA
EXP.

VAN WYCK PACKAGING
PROOF
 PLEASE CHECK CAREFULLY

ATTACHED IS A PROOF THAT NEEDS YOUR IMMEDIATE ATTENTION IN ORDER TO MEET YOUR REQUIRED DELIVERY SCHEDULE.

CUSTOMER: NOVEX PHARMA
 DATE SUBMITTED: 11June01
 DOCKET NO. 7892
 PROOFER: A. Brown

1st Proof 2nd Proof 3rd Proof

Proof OK as is _____

Proof OK with changes _____ Date _____

New Proof Required _____

Customer Please Sign

Please proof carefully. Proofreading is a shared responsibility. What is shown in this proof represents what will be printed. We will not be responsible for errors if work is printed according to Customer's approval.

FORM #24



1-800-265-3708 x-239

fax - (519) 371-4465

vwgraphics@bmts.com



(Read enclosed information leaflet before use)
 HAIR REGROWTH TREATMENT

EXTRA STRENGTH FOR MEN
 TOPICAL SOLUTION USP 5%

MINOXIDIL

60 mL (2 FL OZ)

NDC 60505-7102-1

MINOXIDIL Extra Strength
 TOPICAL SOLUTION USP 5% for Men

Active Ingredient: Minoxidil 5% w/v

Purpose: Hair regrowth treatment for men.

- Use:
- To regrow hair on top of the scalp (vertex only; see pictures on side of carton). Not intended for frontal baldness or receding hairline.
 - It takes time to regrow hair. With minoxidil topical solution 5%, results may occur at 2 months with twice daily usage. For some men, it may take at least 4 months for results to be seen.
 - The amount of hair regrowth is different for each person. Minoxidil topical solution 5% will not work for all men.
 - Clinical research in mostly white men aged 18-49 years with moderate degrees of hair loss showed that minoxidil topical solution 5% provides more hair regrowth than minoxidil topical solution 2%.
 - If your amount of hair loss is more than that shown on the side of this carton, or your hair loss is on the front of the scalp, minoxidil topical solution 5% may not work.
 - Continued use is necessary or hair loss will begin again. If you do not see hair regrowth in 4 months, stop use. In studies with minoxidil topical solution 5%, hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials.

- Warnings:
- Do not use if you are:
 - a woman
 - not sure of the reason for your hair loss
 - under 18 years of age. Not for babies or children
 - using other medicines on the scalp

Not for Use by Women:
 May grow facial hair.
 May be harmful if used during pregnancy or breast-feeding.

- Do not use if you have:
- no family history of hair loss
 - sudden and/or patchy hair loss
 - a red, inflamed, itchy, irritated or painful scalp

- Stop use and see a doctor if you get:
- chest pain, rapid heartbeat, faintness, or dizziness.
 - sudden, unexplained weight gain.
 - swollen hands or feet.
 - scalp irritation that continues or worsens.

For external use only.
 Avoid contact with eyes. In case of accidental contact, rinse with large amounts of cool tap water.

Keep this and all drugs out of the reach of children. Do not use on babies or children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions: For external use only. For use by men only. Apply 1 mL with dropper or sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area. Using more, or using more often will not improve results. Do not apply on other parts of the body. Keep the carton and information leaflet. They contain important information.

35809

VW MINOXIDIL MEN'S 5% TWIN PACK
MAGENTA BLACK

NDC 60505-7102-0

Inactive ingredients: Alcohol 30% v/v, propylene glycol 50% v/v and purified water.

This Package Contains:

- Two 60 mL (2 FL OZ) bottles of minoxidil topical solution 5% (two month supply).
- One child-resistant dropper applicator.
- One sprayer applicator (not child-resistant).
- An information leaflet.

Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

Questions?

Please ask your health care professional or write to:

Apotex Corp.
Consumer Affairs
2400 N. Commerce Pkwy.,
Suite 400
Weston, FL 33326

Manufactured by:
Novex Pharma
Richmond Hill, Ontario
Canada L4C 5H2

Manufactured for:
Apotex Corp.
Weston, FL 33326

NEW FORMULA

MINOXIDIL

TOPICAL SOLUTION USP 5%

EXTRA STRENGTH FOR MEN

HAIR REGROWTH TREATMENT

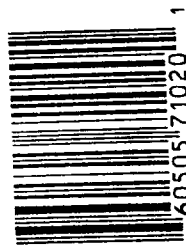
NOT FOR USE BY WOMEN

APPROVED

REGROWS MORE HAIR
RESULTS MAY OCCUR
AT 2 MONTHS

Twin Pack
2-60 mL (2 FL OZ) Bottles

A APOTEX CORP.



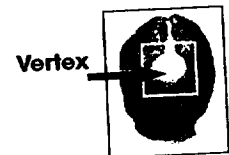
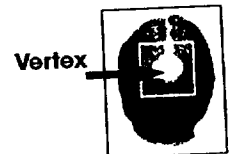
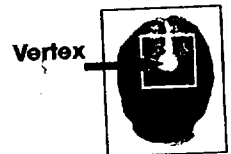
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(L)

EXP.

UNVARNISHED
AREA

Minoxidil topical solution 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 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.

VAN WYCK PACKAGING
PROOF
PLEASE CHECK CAREFULLY

ATTACHED IS A PROOF THAT NEEDS YOUR IMMEDIATE ATTENTION IN ORDER TO MEET YOUR REQUIRED DELIVERY SCHEDULE.

CUSTOMER: NOVEX PHARMA
 DATE SUBMITTED: 11 June 01
 DOCKET NO. 7891
 PROOFER: A. Brown

- 1st Proof 2nd Proof 3rd Proof
 Proof OK as is _____
 Proof OK with changes Date _____
 New Proof Required _____

Customer Please Sign

Please proof carefully. Proofreading is a shared responsibility. What is shown in this proof represents what will be printed. We will not be responsible for errors if work is printed according to Customer's approval.

FORM #24



1-800-265-3708 x-239
 fax - (519) 371-4465
 vwgraphics@bmts.com



(Read enclosed information leaflet before use)

HAIR REGROWTH TREATMENT
 EXTRA STRENGTH FOR MEN
 TOPICAL SOLUTION USP 5%
MINOXIDIL

Min Pock 2-60 mL (2 FL OZ) BOTTLES

NDC 60505-7102-0

MINOXIDIL TOPICAL SOLUTION USP 5%

**Extra Strength
 for Men**

Active Ingredient: Minoxidil 5% w/v

Purpose: Hair regrowth treatment for men.

- Use:**
- To regrow hair on top of the scalp (vertex only, see pictures on side of carton). Not intended for frontal baldness or receding hairline.
 - If it takes time to regrow hair. With minoxidil topical solution 5%, results may occur at 2 months with twice daily usage. For some men, it may take at least 4 months for results to be seen.
 - The amount of hair regrowth is different for each person. Minoxidil topical solution 5% will not work for all men.
 - Clinical research in mostly white men aged 18-49 years with moderate degrees of hair loss showed that minoxidil topical solution 5% provides more hair regrowth than minoxidil topical solution 2%.
 - If your amount of hair loss is more than that shown on the side of this carton, or your hair loss is on the front of the scalp, minoxidil topical solution 5% may not work.
 - Continued use is necessary or hair loss will begin again. If you do not see hair regrowth in 4 months, stop use. In studies with minoxidil topical solution 5%, hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials.

Warnings:

Do not use if you are:

- a woman
- not sure of the reason for your hair loss
- under 18 years of age. Not for babies or children
- using other medicines on the scalp

Not for Use by Women:
 May grow facial hair.
 May be harmful if used during pregnancy or breast-feeding

Do not use if you have:

- no family history of hair loss
- sudden and/or patchy hair loss
- a red, inflamed, infected, irritated or painful scalp

Stop use and see a doctor if you get:

- chest pain, rapid heartbeat, faintness, or dizziness
- sudden, unexplained weight gain
- swollen hands or feet
- scalp irritation that continues or worsens

For external use only.

Avoid contact with eyes. In case of accidental contact, rinse with large amounts of cool tap water.

Keep this and all drugs out of the reach of children. Do not use on babies or children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions:

For external use only. **For use by men only.** Apply 1 mL with dropper or sprayer (6 sprays) **2 times a day directly onto the scalp** in the hair loss area. Using more, or using more often will not improve results. Do not apply on other parts of the body. Keep the carton and information leaflet. They contain important information.

121053

- 4) Simply restart your normal minoxidil topical solution 5% routine. There is no need to use more minoxidil topical solution 5% to make up for missed applications. Missing one day of minoxidil topical solution 5% will not affect your hair regrowth results.

Can I apply minoxidil topical solution 5% and wash my hair an hour later?

No. For minoxidil topical solution 5% to work best, you should allow it to stay on the scalp for about 4 hours before washing.

How to use the Applicators

Applicator Options

We have included two applicators that have been designed especially for men. You can choose whichever one works best for you.

A) Dropper



The child-resistant dropper can be useful for a broad range of hair styles or hair loss because it allows for easy application through the hair and directly onto the scalp.

B) Sprayer



The sprayer may be more useful for larger areas of hair loss (see pictures over).

Using the Applicators

Important: When applying minoxidil topical solution 5%, 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.

A) Dropper

- 1) Squeeze the rubber bulb and put the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of medicine is above the 1 mL line, squeeze the extra amount back into the bottle.
- 2) Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to release the medicine gradually. To prevent the medicine from running off the scalp, apply a small amount at a time.

B) Sprayer

The sprayer (B) applicator is NOT child-resistant. If you have small children, keep the original

child-resistant cap and place it back on the bottle after each use.

- 1) Put the spray applicator into the bottle and twist it on firmly.
- 2) Next, holding the bottle upright, pump the spray attachment 6 times to get one full dose (1 mL). Be careful not to inhale the mist.

Do not use minoxidil topical solution 5% if you are:

- a woman
- not sure of the reason for your hair loss
- under 18 years of age. Not for babies and children.
- using other medicines on the scalp

Not for Use by Women:
May grow facial hair. May be harmful if used during pregnancy or breast-feeding.

Do not use if you have:

- no family history of hair loss
- sudden and/or patchy hair loss
- a red, inflamed, infected, irritated or painful scalp

Stop use and see a doctor if you get:

- chest pain, a rapid heartbeat, faintness or dizziness
- sudden, unexplained weight gain
- swollen hands or feet
- scalp irritation that continues or worsens

For external use only.

Avoid contact with eyes. In case of accidental contact, rinse with large amounts of cool tap water.

Keep this and all drugs out of the reach of children. Do not use on babies or children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

What are the most common side effects with minoxidil topical solution 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 solution 5% contains alcohol, which will cause burning or irritation of the eyes. If minoxidil topical solution 5% accidentally gets into eyes, rinse with large amounts of cool tap water.

Can minoxidil topical solution 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 solution 5%. Over time, the unwanted hair, if caused by minoxidil topical solution 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 solution 5% only to the scalp;
- 2) if you use your hands to apply minoxidil topical solution 5%, wash your hands well immediately afterwards; and
- 3) after your nighttime application of minoxidil topical solution 5%, allow enough drying time before going to bed (usually 2 to 4 hours).

Can I use minoxidil topical solution 5% for baldness or hair loss in babies or children?

No. Minoxidil topical solution 5% 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 write to Apotex Corp. Consumer Affairs, 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326.

Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

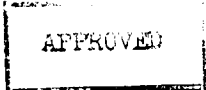
Manufactured by:
Novex Pharma
Richmond Hill, Ontario
Canada L4C 5H2

Manufactured for:
Apotex Corp.
Weston, FL 33326

One 60 mL Bottle: NDC 60505-7102-1
Two 60 mL Bottles: NDC 60505-7102-0

35810

April 2001



OCT - 1 2001

IMPORTANT INFORMATION ABOUT

**Minoxidil
Topical Solution USP**

5%

Extra Strength for Men

Hair Regrowth Treatment

- Provides more hair regrowth than minoxidil topical solution 2%.
- Results may occur at 2 months with twice daily usage. For some men, it may take at least 4 months for results to be seen.

Please read this leaflet carefully. It will help you understand how to use minoxidil topical solution 5% and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using minoxidil topical solution 5%, you should ask your health care professional or write to Apotex Corp. Consumer Affairs, 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326.

What is minoxidil topical solution 5%?

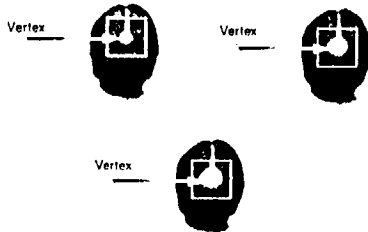
Minoxidil topical solution 5% is a colorless liquid medication containing 5% minoxidil for use only on the scalp to help regrow hair in men.

Who may use minoxidil topical solution 5%?

Minoxidil topical solution 5% is for use only by men. Minoxidil topical solution 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.

over →

Minoxidil topical solution 5% is for men with hair loss or thinning hair that begins on the vertex of the scalp. Minoxidil topical solution 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 solution 5% 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 minoxidil topical solution 5%?

- Women should not use minoxidil topical solution 5% because studies have shown it works no better in women than minoxidil topical solution 2%. Some women may also grow facial hair. In addition, minoxidil topical solution 5% may be harmful if used during pregnancy or breast-feeding.
- Minoxidil topical solution 5% should not be used on babies or for children under 18 years old.
- Minoxidil topical solution 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 solution 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.

Minoxidil topical solution 5% differs from the regular strength product in the following ways:

- Contains 5% minoxidil (the regular strength contains 2%).
- Regrows more hair.
- With minoxidil topical solution 5%, results may occur at 2 months with twice daily use. For some men, it may take at least 4 months for results to be seen.
- Is more likely to cause scalp irritation. If scalp irritation continues or worsens, stop use and see a doctor. See Warnings on carton or bottle label.

Will minoxidil topical solution 5% work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to minoxidil topical solution 5%. The response to minoxidil topical solution 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 solution 5%, make sure you get the medicine directly to the scalp and apply it twice a day, everyday.

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 solution 5% may not work.

How soon can I expect results from using minoxidil topical solution 5%?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with minoxidil topical solution 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 solution 5%.

When you first begin to use minoxidil topical solution 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 a part of the process for how minoxidil topical solution 5% regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

If minoxidil topical solution 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 solution 5%?

If you experience hair regrowth, continued use of minoxidil topical solution 5% is necessary or the hair loss will begin again. In studies with minoxidil topical solution 5%, 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 minoxidil topical solution 5%? Will I keep the new hair?

Continuous use of minoxidil topical solution 5% is needed to maintain hair regrowth. If you stop using minoxidil topical solution 5%, you will probably lose your newly regrown hair in 3 to 4 months.

How do I use minoxidil topical solution 5%?

For best results, apply 1 mL with dropper or sprayer (6 sprays) **2 times a day directly onto the scalp** in the hair loss area. Using more or using more often will not improve results. Each bottle should last about 25-30 days, if used as directed.

It is not necessary to use fingertips when applying minoxidil topical solution 5%. However, if you do use your fingertips, wash your hands well immediately afterwards. Allow time for minoxidil topical solution 5% to dry completely before wearing a hat, or lying on a pillow, etc. Minoxidil topical solution 5% may cause staining of clothing or linens if damp on the scalp. When applying minoxidil topical solution 5% 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 minoxidil topical solution 5%?

Apply minoxidil topical solution 5% once in the morning and once at night. The nighttime applications should occur 2 to 4 hours before going to bed to allow for drying. Each bottle should last about 25-30 days, if used as directed.

What if I miss a dose or forget to use minoxidil topical solution 5%?

If you miss one or two daily doses of minoxidil topical solution 5%, just continue with your next

dose. You should not make up for missed doses.

Can I use minoxidil topical solution 5% more than twice a day? Will it work faster, better?

No. Minoxidil topical solution 5% 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 minoxidil topical solution 5% 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 minoxidil topical solution 5%?

If you wash your scalp before applying minoxidil topical solution 5%, use a mild shampoo.

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

Hair sprays, spritz, or styling aids may be used on your hair while using minoxidil topical solution 5%. For best results, minoxidil topical solution 5% should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying minoxidil topical solution 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 solution 5%?

We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of minoxidil topical solution 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 solution 5% has been washed off the hair and scalp before using color or perm chemicals.
- 2) For best results, do not apply minoxidil topical solution 5% on the same day that you use a chemical treatment on your hair.
- 3) Do not use minoxidil topical solution 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 solution 5% as usual.

over →

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-839

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 75-839

3. NAME AND ADDRESS OF APPLICANT

Novex Pharma
Attention: Marcy Macdonald
380 Eigin Mills Road East
Richmond Hill, Ontario
L4C 5H2

4. LEGAL BASIS FOR SUBMISSION

The basis for Novex Pharma's ANDA for Minoxidil Topical Solution USP 5% is the approved reference listed drug, Rogaine® Extra Strength (For Men), which contains 5% of minoxidil and is the subject of NDA 20834 held by Pharmacia & upjohn.

No relevant patent

Exclusivity statement:

According to the information published in the Approved Drug Products with Therapeutic Equivalence Evaluation list, 19th edition, Pharmacia & Upjohn is entitled to a period of marketing exclusivity for Rogaine® Extra Strength (For Men) as a new product until November 14, 2000.

5. SUPPLEMENT(s)

None

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Minoxidil Topical Solution USP 5%

8. SUPPLEMENT(s) PROVIDE(s) FOR:

None

9. AMENDMENTS AND OTHER DATES:

Original submission April 3, 2000

Amendment November 17, 2000

Amendment July 6, 2001

10. PHARMACOLOGICAL CATEGORY

Hair regrowth treatment

11. Rx or OTC

OTC

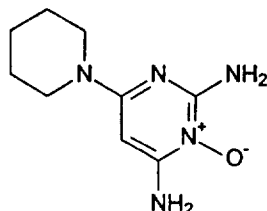
12. RELATED IND/NDA/DMF(s)

NDA 20834 RLD: Rogaine® Extra Strength (For Men) (approval date: 11/14/97) NDA 20834 is held by Pharmacia & upjohn; OTC

13. DOSAGE FORM 14. POTENCY
topical solution 5%

15. CHEMICAL NAME AND STRUCTURE

Minoxidil. 2,4-Pyrimidinediamine, 6-(1-piperidinyl)-, 3-oxide.
C₉H₁₅N₅O. 209.25. 38304-91-5. Regrow hair. USP 24, page 1118



16. RECORDS AND REPORTS
None

17. COMMENTS
None

18. CONCLUSIONS AND RECOMMENDATIONS

This application is approvable.

19. REVIEWER: DATE COMPLETED:
Kathy P. Woodland September 10, 2001

Page(s) 10

Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

Chem Rev 3
9/10/2001

APR 17 2001

38. Chemistry Comments to be Provided to the Applicant

ANDA:75-839

APPLICANT: Novex Pharma

DRUG PRODUCT: Minoxidil Topical Solution USP, 5% (For Men)

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies

1. Please submit the color test method.
2. Please submit dropper calibration data.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response that:

1. You have not responded to the labeling deficiencies faxed to you on November 29, 2000. Please respond to the deficiencies.
2. Please submit any additional room temperature stability data.

Sincerely yours,



Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-839

Bioequivalence Review(s)

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75-839

APPLICANT: NOVEX PHARMA

DRUG PRODUCT: Minoxidil Topical Solution, 5%

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,



Dale P. Conner, Pharm.D.

Director

Division of Bioequivalence

Office of Generic Drugs

Center for Drug Evaluation and Research

Minoxidil Topical Solution
 USP 5 % (50 mg/mL)
 ANDA #75-839
 Reviewer: Patrick Nwakama

Novex Pharma (APOTEX - US AGENT)
 Ontario, Canada
 Submission Date:
 April 3, 2000

Review Of A Bio-Study Waiver Request

Background

1. The firm has requested a waiver of an in vivo bioequivalence study requirement for its proposed product, Minoxidil Topical Solution, 5%. The reference listed drug (RLD) product is Rogaine^R Extra Strength for Men, 5% Minoxidil Topical Solution, manufactured by Pharmacia and Upjohn.
2. Minoxidil Topical Solution is an OTC drug product indicated for the treatment of androgenetic alopecia expressed as baldness of the vertex of the scalp in men.
3. The test and the RLD product are both topical solutions.

Formulation Comparison

Comparative Compositions of the test and reference products are as follows:

Minoxidil Topical Solution, 5% (Novex Pharma)			Rogaine ^R Extra Strength Minoxidil 5% Topical Solution*
Qualitative	Percent composition	mg/mL	Percent composition
Minoxidil			
Alcohol			
Propylene glycol			
Water, purified			

* From COMIS database

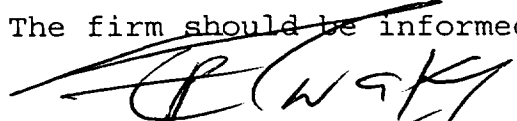
Comments

1. The test product, Minoxidil Topical Solution, 5%, contains the same active ingredient in the same concentration and dosage form as the reference product, Rogaine^R Extra Strength for Men, 5% Minoxidil Topical Solution. The test formulation does not contain any inactive ingredients known to significantly affect absorption of the active ingredient or drug moieties.
2. A waiver of in vivo bioequivalence study requirement may be granted under 21 CFR 320.22 (b)(3) of the Bioavailability/Bioequivalence Regulations.
3. The difference in alcohol content is 5% of RLD.

Recommendation

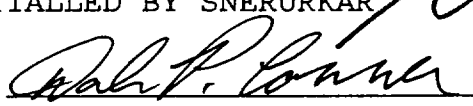
The Division of Bioequivalence agrees that the information submitted by Novex Pharma on its drug product, Minoxidil Topical Solution, 5%, falls under 21 CFR section 320.22 (b) (3) of the Bioavailability/Bioequivalence Regulations. The waiver of an in vivo bioequivalence study for the drug is granted. The Division of Bioequivalence deems the test product, Minoxidil Topical Solution, 5%, bioequivalent to the reference product, Rogaine^R Extra Strength for Men, 5% Minoxidil Topical Solution, manufactured by Pharmacia and Upjohn.

The firm should be informed of the recommendation.


Patrick Nwakama, Pharm.D.
Division of Bioequivalence
Review Branch II

RD INITIALLED BY SNERURKAR
FT INITIALLED BY SNERURKAR


Date: 5/8/00

Concur: 
Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

Date: 5/31/00

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-839

CORRESPONDENCE

July 6, 2001

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place, Room 150
Rockville, MD 20855

ORIG AMENDMENT

N/Am

MINOR AMENDMENT

RE: ANDA 75-839
Minoxidil Topical solution USP
5%

To Whom It May Concern:

Apotex Corp., as the U.S. agent for Novex Pharma, is hereby forwarding in duplicate a minor amendment in response to Minor Amendment letter dated 04/11/01 and Labeling deficiency letter from Lillie Golson, Labeling Review Branch dated 11/27/01. A field copy is also included.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald/Hs

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223





50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

November 17, 2000

ORIG AMENDMENT
NJFA

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

FAX AMENDMENT

RE: ANDA 75-839
Minoxidil Topical solution USP
5%

To Whom It May Concern:

Apotex Corp., as the U.S. agent for Novex Pharma a Division of Apotex Inc., of Ontario, Canada, is hereby forwarding in duplicate a fax amendment in response to the FDA fax deficiency letter dated October 23, 2000. A field copy is also included.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads 'Marcy Macdonald'.

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223





50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL (847) 573-9999 • FAX (847) 573-1001

April 3, 2000

505(j)(2)(A) OK!
D. Davis 4/28/00

Document Control Room
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: Minoxidil Topical Solution USP
5%
Original Abbreviated New Drug Application

To Whom It May Concern:

Pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, as amended September 24, 1994, Apotex Corp., as the U.S. agent for Novex a Division of Apotex Inc. of Ontario, Canada, is hereby forwarding an original abbreviated new drug application (ANDA) for Minoxidil Topical Solution USP 5%.

We are submitting an archival copy under blue cover, a chemistry review copy under red cover, and the bioavailability/bioequivalence review section under orange cover.

Apotex Corp. hereby certifies that in accordance with 21 CFR 314.94(d)(5), a true field copy of the technical sections of this submission under a burgundy cover is also included as a foreign applicant is submitting this ANDA.

We appreciate an expeditious review of this application. Please direct any inquiries regarding this application to me at the addresses listed above.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223

