MINOXIDIL REGULAR STRENGTH FOR MEN- minoxidil solution Proficient Rx LP

Minoxidil Topical Solution for Men

Drug Facts

Active ingredient

Minoxidil, USP 2% w/v

Purpose

Hair regrowth treatment

Use

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

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 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 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.

Directions

- apply one mL with dropper 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 side of this carton
- before use, read all information on carton and enclosed leaflet
- keep the carton. It contains important information.
- in clinical studies of mostly white men aged 18 to 49 years with moderate degrees of hair loss, the following response to minoxidil topical solution 2% for men was reported: 26% of men reported moderate to dense hair regrowth after using minoxidil topical solution 2% for men for 4 months (26% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 11% of men reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 4 months (11% had moderate to dense regrowth; 31% had minimal regrowth).
- store at controlled room temperature 20° to 25°C (68° to 77°F).

Inactive ingredients

alcohol (60% v/v), propylene glycol, purified water

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

Principal Display Panel

Actavis

Compare to the active ingredient in *Men's Rogaine*^{®*}

NDC 71205-**490**-02

Regular Strength

FOR MEN

Minoxidil Topical Solution, USP 2%

HAIR REGROWTH **TREATMENT**

Reactivates Hair Follicles to Stimulate Regrowth

Clinically Provento Help Regrow Hair

Unscented

FOR BEST RESULTS

APPLY DIRECTLY TO SCALP TWICE DAILY

TWO MONTH SUPPLY Two 60 mL (2 fl oz) Bottles





NDC 71205-490-02

Lot #:00000 Exp. 00/00/00

Minoxidil 2%

#02 **Topical Solution**

Each bottle contains: Minoxidil, USP 2% w/v Hair regrowth treatment

See package insert. For external use only

Product ID: SM049002

Dist. By: Actavis Pharma, Inc. Parsippany, NJ 07054 USA Made in Canada

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

Keep medication out of the reach of children

SN# MASTER Minoxidil 2%

#02 Topical Solution Lot #:00000 SN#MASTER

NDC 71205-490-02 Exp:00/00/00

Minoxidil 2%

#02 T Topical Solution SN#MASTER

NDC 71205-490-02 Exp:00/00/00

Minoxidil 2%

Topical Solution

Lot #:00000 NDC 71205-490-02

SN#MASTER Exp:00/00/00

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Hair regrowth treatment for men

MINOXIDIL REGULAR STRENGTH FOR MEN

minoxidil solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71205-490(NDC:0472-0066)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	reuve ingredient/reuve wrotety		
	Ingredient Name	Basis of Strength	Strength
	MINO XIDIL (UNII: 5965120 SH1) (MINO XIDIL - UNII:5965120 SH1)	MINOXIDIL	2 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71205-490- 02	2 in 1 CARTON	10/19/2020		
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074588	04/05/1996		

Labeler - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-490), RELABEL(71205-490)

Revised: 10/2020 Proficient Rx LP