

DR MANALI HAIR SERUM FOR MEN- minoxidil 5% liquid

Dr Manali Products

Active ingredient : minoxidil USP 5%

Hair Growth

Uses: to regrow hair on the top of the scalp

Warnings: For external use only. For use by men only. Flammabk!: Keep away from fire or flame

Warnings: Do not use if:
■ You are a woman
■ You have no family history of hair loss
■ Your hair loss is sudden or patchy
■ You do not know the reason for your hair loss
■ You do not know the reason for your hair loss you are under 18 years of age.
■ Do not use on babies or children
■ Your scalp is red, inflamed, infected, irritated, or painful
■ You use other medications on the scalp

Ask a doctor before use if you have heart disease.

When using this product:
■ Do not apply on other areas of the body
■ Avoid contact with eyes. In case of contact rinse eyes with large amounts of cool tap water
■ It takes time to regrow hair. Results may occur at 2 months with twice daily usage. For some men you may need to use this product 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 all men.

Do not use if :
■ You are a woman
■ You have no family history of hair loss
■ Your hair loss is sudden or patchy
■ You do not know the reason for your hair loss
■ You do not know the reason for your hair loss you are under 18 years of age.
■ Do not use on babies or children
■ Your scalp is red, inflamed, infected, irritated, or painful
■ You use other medications on the scalp

Ask a doctor before use if you have heart disease.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

Apply 1 ml with dropper 2 times a day directly onto scalp in the area of hair loss
■ 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

Store at room temperature 68 to 77 F (or 20 to 25 C), in a dry place. Keep tightly closed..

Inactive Ingredients: Biotin Liposomes (water, alcohol, panthenol, lecithin, tocopheryl acetate, caffeine, biotin), Ethyl Alcohol, Dimethyl Isosorbide, Melatonin, Prickly Pear Extract (glycerin & water & Opuntia Tuna Flower/Stem Extract), Propylene Glycol, Red Clover Extract (Certified Organic Red Clover (Trifolium Pratense) dried Leaf, vegetable glycerin, alcohol, water], Saw Palmetto/Serenoa repens Extract (glycerin, water, Serenoa Serrulata Fruit Extract, Maltodextrin), Vitamin A Liposomes (lecithin, retinal, polysorbate 20)

Questions and Comments? Call 1 30111116 8333

Monday through Friday 9:00 AM -4:00 PM EST

Email us at info@drmanaliproducts.com

FRONT

NDC 83361-000-002

Dr. Manali
Everything Your Hair Needs

Growth Serum
with 5% Minoxidil for Men

Net Wt. 2 fl oz/60ml

Active ingredients	Purpose
Minoxidil USP 5%	Hair Growth

Uses to regrow hair on the top of the scalp

Warnings: For external use only. For use by men only.
Flammable: Keep away from fire or flame

Warnings: Do not use if: ■ You are a woman ■ You have no family history of hair loss ■ Your hair loss is sudden or patchy ■ You do not know the reason for your hair loss ■ You are under 18 years of age. ■ Do not use on babies or children ■ Your scalp is red, inflamed, infected, irritated, or painful ■ You use other medications on the scalp

Ask a doctor before use if you have heart disease. ▶

3 83361 00000 2

Drug Facts continued peel here

BASE

hinge area - does not print

Drug Facts (continued)

Other information: ■ Before use, read all information regarding this product ■ Hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with minoxidil topical solution 5% for men. ■ In clinical studies with mostly men aged 18-49 years with moderate degrees of hair loss, minoxidil topical solution 5% for men provided more hair regrowth than minoxidil topical solution 2%. ■ Store at room temperature 68 to 77 F (or 20 to 25 C), in a dry place. Keep tightly closed.

Inactive Ingredients: Biotin Liposomes (water, alcohol, panthenol, lecithin, tocopheryl acetate, caffeine, biotin), Ethyl Alcohol, Dimethyl Itosorbide, Melatonin, Prickly Pear Extract (glycerin & water & Opuntia Tuna Flower/Stem Extract), Propylene Glycol, Red Clover Extract (Certified Organic Red Clover (Trifolium Pratense) dried Leaf, vegetable glycerin, alcohol, water), Saw Palmetto/Serenoa repens Extract (glycerin, water, Serenoa Semulata Fruit Extract, Maltodextrin), Vitamin A Liposomes (lecithin, retinol, polysorbate 20)

Dr. Manali Products • Petalisco, MD 20854
Questions and Comments? Call 1 301 905 8333
Monday through Friday 9:00 AM - 4:00 PM EST
Email us at info@drmanaliproducts.com

FDA REGISTERED

DMP

Hinge 2"

Seal .125"

BACK

hinge area - does not print

Drug Facts (continued)

When using this product: ■ Do not apply on other areas of the body ■ Avoid contact with eyes. In case of contact rinse eyes with large amounts of cool tap water ■ It takes time to regrow hair. Results may occur at 2 months with twice daily usage. For some men you may need to use this product 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 all men.

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 growth occurs ■ You do not see hair regrowth in 4 months.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

Directions: ■ Apply 1 mL with dropper 2 times a day directly onto scalp in the area of hair loss ■ 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. ▶

Seal .125"

Hinge 2"

DR MANALI HAIR SERUM FOR MEN

minoxidil 5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83361-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MELATONIN (UNII: JL5DK93RCL)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	
PANTHENOL (UNII: WW9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
BIOTIN (UNII: 6SO6U10H04)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
VITAMIN A (UNII: 81G40H8B0T)	
PRICKLY PEAR FRUIT (UNII: 18V8PAQ629)	
RED CLOVER (UNII: L9153EKV2Y)	
TRIFOLIUM PRATENSE LEAF (UNII: 612YOZ36DG)	
WATER (UNII: 059QF0KO0R)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
GLYCERIN (UNII: PDC6A3C0OX)	
SAW PALMETTO (UNII: J7WMH9M8QS)	
CAFFEINE (UNII: 3G6A5W338E)	
OPUNTIA TUNA STEM (UNII: 2HCC68I98K)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
RETINOL (UNII: G2SH0XKK91)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83361-002-02	1 in 1 CARTON	02/01/2024	
1	NDC:83361-002-01	60 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

OTC Monograph Drug	M032	02/01/2024	
--------------------	------	------------	--

Labeler - Dr Manali Products (110035406)

Establishment

Name	Address	ID/FEI	Business Operations
Dr Manali Products		110035406	manufacture(83361-002)

Revised: 1/2024

Dr Manali Products