

**WOMENS MINOXIDIL HAIR REGROWTH- minoxidil
Topiderm, Inc**

Women's Minoxidil Hair Regrowth System

Drug Facts

Active ingredient

Minoxidil 2% w/v

Purpose

Hair regrowth treatment

Use

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

Warnings

For external use only.

Flammable: Keep away from fire or flame

Do not use if

- your amount 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, 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. Results may occur at 2 months with twice a day usage. For some women, 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 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 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 opposite side
- before use, read all information on carton and enclosed leaflet
- keep the insert. It contains important information.
- In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution 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).
- store at USP controlled room temperature 20° to 25°C (68° to 77°F)

Inactive ingredients

Alcohol, Propylene Glycol, Purified Water

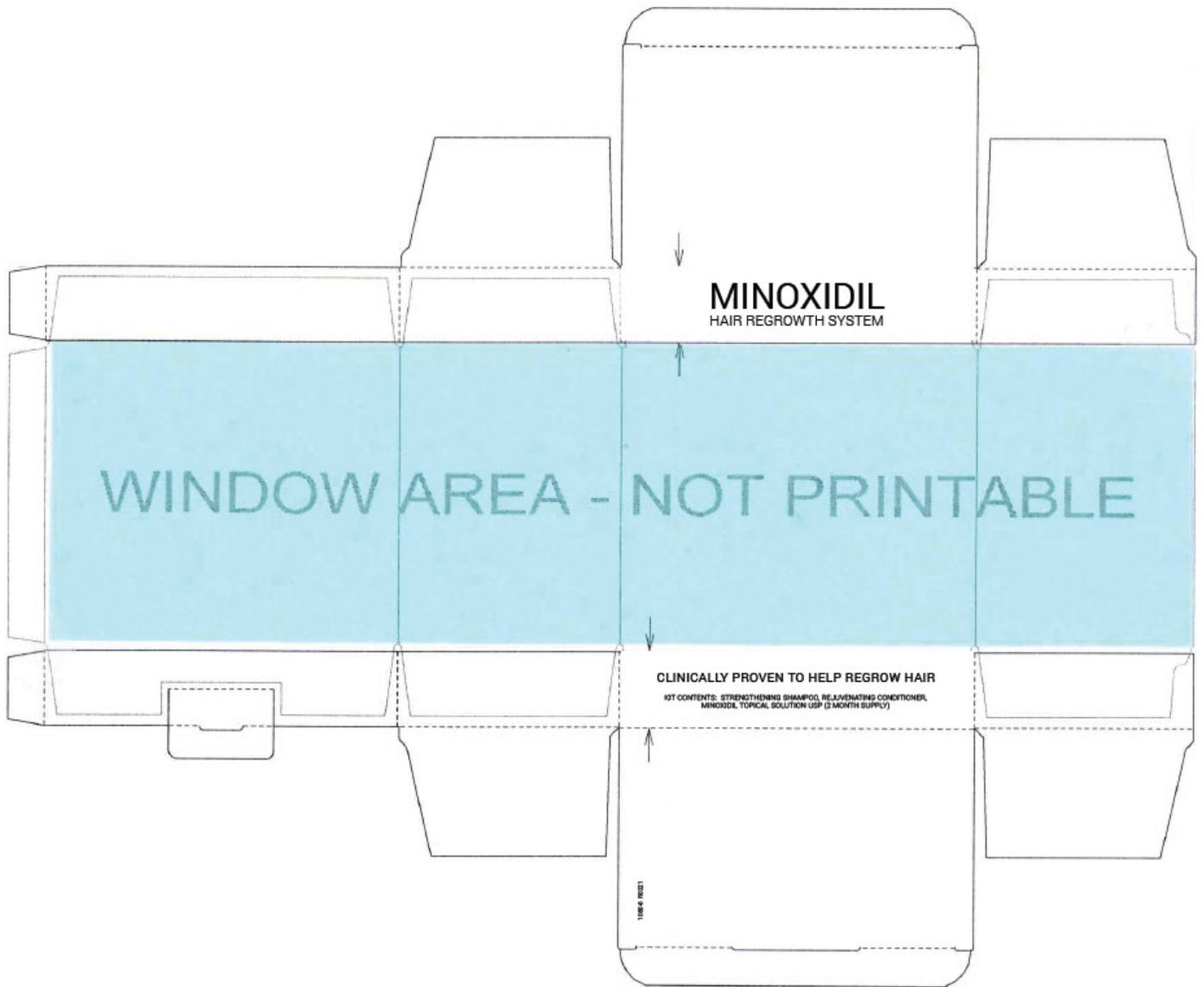
PRINCIPAL DISPLAY PANEL - Kit Carton

MINOXIDIL

HAIR REGROWTH SYSTEM

CLINICALLY PROVEN TO HELP REGROW HAIR

KIT CONTENTS: STRENGTHENING SHAMPOO, REJUVENATING CONDITIONER,
MINOXIDIL TOPICAL SOLUTION USP (2 MONTH SUPPLY)



PRINCIPAL DISPLAY PANEL - 2-60 mL Bottle Dropcard

WOMEN'S
MINOXIDIL
HAIR REGROWTH SYSTEM

2% MINOXIDIL TOPICAL SOLUTION, USP

Reactivates hair follicles to
stimulate regrowth

Clinically proven to help regrow hair

Topical Solution

Unscented

Minoxidil Topical Solution 2% is for women who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Minoxidil Topical Solution

2% has been shown to regrow hair in women with the following degrees of thinning hair or hair loss

If women have more hair loss than shown above, Minoxidil Topical Solution 2% may not work.

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

Two month supply

Two 60 ml (2 fl oz) bottles

WOMEN'S
MINOXIDIL
HAIR REGROWTH SYSTEM

2% MINOXODIL TOPICAL SOLUTION, USP

Reactivates hair follicles to
stimulate regrowth

Clinically proven to help regrow hair

Topical Solution

Unscented

Minoxidil Topical Solution 2% is for women who have a general thinning of hair on the top of the scalp (vertex only, as shown below). **Minoxidil Topical Solution 2%** has been shown to regrow hair in women with the following degrees of thinning hair or hair loss



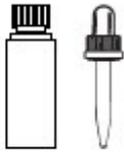
If women have more hair loss than shown above, Minoxidil Topical Solution 2% may not work.



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

Two month supply
Two 60 ml (2 fl oz) bottles

**For Best Results:
Apply Directly to Scalp.
Use Twice Daily.**



This Package Contains:
 Two-60 ml (2 fl oz) Bottles of Minoxidil
 Women's Hair Regrowth Solution
 (two-month supply) with child-resistant
 dropper applicator.

Drug Facts	
Active ingredient	Purpose
Minoxidil 2% w/v	Hair regrowth treatment
Use to regrow hair on the scalp (vertex only, see picture on side of carton)	
Warnings	
For external use only.	
Flammable: Keep away from fire or flame	
Do not use if: - your amount 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, 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. Results may occur at 2 months with twice a day usage. For some women, 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 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 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 opposite side - before use, read all information on carton and enclosed leaflet - keep the insert. It contains important information. - In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution 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). - store at USP controlled room temperature 20° to 25°C (68° to 77°F)	
Inactive ingredients Alcohol, Propylene Glycol, Purified Water	

CDTX1066

R0221

PRINCIPAL DISPLAY PANEL - 200 mL Bottle Label-Shampoo

COMPLIMENTS OF
 TOPIX
 PHARMACEUTICALS, INC

Strengthening
 Basil Root

Shampoo

HAIR GROWTH SYSTEM

Clean | Volumize | Strengthen

Net 6.7 fl. oz. (200 ml)

Available

Custom Branded

800.445.2595

c.service@topixpharm.com

COMPLIMENTS OF

TOPIX

PHARMACEUTICALS, INC

Strengthening Basil Root Shampoo

HAIR GROWTH SYSTEM

Clean | Volumize | Strengthen

Net 6.7 fl. oz. (200 ml)

Available
Custom Branded
800.445.2595
c.service@topixpharm.com

DIRECTIONS

Apply to wet hair, then massage into scalp, through hair, and down to the ends. Rinse thoroughly. Repeat if necessary or recommended by your physician. For best results, follow with the rejuvenating conditioner. Can be used daily.

INGREDIENTS

Purified Water, Cocamidopropyl Betaine, Sodium Lauroyl Sarcosinate, Sodium Cocoyl Isethionate, Sodium Lauryl Sulfoacetate, Glycerin, Panthenol, Propylene Glycol, Tocopheryl Acetate, Dioscorea Villosa (Wild Yam) Root Extract, Ocimum Basilicum (Basil) Root Extract, Trifolium Pratense (Clover) Flower Extract, Eriobotrya Japonica (Loquat) Leaf Extract, Pisum Sativum (Pea) Sprout Extract, Ximenia Americana Seed Oil, Potassium Sorbate, Sphinganine, Citric Acid, Esculin,

Glycol Distearate, Laureth-9, Amodimethicone, C11-15 Pareth-7, Dipropylene Glycol, Dextran, Decyl Glucoside, Polyquaternium-10, Polyquaternium-7, Polysilicone-29, PEG-55 Propylene Glycol Oleate, Menthone Glycerin Acetal, Trideceth-12, Acetyl Tetrapeptide-3, Butylene Glycol, Benzyl Alcohol, Carbomer, Sodium Benzoate, Sodium Hydroxide, BHT, Disodium EDTA, Phenoxyethanol.

R0121

Made in U.S.A.

1040

PRINCIPAL DISPLAY PANEL - 200 mL Bottle Label-Conditioner

COMPLIMENTS OF
TOPIX
PHARMACEUTICALS, INC

Rejuvenating
Basil Root
Conditioner

HAIR GROWTH SYSTEM

Condition | Volumize | Rejuvenate

Net 6.7 fl. oz. (200 ml)

Available
Custom Branded
800.445.2595
c.service@topixpharm.com

COMPLIMENTS OF

TOPIX

PHARMACEUTICALS, INC

Rejuvenating Basil Root Conditioner

HAIR GROWTH SYSTEM

Condition | Volumize | Rejuvenate

Net 6.7 fl. oz. (200 ml)

Available
Custom Branded
800.445.2595
c.service@topixpharm.com

DIRECTIONS

Apply to wet hair, then massage into scalp, through hair, and down to the ends. Rinse thoroughly. Repeat if necessary or recommended by your physician. For best results, follow with the rejuvenating conditioner. Can be used daily.

INGREDIENTS

Purified Water, Cocamidopropyl Betaine, Sodium Lauroyl Sarcosinate, Sodium Cocoyl Isethionate, Sodium Lauryl Sulfoacetate, Glycerin, Panthenol, Propylene Glycol, Tocopheryl Acetate, Dioscorea Villosa (Wild Yam) Root Extract, Ocimum Basilicum (Basil) Root Extract, Trifolium Pratense (Clover) Flower Extract, Eriobotrya Japonica (Loquat) Leaf Extract, Pisum Sativum (Pea) Sprout Extract, Ximenia Americana Seed Oil, Potassium Sorbate, Sphinganine, Citric Acid, Esculin,

Glycol Distearate, Laureth-9, Amodimethicone, C11-15 Pareth-7, Dipropylene Glycol, Dextran, Decyl Glucoside, Polyquaternium-10, Polyquaternium-7, Polysilicone-29, PEG-55 Propylene Glycol Oleate, Menthone Glycerin Acetal, Trideceth-12, Acetyl Tetrapeptide-3, Butylene Glycol, Benzyl Alcohol, Carbomer, Sodium Benzoate, Sodium Hydroxide, BHT, Disodium EDTA, Phenoxyethanol.

R0121

Made in U.S.A.

1040

WOMENS MINOXIDIL HAIR REGROWTH

minoxidil kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-166
---------------------	----------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-166-01	1 in 1 CARTON	06/16/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BOTTLE	120 mL
Part 2	1 BOTTLE	200 mL
Part 3	1 BOTTLE	200 mL

Part 1 of 3

WOMENS MINOXIDIL HAIR GROWTH SYSTEM

minoxidil liquid

Product Information

Item Code (Source)	NDC:51326-161
---------------------------	---------------

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:51326-161-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	03/26/2021	

Part 2 of 3

STRENGTHENING BASIL ROOT

shampoos (non-coloring) shampoo

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
INGR	SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
INGR	SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8)	
INGR	TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	SPHINGANINE (UNII: YT0ZSD64HM)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

INGR	ESCOLIN (UNII: 1Y1L18LQAF)	
INGR	GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
INGR	POLIDOCANOL (UNII: 0AWH8BFG9A)	
INGR	C11-15 ALKETH-7 (UNII: 261HPE0IS3)	
INGR	DIPROPYLENE GLYCOL (UNII: E107L85C40)	
INGR	DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
INGR	POLYQUATERNIUM-10 (400 MPA.S AT 2%) (UNII: HB1401PQFS)	
INGR	POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
INGR	PEG-55 PROPYLENE GLYCOL OLEATE (UNII: 7RDE7PJS40)	
INGR	MENTHONE 1,2-GLYCEROL KETAL, (+/-)- (UNII: 7QQ1EE6RCP)	
INGR	TRIDECETH-12 (UNII: YFY3KG5Y7O)	
INGR	ACETYL TETRAPEPTIDE-3 (UNII: D1HW9N9QBX)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	BENZYL ALCOHOL (UNII: LKG8494WBH)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	BASIL (UNII: 2U0KZ P0FDW)	
INGR	LOQUAT (UNII: DM9CY56A36)	
INGR	PEA (UNII: W4X7H8GYFM)	
INGR	AMODIMETHICONE (1300 CST) (UNII: 3V7U636DWN)	
INGR	DEXTRAN 110 (UNII: 05Q25F6XJ3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		03/26/2021	

Part 3 of 3

REJUVENATING BASIL ROOT CONDITIONER

shampoos (non-coloring) shampoo

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	STEARALKONIUM CHLORIDE (UNII: 00UO26BB88)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
INGR	TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	SPHINGANINE (UNII: YT0ZSD64HM)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	RESVERATROL (UNII: Q369O8926L)	
INGR	SILIBININ (UNII: 4RKY41TBTF)	
INGR	CAFFEINE (UNII: 3G6A5W338E)	
INGR	ESCULIN (UNII: 1Y1L18LQAF)	
INGR	POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	ACETYL TETRAPEPTIDE-3 (UNII: D1HW9N9QBX)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	ZINC PIDOLATE (UNII: C32PQ86DH4)	
INGR	COPPER PIDOLATE (UNII: 497G7G1SL1)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	BASIL (UNII: 2U0KZP0FDW)	
INGR	LOQUAT (UNII: DM9CY56A36)	
INGR	PEA (UNII: W4X7H8GYFM)	
INGR	TEA LEAF OIL (UNII: VC855RRT77)	
INGR	DEXTRAN 110 (UNII: 05Q25F6XJ3)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		200 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		03/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078176	06/16/2023	

Labeler - Topiderm, Inc (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-166)

Revised: 6/2023

Topiderm, Inc