

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

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**Mens Minoxidil Hair Regrowth System**

***Drug Facts***

**Active ingredient**

Minoxidil 5% w/v

**Purpose**

Hair regrowth treatment for men

**Use**

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

**Warnings**

**For external use only. For use by men only.**

**Flammable:** Keep away from fire or flame

**Do not use if**

- you are a woman
- your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical solution is not intended for frontal baldness or receding hairline
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- 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 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 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.
- hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men
- in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution
- store at controlled room temperature 20° to 25°C (68° to 77°F).

### **Inactive ingredients**

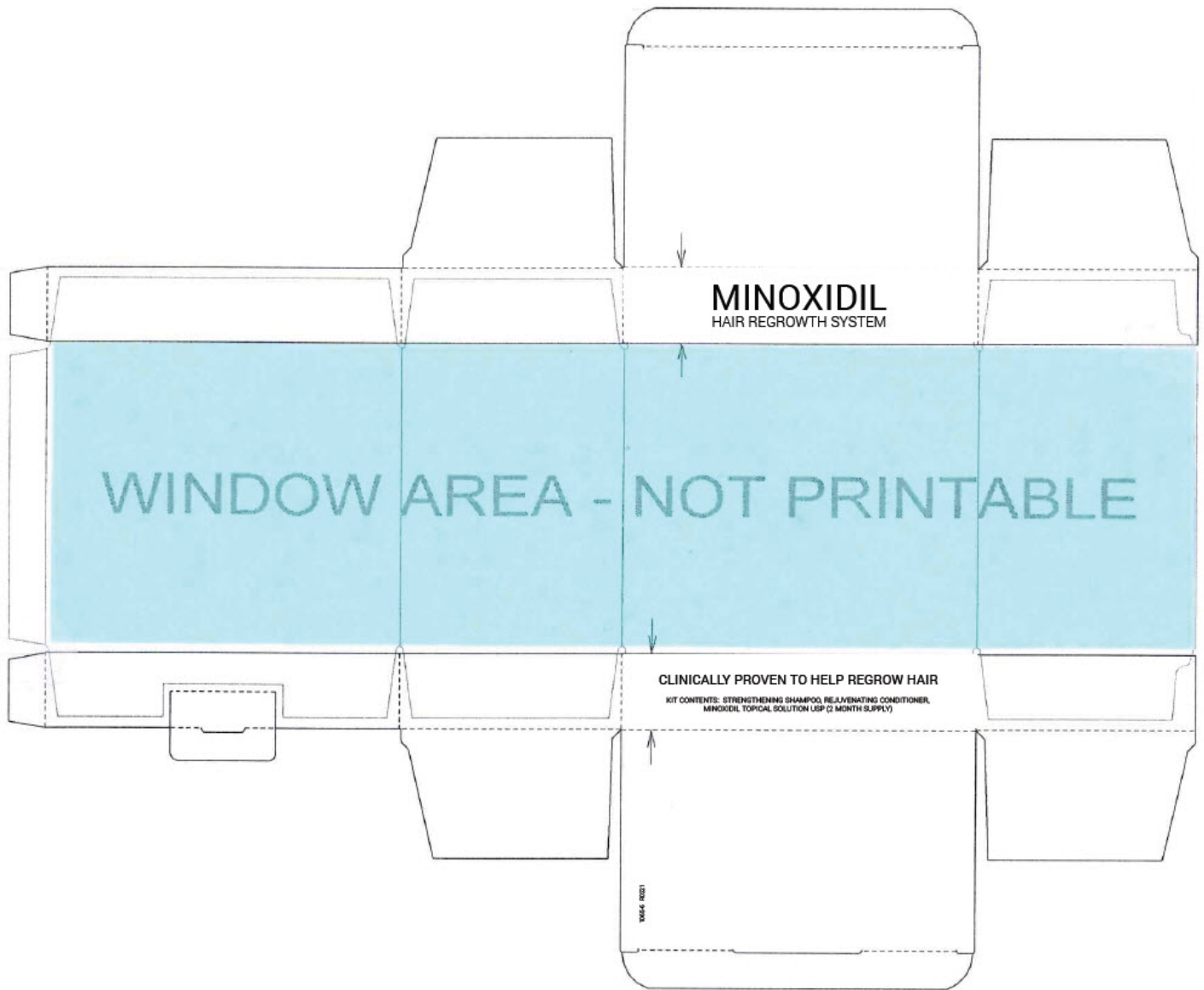
Alcohol, Propylene Glycol, Purified Water

### **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**

**MEN'S  
MINOXIDIL  
HAIR REGROWTH SYSTEM**

**5% MINOXIDIL TOPICAL SOLUTION, USP**

Reactivates hair follicles to  
stimulate regrowth

Clinically proven to help regrow hair

Topical Solution

Unscented

Minoxidil Topical Solution 5% is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown). 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.

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

# MEN'S MINOXIDIL HAIR REGROWTH SYSTEM

5% MINOXIDIL TOPICAL SOLUTION, USP

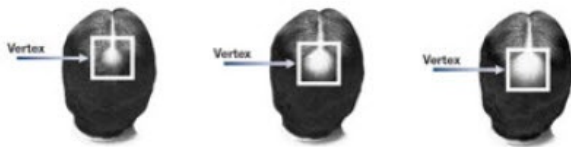
Reactivates hair follicles to  
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Unscented

Minoxidil Topical Solution 5% is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown). 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.

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 Men's Hair Regrowth Solution (two-month supply) with child-resistant dropper applicator.

### Drug Facts

Active ingredient	Purpose
Minoxidil 5% w/v	Hair regrowth treatment for men

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

### Warnings

For external use only. For use by men only.

**Flammable:** Keep away from fire or flame

Do not use if: • you are a woman • your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical solution is not intended for frontal baldness or receding hairline • you have no family history of hair loss • your hair loss is sudden and/or patchy • 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 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 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 rightaway.

**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. • hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with 5% minoxidil topical solution for men • in clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, 5% minoxidil topical solution for men provided more hair regrowth than 2% minoxidil topical solution • store at controlled room temperature 20° to 25°C (68° to 77°F).

**Inactive ingredients** Alcohol, Propylene Glycol, Purified Water

**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](mailto: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 a small amount to wet hair. Work product in thoroughly from mid-shaft to ends. Rinse hair thoroughly. For best results, follow with the hair growth serum.

**INGREDIENTS**

Purified Water, Stearalkonium Chloride, Cetearyl Alcohol, Stearyl Alcohol, Ocimum Basilicum (Basil) Root Extract, Trifolium Pratense (Clover) Flower Extract, Eriobotrya Japonica (Loquat) Leaf Extract, Pisum Sativum (Pea) Sprout Extract, Camellia Sinensis (Green Tea) Leaf Extract, Ximenia Americana Seed Oil, Potassium Sorbate, Sphinganine, Cetearth-21, Citric Acid, Resveratrol, Silybin, Caffeine, Esculin, Dextran, PEG-40 Hydrogenated Castor Oil, Cyclopentasiloxane, Acetyl Tetrapeptide-3, Butylene Glycol, Lecithin, Zinc PCA, Copper PCA, Sodium Chloride, Sodium Benzoate, Disodium EDTA, Phenoxyethanol.

R0121

Made in U.S.A.

1050

**MENS MINOXIDIL HAIR REGROWTH**

minoxidil kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51326-165
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-165-01	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

## MENS MINOXIDIL HAIR GROWTH SYSTEM

minoxidil solution

### Product Information

<b>Item Code (Source)</b>	NDC:51326-160
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<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	50 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:51326-160-16	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	ANDA076239	03/23/2021	

## 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	<b>WATER</b> (UNII: 059QF0K00R)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	
INGR	<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
INGR	<b>SODIUM COCOYL ISETHIONATE</b> (UNII: 518XTE8493)	
INGR	<b>SODIUM LAURYL SULFOACETATE</b> (UNII: D0Y70F2B9J)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
INGR	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>DIOSCOREA VILLOSA TUBER</b> (UNII: IWY3IWX2G8)	
INGR	<b>TRIFOLIUM PRATENSE FLOWER</b> (UNII: 4JS0838828)	
INGR	<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
INGR	<b>SPHINGANINE</b> (UNII: YT0ZSD64HM)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
INGR	<b>ESCULIN</b> (UNII: 1Y1L18LQAF)	
INGR	<b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)	
INGR	<b>POLIDOCANOL</b> (UNII: 0AWH8BFG9A)	
INGR	<b>C11-15 ALKETH-7</b> (UNII: 261HPE0IS3)	
INGR	<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
INGR	<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
INGR	<b>POLYQUATERNIUM-10 (400 MPA.S AT 2%)</b> (UNII: HB1401PQFS)	
INGR	<b>POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 160000 MW)</b> (UNII: 0L414VCS5Y)	
INGR	<b>PEG-55 PROPYLENE GLYCOL OLEATE</b> (UNII: 7RDE7PJS40)	
INGR	<b>MENTHONE 1,2-GLYCEROL KETAL, (+/-)-</b> (UNII: 7QQ1EE6RCP)	
INGR	<b>TRIDECETH-12</b> (UNII: YFY3KG5Y7O)	
INGR	<b>ACETYL TETRAPEPTIDE-3</b> (UNII: D1HW9N9QBX)	
INGR	<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	

INGR	<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
INGR	<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
INGR	<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
INGR	<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>BASIL</b> (UNII: 2U0KZP0FDW)	
INGR	<b>LOQUAT</b> (UNII: DM9CY56A36)	
INGR	<b>PEA</b> (UNII: W4X7H8GYFM)	
INGR	<b>AMODIMETHICONE (1300 CST)</b> (UNII: 3V7U636DWN)	
INGR	<b>DEXTRAN 110</b> (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		03/23/2021	

### 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	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>STEARALKONIUM CHLORIDE</b> (UNII: 00UO26BB88)	
INGR	<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
INGR	<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
INGR	<b>TRIFOLIUM PRATENSE FLOWER</b> (UNII: 4JS0838828)	
INGR	<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
INGR	<b>SPHINGANINE</b> (UNII: YT0ZSD64HM)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	

INGR	<b>RESVERATROL</b> (UNII: Q369O8926L)	
INGR	<b>SILIBININ</b> (UNII: 4RKY41TBTF)	
INGR	<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
INGR	<b>ESCULIN</b> (UNII: 1Y1L18LQAF)	
INGR	<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
INGR	<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
INGR	<b>ACETYL TETRAPEPTIDE-3</b> (UNII: D1HW9N9QBX)	
INGR	<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
INGR	<b>ZINC PIDOLATE</b> (UNII: C32PQ86DH4)	
INGR	<b>COPPER PIDOLATE</b> (UNII: 497G7G1SL1)	
INGR	<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
INGR	<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
INGR	<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>BASIL</b> (UNII: 2U0KZP0FDW)	
INGR	<b>LOQUAT</b> (UNII: DM9CY56A36)	
INGR	<b>PEA</b> (UNII: W4X7H8GYFM)	
INGR	<b>TEA LEAF OIL</b> (UNII: VC855RRT77)	
INGR	<b>DEXTRAN 110</b> (UNII: 05Q25F6XJ3)	
INGR	<b>LECITHIN, SOYBEAN</b> (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		03/23/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	06/16/2023	

**Labeler** - Topiderm, Inc (049121643)

**Registrant** - Topiderm, Inc. (049121643)

### Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-165)

