

**REPLENIX LIP THERAPY HOMOSALATE- homosalate lipstick**  
**Topiderm, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**REPLENIX® Lip Therapy**  
**homosalate**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Homosalate 15.0%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5.0%	Sunscreen
Avobenzone 3.0%	Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

**Warnings**

**For lip application only.**

This product delivers a temporary tingling sensation to the lips. Only apply product inside the line of your lips.

**When using this product** keep out of eyes, rinse with water to remove.

**Stop use if** signs of irritation or rash appear. If irritation or rash persists consult a doctor.

**Keep out of reach of children.**

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

Apply a generous coat to bare lips as often as desired, staying inside the lip line. Visible volume and natural color typically lasts 1-2 hours. Individual results may vary.

- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sunscreen measures including:
  - limit time in the sun, especially from 10a.m.-2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses

## **Inactive ingredients**

Hydrogenated Polyisobutene, Ethylene/Propylene/Styrene Copolymer, Butylene/Ethylene/Styrene Copolymer, Octocrylene, Benzyl Nicotinate, Glycerin, Cetearyl Ethylhexanoate, Sorbitan Isostearate, Portulaca Pilosa Extract, Sucrose Cocoate, Palmitoyl Tripeptide-38, Sodium Hyaluronate, Menthone Glycerin Acetal, Stevia Rebaudiana Leaf/Stem Powder, Niacinamide, Tocopheryl Acetate, Hydrolyzed Sodium Hyaluronate, Glutathione, Ergothioneine, Ceramide NP, Ceramide AP, Ceramide EOP, Phytosphingosine, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Yucca Schidigera Root Extract, Salix Alba (Willow) Bark Extract, Panthenol, Essential Oil of Spearmint (Mentha Viridis), Essential Oil of Peppermint (Mentha Piperita), Flavor.

## **PRINCIPAL DISPLAY PANEL - 4 ml Bottle Carton**

REPLENIX®

PURE HYDRATION

Plumping Lip Treatment

Broad Spectrum SPF 30 Sunscreen

Net 0.14 fl. oz. (4 ml)

Topix Pharmaceuticals, Inc. N. Amityville, NY 11701

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*Broad Spectrum SPF 30 Sunscreen*

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**LIP TREATMENT  
SPF 30**

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**Warnings**

For lip application only.  
This product delivers a temporary tingling sensation to the lips. Only apply product inside the line of your lips.  
When using this product keep out of eyes, rinse with water to remove. Stop use if signs of irritation or rash appear. If irritation or rash persists consult a doctor.  
Keep out of reach of children.  
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**Directions**

Apply a generous coat to bare lips as often as desired, staying inside the lip line. Visible volume and natural color typically lasts 1-2 hours. Individual results may vary. ■ Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sunscreen measures including:  
• Limit time in the sun, especially from 10a.m.-2 p.m.

**LIP TREATMENT  
BROAD SPECTRUM  
UVA/UVB SPF 30**

This multi-functional, pigment free lip treatment protects lips while helping to restore hydration and youthful volume.

**PRODUCT HIGHLIGHTS**

Sunscreen  
Hydrator  
Collagen Treatment  
Visible Volumizer

- + SPF 30: Protect
- + Hyaluronic Acid: Hydrate
- + Peptides: Volumize
- + Ceramides: Soften

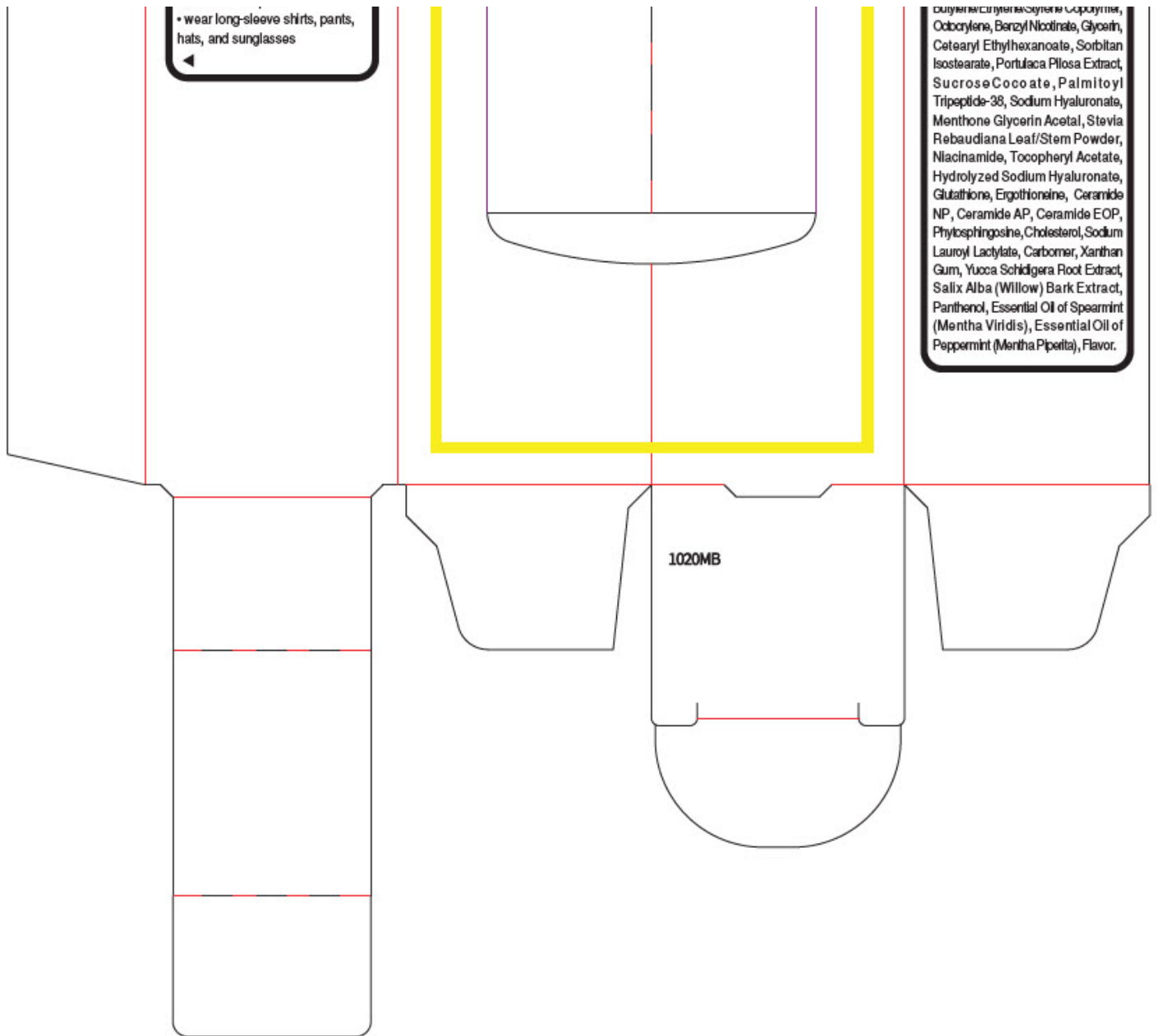
Visible volume and natural color typically lasts 1-2 hours. Individual results may vary.

**CAUTION:** This product delivers a temporary tingling sensation to the lips and draws color where applied. For best results, use 2-4x daily.  
**Only apply product inside the line of your lips.**

**Drug Facts Con't**

Inactive ingredients
Hydrogenated Polyisobutene,
Ethylene/Propylene/Styrene Copolymer,
Octadecyl Stearate, Stearic Acid,

R0723



## REPLENIX LIP THERAPY HOMOSALATE

homosalate lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51326-102
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>HYDROGENATED POLYBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ)	
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM)	
<b>BENZYL NICOTINATE</b> (UNII: S497LCF9C9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CETEARYL ETHYLHEXANOATE</b> (UNII: 9M64UO4C25)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>PORTULACA PILOSA WHOLE</b> (UNII: II29C6E5R3)	
<b>SUCROSE COCOATE</b> (UNII: 3H18P0UK73)	
<b>PALMITOYL LYSYLDIOXYMETHIONYLLYSINE</b> (UNII: T7A529FB8O)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>MENTHONE 1,2-GLYCEROL KETAL, (+/-)-</b> (UNII: 7QQ1EE6RCP)	
<b>STEVIA REBAUDIUNA LEAF</b> (UNII: 6TC6NN0876)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>GLUTATHIONE</b> (UNII: GAN16C9B8O)	
<b>ERGOTHIONEINE</b> (UNII: BDZ3DQM98W)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>CERAMIDE AP</b> (UNII: F1X8L2B00J)	
<b>CERAMIDE 1</b> (UNII: 5THT33P7X7)	
<b>PHYTOSPHINGOSINE</b> (UNII: GIN46U9Q2Q)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>SODIUM LAUROYL LACTYLATE</b> (UNII: 7243K85WFO)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>YUCCA SCHIDIGERA ROOT</b> (UNII: E2H9ET15AT)	
<b>SALIX ALBA BARK</b> (UNII: 205MXS71H7)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-102-04	4 g in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/02/2022	

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Topiderm, Inc.		049121643	MANUFACTURE(51326-102)

Revised: 2/2023

Topiderm, Inc.