

**MENTHOLATUM NATURAL ICE ORIGINAL- dimethicone, octinoxate,  
octisalate ointment**  
**The Mentholatum Company**

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**Drug Facts - Mentholatum Natural Ice**

**Active ingredients**

Dimethicone 1%

Octinoxate 7.5%

Octisalate 5%

**Purpose**

Dimethicone - Skin protectant

Octinoxate - Sunscreen

Octisalate - Sunscreen

**Uses**

- helps prevent sunburn
- temporarily protects chapped or cracked lips

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

**For external use only**

**Do not use**

on damaged or broken skin

**When using this product**

keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if**

- rash occurs
- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor

**Other information**

- protect this product from excessive heat and direct sun

**Inactive ingredients**

mineral oil, ozokerite, petrolatum, lanolin, fragrance, menthol

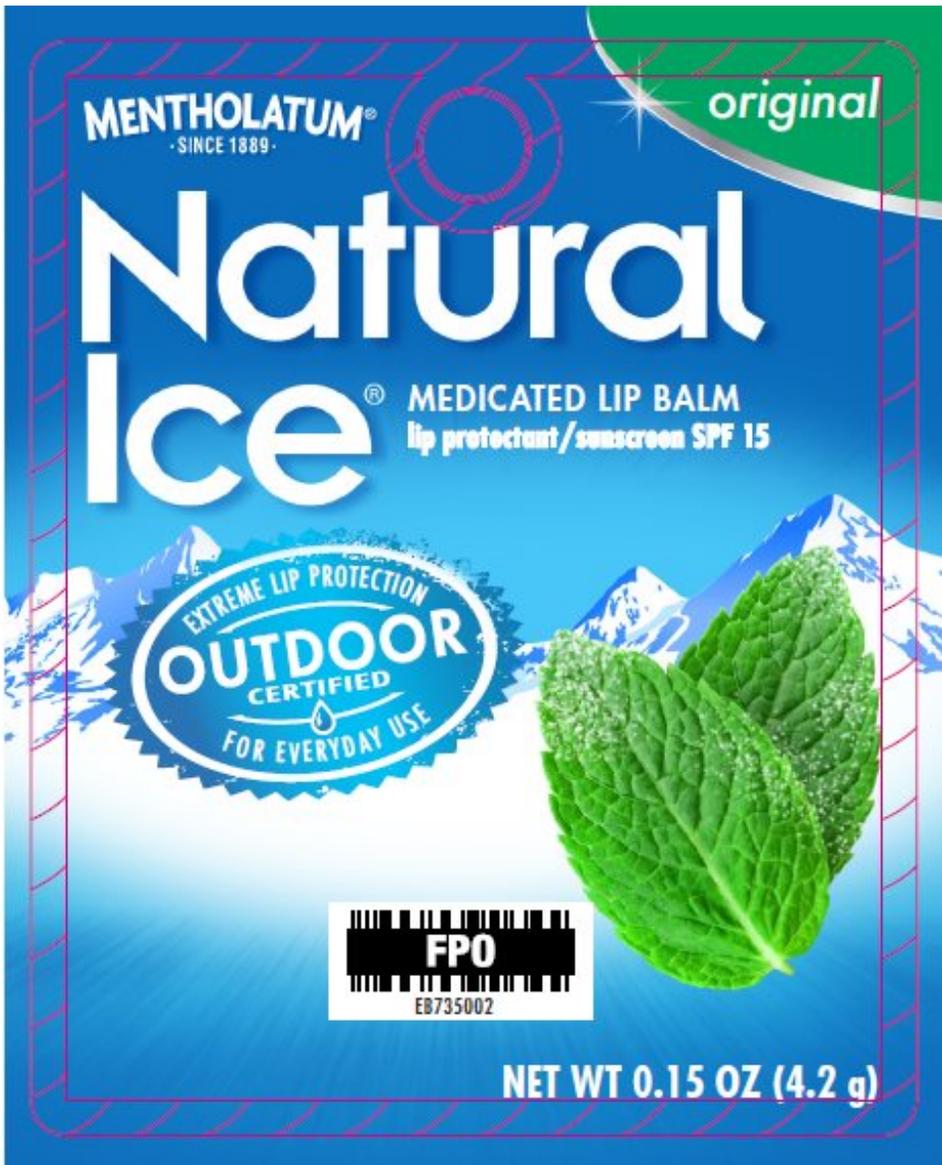
**Questions?**

**1-877-636-2677**

MON-FRI 9AM to 5PM (EST)

mentholatum.com

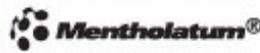
**Principal Display Panel**



Principal Display Panel

# Natural Ice<sup>®</sup> ORIGINAL

Medicated Lip Protectant/Sunscreen SPF 15



Manufactured By:  
The Mentholatum Co.  
Orchard Park, NY 14127



<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Active Ingredients</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Dimethicone 1%.....</td> <td>Skin Protectant</td> </tr> <tr> <td>Octinoxate 7.5%.....</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5%.....</td> <td>Sunscreen</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ helps prevent sunburn</li> <li>■ temporarily protects chapped or cracked lips</li> </ul> <p><b>Warnings</b></p> <p><b>Skin Cancer/Skin Aging Alert:</b> Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.</p> <p><b>For external use only</b></p> <p><b>Do not use on damaged or broken skin</b></p> <p><b>When using this product keep out of eyes. Rinse with water to remove.</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ rash occurs</li> <li>■ condition worsens</li> <li>■ symptoms last more than 7 days or clear up and occur again within a few days</li> </ul> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. ▶</p> <p style="font-size: small;">Retain this card for complete information.</p>	Active Ingredients	Purpose	Dimethicone 1%.....	Skin Protectant	Octinoxate 7.5%.....	Sunscreen	Octisalate 5%.....	Sunscreen	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ apply liberally 15 minutes before sun exposure</li> <li>■ use a water resistant sunscreen if swimming or sweating</li> <li>■ reapply at least every 2 hours</li> <li>■ children under 6 months: ask a doctor</li> </ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>■ protect this product from excessive heat and direct sun</li> </ul> <p><b>Inactive Ingredients</b> mineral oil, ozokerite, petrolatum, lanolin, fragrance, menthol</p> <p><b>Questions?</b> 1-877-636-2677 MON-FRI 9AM to 5PM (EST) mentholatum.com</p> <p style="font-size: x-small;">EB735002 <span style="float: right;">©2021</span></p> <div style="text-align: center;">  <p>3 10742 00041 2</p> </div>
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<b>MENTHOLATUM NATURAL ICE ORIGINAL</b>			
dimethicone, octinoxate, octisalate ointment			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-3004
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE		10 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE		75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE		50 mg in 1 g
Inactive Ingredients			
	Ingredient Name		Strength

<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>LEVOMENTHOL</b> (UNII: BZ1R15MTK7)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-3004-1	1 in 1 BLISTER PACK	01/19/1999	04/01/2019
1		4.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10742-3004-9	4.5 g in 1 TUBE; Type 0: Not a Combination Product	01/19/1999	04/01/2019
3	NDC:10742-3004-2	1 in 1 BLISTER PACK	04/02/2019	
3		4.2 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:10742-3004-8	4.2 g in 1 TUBE; Type 0: Not a Combination Product	04/02/2019	
5	NDC:10742-3004-3	1 in 1 BLISTER PACK	01/19/1999	
5		4.5 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:10742-3004-4	4.5 g in 1 TUBE; Type 0: Not a Combination Product	01/19/1999	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/19/1999	

**Labeler** - The Mentholatum Company (002105757)

**Registrant** - The Mentholatum Company (002105757)

### Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-3004)