

**MENTHOLATUM MEDICATED LIP BALM ORIGINAL- dimethicone, octinoxate, octisalate ointment**  
**The Mentholatum Company**

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**Drug Facts - Mentholatum Medicated Lip Balm**

**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**

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

**Questions?**

Toll free **1-877-636-2677**

MON-FRI 9 AM to 5 PM (EST)

**Principal Display Panel**



**Principal Display Panel**

**MENTHOLATUM®**  
**MEDICATED LIP BALM**  
 lip protectant/sunscreen SPF 15



**ORIGINAL FLAVOR**

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredients</b>	<b>Purpose</b>	<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
Dimethicone 1%.....	Skin protectant	<b>Directions</b>	
Octinoxate 7.5%.....	Sunscreen	<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>	
Octisalate 5%.....	Sunscreen	<b>Other information</b>	
<b>Uses</b>		<ul style="list-style-type: none"> <li>■ protect this product from excessive heat and direct sun</li> </ul>	
<ul style="list-style-type: none"> <li>■ helps prevent sunburn</li> <li>■ temporarily protects chapped or cracked lips</li> </ul>		<b>Inactive ingredients</b>	
<b>Warnings</b>		fragrance, lanolin, menthol, mineral oil, ozokerite, petrolatum	
<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>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if</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>		<b>Questions?</b>	
		Toll free 1-877-636-2677 MON-FRI 9 AM to 5 PM (EST) www.mentholatum.com	

Menthoholatum®

EB644001

Manufactured by:  
 The Mentholatum Company  
 Orchard Park, NY 14127 USA



**MENTHOLATUM MEDICATED LIP BALM ORIGINAL**

dimethicone, octinoxate, octisalate ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-8865
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 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

## Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
MINERAL OIL (UNII: T5L8T28FGP)	
CERESIN (UNII: Q1LS2UJO3A)	
PETROLATUM (UNII: 4T6H12BN9U)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8865-1	1 in 1 BLISTER PACK	08/01/2016	
1		4.2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10742-8865-3	3 in 1 BLISTER PACK	10/01/2018	
2		4.2 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/01/2016	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-8865)

Revised: 12/2024

The Mentholatum Company