

BLISTEX MEDICATED LIP BALM- dimethicone, oxybenzone, and padimate o stick
Blis tex 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.

Blis tex®
Medicated Lip Balm

Drug Facts

Active ingredients	Purpose
Dimethicone 2.0% (w/w)	Lip protectant
Oxybenzone 2.5% (w/w)	Sunscreen
Padimate O 6.6% (w/w)	Sunscreen

Uses

- temporarily protects and helps relieve chapped or cracked lips
- helps prevent sunburn

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 help 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

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
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor

Inactive ingredients

beeswax, camphor, cetyl alcohol, cetyl palmitate, euphorbia cerifera (candelilla) wax, flavors, isopropyl myristate, isopropyl palmitate, isopropyl stearate, lanolin, lanolin oil, menthol, methylparaben, mineral oil, ozokerite, paraffin, petrolatum, polybutene, propylparaben, red 6 lake, theobroma cacao (cocoa) seed butter, titanium dioxide

Other information

- protect the product in this container from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL - 4.25 g Cylinder Blister Pack

**Blistex® MEDICATED LIP BALM
LIP PROTECTANT/SUNSCREEN**

SPF 15

**Blistex® MEDICATED LIP BALM
NET WT. .15 oz (4.25g)**

SPF 15

Blistex® MEDICATED LIP BALM

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P.O. Box 5392, Oak Brook, IL

60522 C36186

23012TE

DO NOT USE IF SEAL IS MISSING.

Lift for Drug Facts

Blistex MEDICATED LIP BALM
LIP PROTECTANT/SUNSCREEN

SPF 15

Blistex MEDICATED LIP BALM
NET WT. .15 oz (4.25g)

SPF 15

Blistex MEDICATED LIP BALM

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DO NOT USE IF SEAL IS BROKEN

Lift for Drug Facts

SEALED FOR YOUR PROTECTION

PULL TO REMOVE

SEALED FOR YOUR PROTECTION

Drug Facts

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Oxybenzone 2.5% (w/w)
Padimate O 6.6% (w/w)

Purpose

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Sunscreen
Sunscreen

Uses

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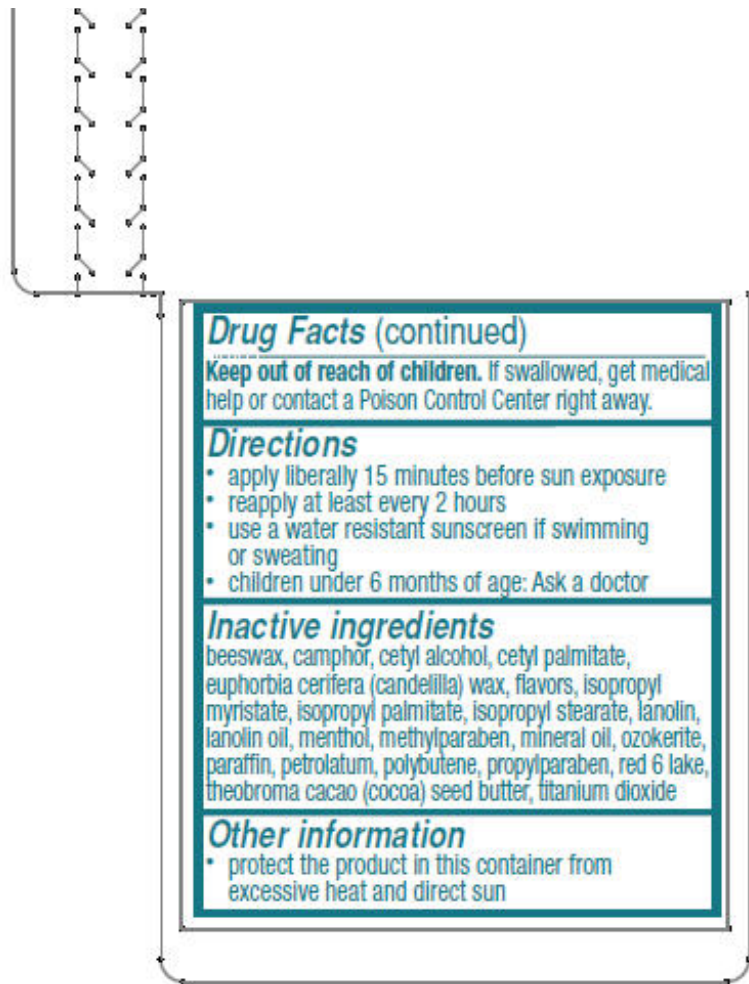
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-9822
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	2 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g
Padimate O (UNII: Z11006CMUZ) (Padimate O - UNII:Z11006CMUZ)	Padimate O	6.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
yellow wax (UNII: 2ZA36H0S2V)	
cetyl alcohol (UNII: 936JST6JCN)	
cetyl palmitate (UNII: 5ZA2S6B08X)	
candelilla wax (UNII: WL0328HX19)	

isopropyl myristate (UNII: 0RE8K4LNJS)
isopropyl palmitate (UNII: 8CRQ2TH63M)
isopropyl stearate (UNII: 43253ZW1MZ)
lanolin (UNII: 7EV65EAW6H)
lanolin oil (UNII: OVV5IJ58F)
menthol, unspecified form (UNII: L7T10EIP3A)
methylparaben (UNII: A2I8C7HI9T)
mineral oil (UNII: T5L8T28FGP)
paraffin (UNII: I9O0E3H2ZE)
petrolatum (UNII: 4T6H12BN9U)
polybutene (1400 MW) (UNII: 1NA5AO9GH7)
propylparaben (UNII: Z8IX2SC1OH)
D&C Red No. 6 (UNII: 481744AI4O)
aluminum oxide (UNII: LMI26O6933)
cocoa butter (UNII: 512OYT1CRR)
titanium dioxide (UNII: 15FIX9V2JP)

Product Characteristics

Color	PINK	Score	
Shape	BULLET	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-9822-3	3 in 1 BLISTER PACK	11/0 1/20 10	
1	NDC:10 157-9822-1	4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
2	NDC:10 157-9822-4	4 in 1 BLISTER PACK	11/0 1/20 10	
2	NDC:10 157-9822-1	4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	11/0 1/20 10	

Labeler - Blistex Inc. (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10 157-9822)