

BLISTEX MEDICATED MINT BALM- dimethicone, octinoxate, and octisalate stick

Blistex Inc

Blistex® Medicated Mint Balm

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 6.6% (w/w)	Sunscreen
Octisalate 4.4% (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

Other information

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

Inactive ingredients

beeswax, camphor, cetyl alcohol, cetyl palmitate, euphorbia cerifera (candelilla) wax, flavor, isopropyl myristate, lanolin, lanolin oil, menthol, mineral oil, ozokerite, paraffin, petrolatum, phenoxyethanol, polybutene, theobroma cacao (cocoa) seed butter, titanium dioxide

PRINCIPAL DISPLAY PANEL - 4.25 g Cylinder Carton

Blistex®

LIP PROTECTANT/SUNSCREEN

MEDICATED MINT BALM

Seals In Moisture
To Soothe & Prevent Dry Lips

Net Wt. 0.15 oz. (4.25 g)

SPF 15

**Smooth
Easy-Gliding
Protection**

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SATISFACTION
GUARANTEED
Blistex

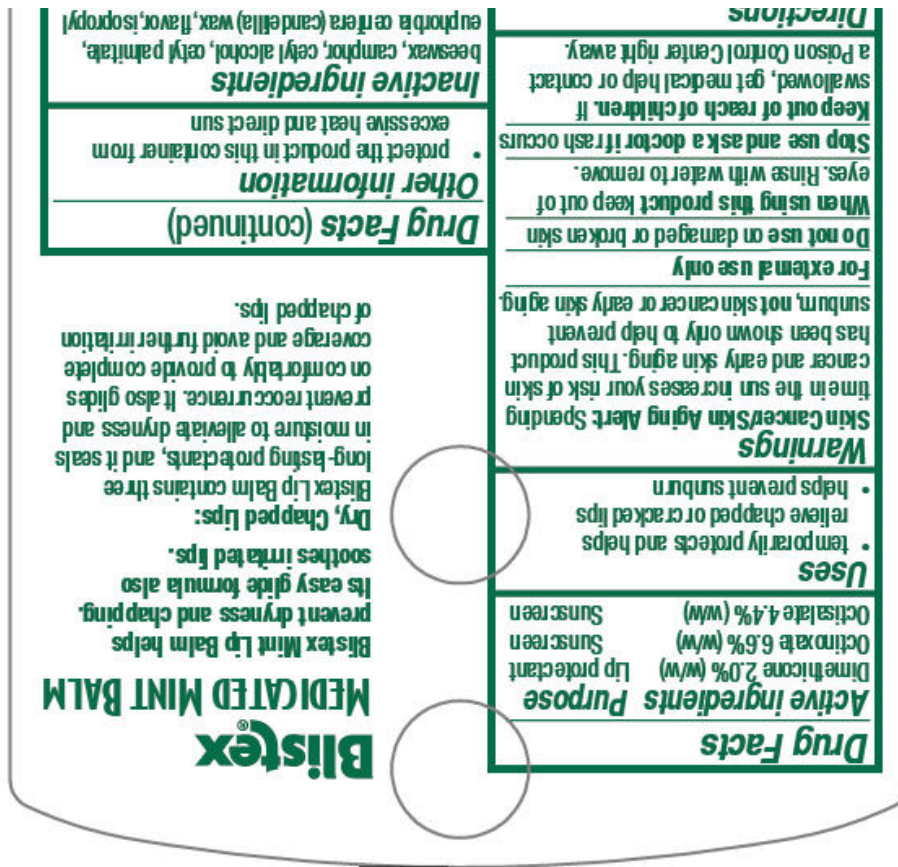
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myristate, lanolin, lanolin oil, menthol, mineral oil,
ozokerite, paraffin, petrolatum, phenoxethanol,
polybutene, theobroma cacao (cocoa) seed butter,
titanium dioxide

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P.O. Box 5392, Oak Brook, IL 60522-5392

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-1120
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
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.6 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
LANOLIN OIL (UNII: OVV5IJ58F)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

LANOLIN (UNII: 7EV65EAW6H)
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)
CETYL PALMITATE (UNII: 5ZA2S6B08X)
CETYL ALCOHOL (UNII: 936JST6JCN)
PARAFFIN (UNII: I9O0E3H2ZE)
COCOA BUTTER (UNII: 512OYT1CRR)
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR (UNII: F89Z8SAG3O)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-1120-1	1 in 1 CARTON	01/15/2018	
1		4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
2	NDC:10157-1120-2	2 in 1 CARTON	02/08/2024	
2		4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
3	NDC:10157-1120-3	3 in 1 CARTON	01/15/2018	
3		4.25 g in 1 CYLINDER; Type 0: Not a Combination Product		
4	NDC:10157-1120-4	4 in 1 CARTON	01/15/2018	
4		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 drug	M016	01/15/2018	

Labeler - Blistex Inc (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10157-1120)