

BLISTEX MEDICATED BERRY BALM- dimethicone, padimate o, and oxybenzone 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 Berry 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, flavor, 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

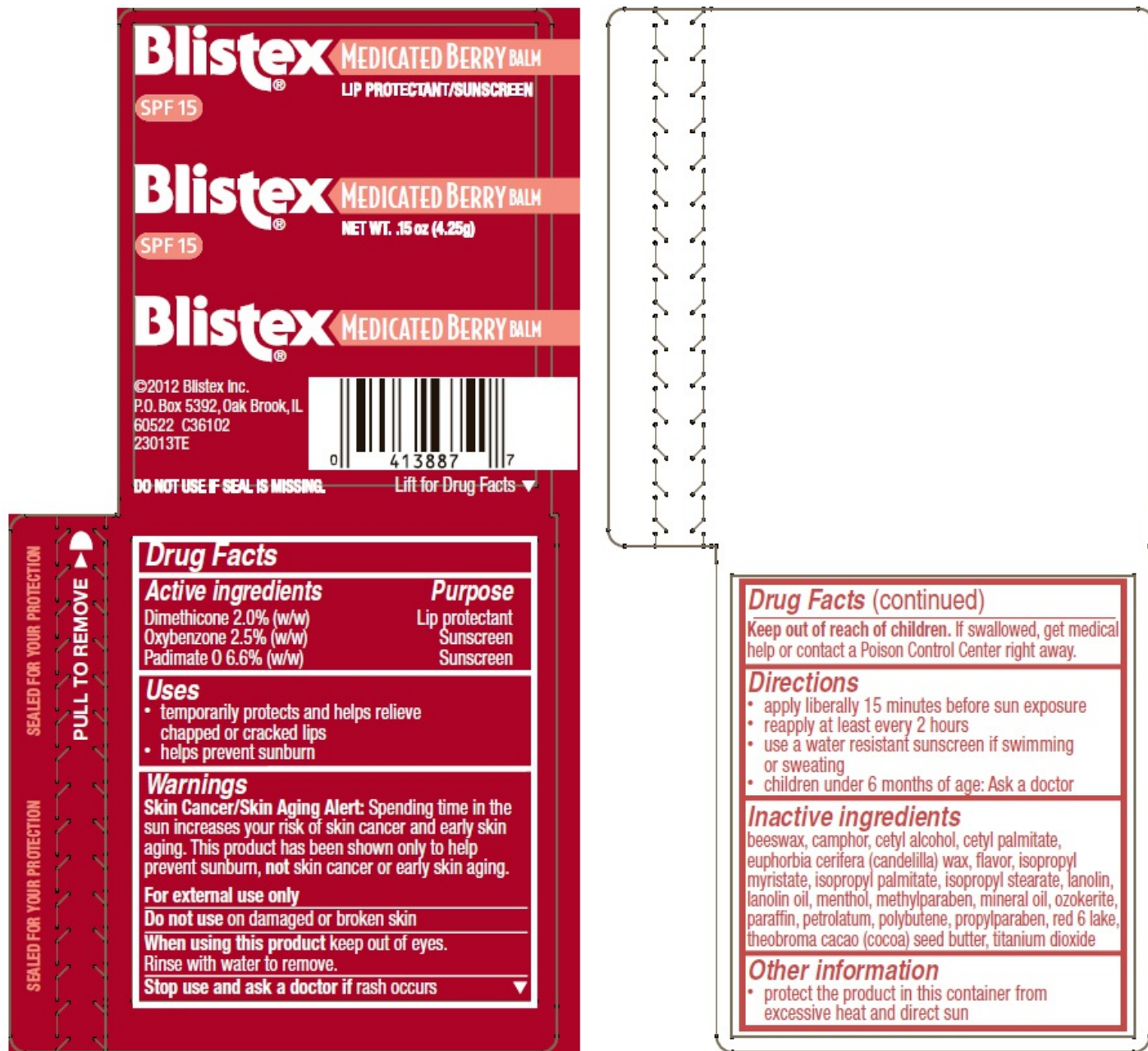
- protect the product in this container from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL - 4.25 g Cylinder Carton

Blistex® MEDICATED BERRY BALM

NET WT. .15 oz (4.25g)

SPF 15



BLISTEX MEDICATED BERRY BALM

dimethicone, padimate o, and oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-9713
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
Padimate O (UNII: Z11006CMUZ) (Padimate O - UNII:Z11006CMUZ)	Padimate O	6.6 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 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: OVV5IU58F)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
D&C RED NO. 6 (UNII: 481744AI4O)	
ALUMINUM OXIDE (UNII: LM26O6933)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	Score	
Shape	BULLET	Size	
Flavor	RASPBERRY (fruity)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-9713-3	3 in 1 CARTON		
1	NDC:10 157-9713-1	4.25 g in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/01/2010	

Labeler - Blistex Inc (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10157-9713)

Revised: 3/2013

Blistex Inc