BLISTEX DAILY CONDITIONING TREATMENT- petrolatum, octinoxate, and oxybenzone paste

Blistex 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_®

Daily Conditioning Treatment

Drug Facts

Active ingredients	Purpose
Octinoxate 7.3% (w/w)	Sunscreen
Oxybenzone 4.5% (w/w)	Sunscreen
Petrolatum 54.86% (w/w)	Lip protectant

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

aloe barbadensis leaf extract, camphor, cetyl alcohol, cocoyl hydrolyzed soy protein, euphorbia cerifera (candelilla) wax, flavor, lanolin, menthol, ozokerite, phenol, saccharin, theobroma cacao (cocoa) seed butter, tocopheryl acetate

PRINCIPAL DISPLAY PANEL - 7.08 g Jar Blister Pack

NDC 10157-9535-2

 $Blis\,tex_{\hbox{$\mathbb{R}$}}$

LIP PROTECTANT/SUNSCREEN

 $DCT^{\ @}$

Daily Conditioning Treatment For Lips®

Cocoa Butter, Aloe & Vitamin E

To Maintain Healthy, Moist Lips

SPF 20

NET WT. .25 oz (7.08g)

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Blistex

DCT ® Daily Conditioning Treatment Fo

Blistex DCT combines moisturizers, protectants and vitamin E to provide a daily maintenance regimen for your lips.

DCT keeps your lips in perfect condition every day of the year, in all climates, through all activities. DCT also provides SPF 20 protection. Remember, LIPS DON'T TAN, BUT THEY DO BURN.®

Smooth & Supple Lips:

DCT nurtures your lips with two proven moisturizers, aloe and cocoa butter, plus vitamin E. DCT softens and smoothes the surface of lips to help them look and feel young. DCT helps to prevent and replenish moisture-starved cells that can occur from daily exposure to dry air and other environmental conditions.

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Card is 100% Recyclable.

Drug Facts (continued)

(candelilla) wax, flavor, lanolin, menthol, ozokerite, phenol, saccharin, theobroma cacao (cocoa) seed butter, tocopheryl acetate



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BLISTEX DAILY CONDITIONING TREATMENT

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-9535
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petro latum	54.86 g in 100 g		
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.3 g in 100 g		
Oxybenzone (UNII: 9500S7VE0Y) (Oxybenzone - UNII:9500S7VE0Y)	Oxybenzone	4.5 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
LANOLIN (UNII: 7EV65EAW6H)		
CERESIN (UNII: Q1LS2UJO3A)		
CANDELILLA WAX (UNII: WL0328 HX19)		
Cocoa Butter (UNII: 512OYT1CRR)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
Menthol (UNII: L7T10EIP3A)		
Phenol (UNII: 339 NCG44TV)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
SACCHARIN (UNII: FST467XS7D)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10157-9535-2	1 in 1 BLISTER PACK		
1	7 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	02/14/2014	

Labeler - Blistex Inc. (005126354)

Establishment			
Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-9535)

Revised: 1/2014 Blistex Inc.