

BLISTEX LIP VIBRANCE- octinoxate, oxybenzone, and dimethicone 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®
Lip Vibrance™

Drug Facts

| Active ingredients | Purpose |
|---------------------------|----------------|
| Dimethicone 2.0% (w/w) | Lip protectant |
| Octinoxate 7.5% (w/w) | Sunscreen |
| Oxybenzone 2.5% (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

arachidyl alcohol, arachidyl glucoside, behenyl alcohol, bis-diglyceryl polyacyladipate-2, butylene glycol, butyrospermum parkii (shea butter), D&C red no. 6, D&C red no. 7, ethylhexyl palmitate, flavors, hydrogenated polyisobutene, iron oxides, isostearoyl hydrolyzed silk, mica, microcrystalline wax, mineral oil, ozokerite, panthenyl ethyl ether, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polybutene, polyethylene, PPG-5-ceteth-20, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium hyaluronate, titanium dioxide, tocopheryl acetate, vitis vinifera (grape) seed oil

Other information

- protect the product from excessive heat and direct sun

PRINCIPAL DISPLAY PANEL - 3.69g Container Blister Pack

NDC 10157-9831-1

Blis tex[®]

LIP PROTECTANT/SUNSCREEN

LIP

VIBRANCE[™]

New!

A Touch Of Color & Shimmer
That Really Lasts

Rich Moisturization & Protection

Total Care For Your Lips' Complexion

SPF 15

Built-in Mirror

NET WT. .13 oz (3.69g)

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Lip protectant
Sunscreen

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Lip Vibrance provides a touch of lasting

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color and shimmer plus the moisturization and protection you expect from Blistex for the ultimate in healthy-looking lips.

Soft, Smooth Lips

A rich moisturizing and protective formula—with shea butter, grapeseed oil and vitamin E—conditions lips and provides a smooth texture.

Subtle Color and Shimmer That Lasts

Lip Vibrance improves the look of dull, lackluster lips with a touch of color and sheer gloss that lasts longer than you would expect. Your lips' complexion will have an even tone that radiates health.

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

**SATISFACTION
GUARANTEED**
Blistex

♻️ Card is 100% Recyclable. #41191

Drug Facts (continued)

ethyl ether, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polybutene, polyethylene, PPG-5-ceteth-20, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium hyaluronate, titanium dioxide, tocopheryl acetate, vitis vinifera (grape) seed oil

Other information

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10157-9831 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51) | Octinoxate | 7.5 g in 100 g |
| Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y) | Oxybenzone | 2.5 g in 100 g |
| Dimethicone (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O) | Dimethicone | 2 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| arachidyl alcohol (UNII: 1QR1QRA9BU) | |
| arachidyl glucoside (UNII: 6JVV35JOOJ) | |
| docosanol (UNII: 9G1OE216XY) | |
| butylene glycol (UNII: 3XUS85K0RA) | |
| shea butter (UNII: K49155WL9Y) | |
| D&C red no. 6 (UNII: 481744AI4O) | |
| D&C red no. 7 (UNII: ECW0LZ41X8) | |
| ethylhexyl palmitate (UNII: 2865993309) | |
| mica (UNII: V8A1AW0880) | |
| microcrystalline wax (UNII: XOF597Q3KY) | |
| mineral oil (UNII: T5L8T28FGP) | |
| panthenyl ethyl ether (UNII: F4WMF8NX3B) | |
| paraffin (UNII: I9O0E3H2ZE) | |
| pentaerythrityl tetraethylhexanoate (UNII: XJ7052W897) | |
| petrolatum (UNII: 4T6HI2BN9U) | |
| phenoxyethanol (UNII: HIE492ZZ3T) | |
| phenyl trimethicone (UNII: DR0K5NOJ4R) | |
| high density polyethylene (UNII: UG00KM4WR7) | |
| PPG-5-ceteth-20 (UNII: 4AAN25P8P4) | |
| castor oil (UNII: D5340Y2I9G) | |
| saccharin (UNII: FST467XS7D) | |
| silica dimethyl silylate (UNII: EU2PSP0G0W) | |
| hyaluronate sodium (UNII: YSE9PPT4TH) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| .alpha.-tocopherol acetate (UNII: 9E8X80D2L0) | |
| grape seed oil (UNII: 930MLC8XGG) | |
| ferric oxide red (UNII: 1K09F3G675) | |
| ceresin (UNII: Q1LS2UJO3A) | |
| sandalwood (UNII: 3641YW25N2) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------|----------------------|--------------------|
| 1 | NDC:10157-9831-1 | 1 in 1 BLISTER PACK | | |
| 1 | | 3.69 g in 1 CYLINDER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part347 | 05/31/2013 | |

Labeler - Blistex Inc. (005126354)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|-------------------------|
| Blistex Inc. | | 005126354 | MANUFACTURE(10157-9831) |

