

**BLISTEX ENHANCEMENT SERIES (ULTRA-RICH HYDRATION AND LIP VIBRANCE)-
dimethicone, octinoxate and oxybenzone**

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.

Blistex® Enhancement Series® (Ultra-Rich Hydration™ and Lip Vibrance®)

ULTRA-RICH HYDRATION™

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 6.8% (w/w)	Sunscreen
Oxybenzone 3.0% (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

aloe barbadensis leaf extract, alumina, arachidyl alcohol, arachidyl glucoside, beeswax, behenyl alcohol, bis-diglyceryl polyacyladipate-2, blue 1 lake, butyrospermum parkii (shea butter), ceresin,

cetyl dimethicone, cetyl palmitate, chamomilla recutita (matricaria) flower extract, flavors, helianthus annuus (sunflower) seed oil, hydrogenated castor oil, hydrogenated polyisobutene, isopropyl myristate, isostearoyl hydrolyzed silk, jojoba esters, microcrystalline wax, olea europaea (olive) fruit oil, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polyhydroxystearic acid, saccharin, silica, theobroma cacao (cocoa) seed butter, titanium dioxide, tocopheryl acetate, triticum vulgare (wheat) germ oil

LIP VIBRANCE®

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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

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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

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

PRINCIPAL DISPLAY PANEL - Kit Blister Pack

NDC 10157-9866-1

Blistex®
LIP PROTECTANT/SUNSCREEN

ENHANCEMENT SERIES®

VALUE PACK

Dual-layer deep hydration

A touch of color & total care

SPF 15

2 Sticks Net Wt. 0.13 oz. (3.69 g) Ea.

SPF 15



ULTRA-RICH HYDRATION™

Inner: Deeply hydrates with 80% moisturizers
Outer: Smoothes & seals with lush protectants

<p>Drug Facts</p> <p>Active ingredients Purpose Dimethicone 2.0% (w/w) Lip protectant Octinoxate 6.8% (w/w) Sunscreen Oxybenzone 3.0% (w/w) Sunscreen</p> <p>Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn</p> <p>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.</p> <p>For external use only Do not use on damaged or broken skin</p>	<p>When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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</p> <p>Other information • protect the product in this container from excessive heat and direct sun</p>	<p>Inactive ingredients aloe barbadensis leaf extract, alumina, arachidyl alcohol, arachidyl glucoside, beeswax, behenyl alcohol, bis-diglyceryl polyacyladipate-2, blue 1 lake, butyrospermum parkii (shea butter), ceresin, cetyl dimethicone, cetyl palmitate, chamomilla recutita (matricaria) flower extract, flavors, helianthus annuus (sunflower) seed oil, hydrogenated castor oil, hydrogenated polyisobutene, isopropyl myristate, isostearyl hydrolyzed silk, jojoba esters, microcrystalline wax, olea europaea (olive) fruit oil, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polyhydroxystearic acid, saccharin, silica, theobroma cacao (cocoa) seed butter, titanium dioxide, tocopheryl acetate, triticum vulgare (wheat) germ oil</p>
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LIP VIBRANCE.

Beautiful, buildable color and shimmer that really lasts, plus shea butter, grapeseed oil and vitamin E.

<p>Drug Facts</p> <p>Active ingredients Purpose Dimethicone 2.0% (w/w) Lip protectant Octinoxate 7.5% (w/w) Sunscreen Oxybenzone 2.5% (w/w) Sunscreen</p> <p>Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn</p> <p>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.</p> <p>For external use only</p>	<p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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</p> <p>Other information • protect the product in this container from excessive heat and direct sun</p>	<p>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, isostearyl hydrolyzed silk, mica, microcrystalline wax, mineral oil, ozokerite, panthenyl ethyl ether, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polybutene, polyethylene, PPG-5-ceteeth-20, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium hyaluronate, titanium dioxide, tocopheryl acetate, vitis vinifera (grape) seed oil</p>
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SATISFACTION GUARANTEED
Blistex

BLISTEX ENHANCEMENT SERIES (ULTRA-RICH HYDRATION AND LIP VIBRANCE)

dimethicone, octinoxate and oxybenzone kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-9866
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 157-9866-1	1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CYLINDER	3.69 g
Part 2	1 CYLINDER	3.69 g

Part 1 of 2

BLISTEX ULTRA-RICH HYDRATION

dimethicone, octinoxate, and oxybenzone stick

Product Information

Route of Administration	TOPICAL
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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	6.8 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
yellow wax (UNII: 2ZA36H0S2V)	
pentaerythrityl tetraethylhexanoate (UNII: XJ7052W897)	
petrolatum (UNII: 4T6H12BN9U)	
paraffin (UNII: I9O0E3H2ZE)	
hydrogenated castor oil (UNII: ZF94AP8MEY)	
microcrystalline wax (UNII: XOF597Q3KY)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
titanium dioxide (UNII: 15FIX9V2JP)	

shea butter (UNII: K49155WL9Y)
aluminum oxide (UNII: LM26O6933)
silicon dioxide (UNII: ETJ7Z6XBU4)
cetyl palmitate (UNII: 5ZA2S6B08X)
arachidyl alcohol (UNII: 1QR1QRA9BU)
docosanol (UNII: 9G1OE216XY)
arachidyl glucoside (UNII: 6JVV35JOOJ)
olive oil (UNII: 6UYK2W1W1E)
aloe vera leaf (UNII: ZY81Z83H0X)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
wheat germ oil (UNII: 14C97E680P)
phenyl trimethicone (UNII: DR0K5NOJ4R)
sunflower oil (UNII: 3W1JG795YI)
chamomile (UNII: FGL3685T2X)
ceresin (UNII: Q1LS2UJO3A)
cocoa butter (UNII: 512OYT1CRR)
saccharin (UNII: FST467XS7D)
FD&C blue no. 1 (UNII: H3R47K3TBD)
phenoxyethanol (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3.69 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	05/30/2014	

Part 2 of 2

BLISTEX LIP VIBRANCE

dimethicone, octinoxate, and oxybenzone stick

Product Information

Route of Administration	TOPICAL
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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	7.5 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
arachidyl alcohol (UNII: 1QR1QRA9BU)	
ceresin (UNII: Q1LS2UJO3A)	
paraffin (UNII: I9O0E3H2ZE)	
microcrystalline wax (UNII: XOF597Q3KY)	
petrolatum (UNII: 4T6H12BN9U)	
mineral oil (UNII: T5L8T28FGP)	
arachidyl glucoside (UNII: 6JVV35JOOJ)	
docosanol (UNII: 9G1OE216XY)	
butylene glycol (UNII: 3XUS85K0RA)	
shea butter (UNII: K49155WL9Y)	
D&C red no. 7 (UNII: ECW0LZ41X8)	
D&C red no. 6 (UNII: 481744A140)	
ethylhexyl palmitate (UNII: 2865993309)	
phenoxyethanol (UNII: HIE492ZZ3T)	
mica (UNII: V8A1AW0880)	
panthenyl ethyl ether (UNII: F4WMF8NX3B)	
pentaerythrityl tetraethylhexanoate (UNII: XJ7052W897)	
high density polyethylene (UNII: UG00KM4WR7)	
PPG-5-ceteth-20 (UNII: 4AAN25P8P4)	
ferric oxide red (UNII: 1K09F3G675)	
titanium dioxide (UNII: 15FIX9V2JP)	
phenyl trimethicone (UNII: DR0K5NOJ4R)	
grape seed oil (UNII: 930MLC8XGG)	
castor oil (UNII: D5340Y2I9G)	
sandalwood (UNII: 3641YW25N2)	
saccharin (UNII: FST467XS7D)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
Polybutene (1400 MW) (UNII: 1NA5AO9GH7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3.69 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	05/31/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	02/01/2015	

Labeler - Blistex Inc. (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10 157-9866)

Revised: 12/2014

Blistex Inc.