

BLISTEX ENHANCEMENT SERIES (LIP VIBRANCE, DEEP RENEWAL AND ULTRA-RICH HYDRATION)- dimethicone, octinoxate, oxybenzone, avobenzone, and octocrylene
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® (Lip Vibrance®, Deep Renewal® and Ultra-Rich Hydration™)

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

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

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

DEEP RENEWAL®

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avobenzone 3.0% (w/w)	Sunscreen
Dimethicone 2.0% (w/w)	Lip protectant
Octinoxate 7.5% (w/w)	Sunscreen
Octocrylene 2.7% (w/w)	Sunscreen
Oxybenzone 2.5% (w/w)	Sunscreen

Uses

- temporarily protects and helps relieve chapped or cracked lips
- helps prevent sunburn

Warnings

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
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long sleeve shirts, pants, hats, and sunglasses
- 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

atelocollagen, beeswax, butylene glycol, dipalmitoyl hydroxyproline, ethylhexyl palmitate, flavor,

jojoba esters, lanolin alcohol, microcrystalline wax, octyldodecanol, pentaerythrityl tetraisostearate, petrolatum, phenoxyethanol, polybutene, polyethylene, PTFE, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium chondroitin sulfate, sodium hyaluronate, sorbic acid, squalane, tetrahexyldecyl ascorbate, tocopheryl acetate, ubiquinone

ULTRA-RICH HYDRATION™

Drug Facts

Active ingredients	Purpose
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

PRINCIPAL DISPLAY PANEL - 3 Stick Blister Pack

NDC 10157-9861-1

Blis tex®

LIP PROTECTANT/SUNSCREEN

ENHANCEMENT SERIES®

soft • beautiful • youthful

BUY 2 GET 1 FREE

NEW!

BROAD SPECTRUM

SPF15

SPF15

SPF15

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

NDC 10157-9861-1

Blistex

LIP PROTECTANT/SUNSCREEN

ENHANCEMENT SERIES[®]

soft • beautiful • youthful

BUY 2 GET 1 FREE

NEW!

SPF15

SPF15

BROAD SPECTRUM
SPF15

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

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

Drug Facts		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.	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-ceteth-20, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium hyaluronate, titanium dioxide, tocopheryl acetate, vitis vinifera (grape) seed oil
Active ingredients Dimethicone 2.0% (w/w) Octinoxate 7.5% (w/w) Oxybenzone 2.5% (w/w)	Purpose Lip protectant Sunscreen Sunscreen		
Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn		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
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			

DEEP RENEWAL. The anti-aging lip treatment with coenzyme Q-10, clinically proven to visibly reduce fine lines and wrinkles in just four weeks.

Drug Facts		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.	Other information • protect the product in this container from excessive heat and direct sun
Active ingredients Avobenzone 3.0% (w/w) Dimethicone 2.0% (w/w) Octinoxate 7.5% (w/w) Octocrylene 2.7% (w/w) Oxybenzone 2.5% (w/w)	Purpose Sunscreen Lip protectant Sunscreen Sunscreen Sunscreen		
Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn		Directions • apply liberally 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m.-2 p.m. • wear long sleeve shirts, pants, hats, and sunglasses • children under 6 months of age: Ask a doctor	Inactive ingredients atelocollagen, beeswax, butylene glycol, dipalmitoyl hydroxyproline, ethylhexyl palmitate, flavor, jojoba esters, lanolin alcohol, microcrystalline wax, octyldodecanol, pentaerythrityl tetraiscostearate, petrolatum, phenoxyethanol, polybutene, polyethylene, PTFE, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium chondroitin sulfate, sodium hyaluronate, sorbic acid, squalane, tetrahexyldecyl ascorbate, tocopheryl acetate, ubiquinone
Warnings For external use only Do not use on damaged or broken skin When using this product keep out			

ULTRA-RICH HYDRATION™ Inner: Deeply Hydrates With 80% Moisturizers Outer: Smoothes & Seals With Lush Protectants

Drug Facts		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.	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
Active ingredients Dimethicone 2.0% (w/w) Octinoxate 6.8% (w/w) Oxybenzone 3.0% (w/w)	Purpose Lip protectant Sunscreen Sunscreen		
Uses • temporarily protects and helps relieve chapped or cracked lips • helps prevent sunburn		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
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			



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

dimethicone, octinoxate, oxybenzone, avobenzone, and octocrylene kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-9861
---------------------	----------------	---------------------------	----------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-9861-1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 CYLINDER	3.69 g
Part 2	1 CYLINDER	3.69 g
Part 3	1 CYLINDER	3.69 g

Part 1 of 3

BLISTEX LIP VIBRANCE

dimethicone, octinoxate and oxybenzone stick

Product Information

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	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: 4T6HI2BN9U)	

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: 481744A14O)
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	

Part 2 of 3

BLISTEX DEEP RENEWAL

avobenzone, octinoxate, octocrylene, oxybenzone, and dimethicone stick

Product Information

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	7.5 g in 100 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	2.5 g in 100 g
Avobenzon e (UNII: G63QQF2NOX) (Avobenzon e - UNII:G63QQF2NOX)	Avobenzon e	3 g in 100 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	2.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
yellow wax (UNII: 2ZA36H0S2V)	
butylene glycol (UNII: 3XUS85K0RA)	
dipalmitoyl hydroxyproline (UNII: E6AHA53N1H)	
ethylhexyl palmitate (UNII: 2865993309)	
lanolin alcohols (UNII: 884C3FA9HE)	
microcrystalline wax (UNII: XOF597Q3KY)	
octyldodecanol (UNII: 461N1O614Y)	
pentaerythrityl tetraiso stearate (UNII: 9D7IK5483F)	
petrolatum (UNII: 4T6HI2BN9U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
high density polyethylene (UNII: UG00KM4WR7)	
polytetrafluoroethylene (UNII: E1NC1JVS3O)	
castor oil (UNII: D5340Y2I9G)	
saccharin (UNII: FST467XS7D)	
silica dimethyl silylate (UNII: EU2PSP0G0W)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
sorbic acid (UNII: X045WJ989B)	
squalane (UNII: GW89575KF9)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
Polybutene (1400 MW) (UNII: 1NA5AO9GH7)	
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)	
CHONDRO ITIN SULFATE SODIUM (SHARK) (UNII: Q75WVO004L)	
UBIDECARENONE (UNII: EJ27X76M46)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

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	11/01/2012	

Part 3 of 3

BLISTEX ULTRA-RICH HYDRATION

dimethicone, octinoxate, and oxybenzone stick

Product Information

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	6.8 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: 3W1JG795Y)	
CHAMOMILE (UNII: FGL3685T2X)	
ceresin (UNII: Q1LS2UJO3A)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SACCHARIN (UNII: FST467XS7D)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/01/2014	

Labeler - Blistex Inc. (005126354)**Establishment**

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE(10157-9861)

Revised: 6/2014

Blistex Inc.