

BLISTEX REVIVE AND RESTORE- dimethicone, octinoxate, oxybenzone, and lanolin
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®
REVIVE &
RESTORE™

Drug Facts - Revive

<i>Active ingredients</i>	<i>Purpose</i>
Dimethicone 1.0%(w/w)	Skin protectant
Octinoxate 7.5%(w/w)	Sunscreen
Oxybenzone 2.5%(w/w)	Sunscreen

Uses

- temporarily protects and helps relieve chapped or cracked lips
- helps protect lips from the drying effects of wind and cold weather
- helps prevent sunburn

Warnings

- Stop use if skin rash occurs

Directions

- apply liberally before sun exposure and as needed
- children under six months of age:
ask a doctor

Inactive ingredients

acer saccharum (sugar maple) extract, aloe barbadensis leaf extract, beeswax, bis-diglyceryl polyacyladipate-2, butyrospermum parkii (shea butter), C10-30 cholesterol/lanosterol esters, caprylic/capric triglyceride, cholesteryl/beheryl/octyldodecyl lauroyl glutamate, citrus aurantium dulcis (orange) fruit extract, citrus medica limonum (lemon) extract, flavors, menthol, microcrystalline wax, myristyl myristate, octyldodecanol, phenoxyethanol, polybutene, purified water, ricinus communis (castor) seed oil, saccharin, saccharum officinarum (sugar cane) extract, vaccinium myrtillus (bilberry) extract

Drug Facts - Restore

Active ingredients

Lanolin 15.0%(w/w)

Purpose

Skin protectant

Uses

- temporarily protects and helps relieve chapped or cracked lips
- helps protect lips from the drying effects of wind and cold weather

Directions

- apply as needed

Inactive ingredients

beeswax, bis-diglyceryl polyacyladipate-2, brassica campestris/aleurites fordii oil copolymer, C10-30 cholesterol/lanosterol esters, flavors, hydrogenated polyisobutene, jojoba esters, microcrystalline wax, myristyl myristate, octyldodecanol, phenoxyethanol, polybutene, saccharin, simmondsia chinensis (jojoba) seed oil, squalane, theobroma cacao (cocoa) seed butter, tocopheryl acetate

PRINCIPAL DISPLAY PANEL - Kit Package

NDC 10157-9848-2

Blis tex®

REVIVE: LIP PROTECTANT/SUNSCREEN

RESTORE: LIP PROTECTANT

**REVIVE &
RESTORE™****REVIVE FORMULA**

**Leaves lips smooth, invigorated & protected
Shea butter, fruit extracts & SPF 15**

RESTORE FORMULA

**Makes lips soft, healthy & radiant
Phyto-nutrients & Vitamin E**

JARS NEST
AND LOCK
TOGETHER

2 JARS
NET WT.
.20 oz.
(5.67g)ea.

NEW!

NDC 10157-9848-2

Blistex[®]

REVIVE: LIP PROTECTANT/SUNSCREEN
RESTORE: LIP PROTECTANT

REVIVE & RESTORE™

NEW!

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(5.67g) ea.

Blistex REVIVE & RESTORE™

Revive & Restore provides two distinct lip care formulas that can be used separately or alternately to make your lips feel renewed and look their healthy best.

Use Revive during the day or whenever you want to refresh or protect your lips.

Use Restore at night or whenever you need to soften and revitalize rough lips.

Interlocking jars make it easy to store them together or carry individually.

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Drug Facts - Revive		Drug Facts - Restore	
Active ingredients	Purpose	Active ingredients	Purpose
Dimethicone 1.0%(w/w)	Skin protectant	Lanolin 15.0%(w/w)	Skin protectant
Octinoxate 7.5%(w/w)	Sunscreen		
Oxybenzone 2.5%(w/w)	Sunscreen		
Uses		Uses	
<ul style="list-style-type: none"> temporarily protects and helps relieve chapped or cracked lips helps protect lips from the drying effects of wind and cold weather helps prevent sunburn 		<ul style="list-style-type: none"> temporarily protects and helps relieve chapped or cracked lips helps protect lips from the drying effects of wind and cold weather 	
Warnings		Directions	
<ul style="list-style-type: none"> Stop use if skin rash occurs 		<ul style="list-style-type: none"> apply as needed 	
Directions		Inactive ingredients	
<ul style="list-style-type: none"> apply liberally before sun exposure and as needed children under six months of age: ask a doctor 		beeswax, bis-diglyceryl polyacyladipate-2, brassica campestris/aleurites fordii oil copolymer, C10-30 cholesterol/lanosterol esters, flavors, hydrogenated polyisobutene, jojoba esters, microcrystalline wax, myristyl myristate, octyldodecanol, phenoxyethanol, polybutene, saccharin, simmondsia chinensis (jojoba) seed oil, squalane, theobroma cacao (cocoa) seed butter, tocopheryl acetate	
Inactive ingredients		# 42500 ©2011 Blistex Inc. P.O. Box 5392 Oak Brook, IL 60522-5392 ♻️ Card is 100% Recyclable.	
acer saccharum (sugar maple) extract, aloe barbadensis leaf extract, beeswax, bis-diglyceryl polyacyladipate-2, butyrospermum parkii (shea butter), C10-30 cholesterol/lanosterol esters, caprylic/capric triglyceride, cholesteryl/behenyl/octyldodecyl lauroyl glutamate, citrus aurantium dulcis (orange) fruit extract, citrus medica limonum (lemon) extract, flavors, menthol, microcrystalline wax, myristyl myristate, octyldodecanol, phenoxyethanol, polybutene, purified water, ricinus communis (castor) seed oil, saccharin, saccharum officinarum (sugar cane) extract, vaccinium myrtillus (bilberry) extract			
		SATISFACTION GUARANTEED 	
		 0 41388 00259 0	

BLISTEX REVIVE AND RESTORE

dimethicone, octinoxate, oxybenzone, and lanolin kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10157-9848
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-9848-2	1 in 1 PACKAGE		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 JAR	5.67 g
Part 2	1 JAR	5.67 g

Part 1 of 2

BLISTEX REVIVE

dimethicone, octinoxate, and oxybenzone paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 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
ACER SACCHARUM BARK/SAP (UNII: Z120VL0KAC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON (UNII: 24RS0A988O)	
MENTHOL (UNII: L7T10EIP3A)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
CASTOR OIL (UNII: D5340Y2I9G)	
SACCHARIN (UNII: FST467XS7D)	
SUGARCANE (UNII: 81H2R5AOH3)	
BILBERRY (UNII: 9P2U39H18W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5.67 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	06/13/2011	

Part 2 of 2

BLISTEX RESTORE

lanolin paste

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SACCHARIN (UNII: FST467XS7D)	
JOJOBA OIL (UNII: 724GKU717M)	
SQUALANE (UNII: GW89575KF9)	
COCOA BUTTER (UNII: 512OYT1CRR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5.67 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/13/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	06/13/2011	

Labeler - Blistex Inc. (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	MANUFACTURE

Revised: 8/2011

Blistex Inc.