

DEEP RENEWAL BROAD SPECTRUM- dimethicone, avobenzone, homosalate, and octisalate 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.

Deep Renewal® Broad Spectrum

Drug Facts

Active ingredients	Purpose
Avobenzone 3.0% (w/w)	Sunscreen
Dimethicone 2.0% (w/w)	Lip protectant
Homosalate 9.0% (w/w)	Sunscreen
Octisalate 4.4% (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, flavors, jojoba esters, lanolin alcohol, microcrystalline wax, octyldodecanol, pentaerythrityl tetraisostearate,

pentylene glycol, petrolatum, phenoxyethanol, polybutene, ricinus communis (castor) seed oil, saccharin, silica, silica dimethyl silylate, sodium chondroitin sulfate, sodium hyaluronate, sorbic acid, squalane, tetrahexyldecyl ascorbate, tocopheryl acetate, ubiquinone

PRINCIPAL DISPLAY PANEL - 3.69 g Cylinder Blister Pack

Blistex®

LIP PROTECTANT/SUNSCREEN

DEEP

RENEWAL®

FOR YOUNGER LOOKING LIPS

Smooths & Softens Lips

Moisturizes, Protects
& Revitalizes

ENHANCEMENT SERIES®

coenzyme

Q·10

with

Hyaluronic

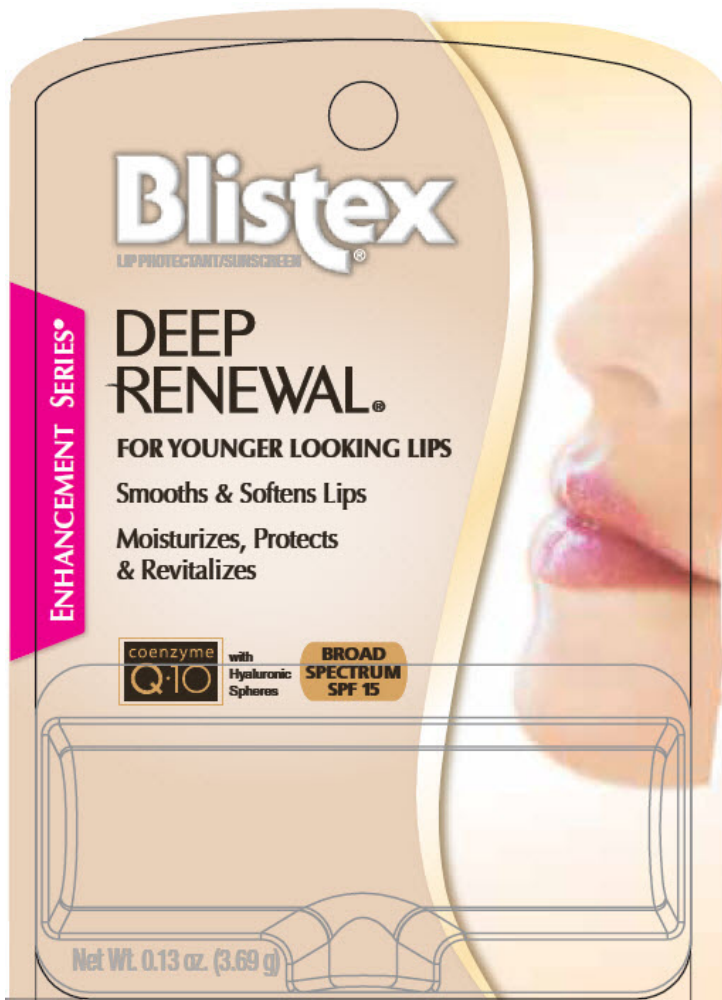
Spheres

BROAD

SPECTRUM

SPF 15

Net Wt. 0.13 oz. (3.69 g)



Drug Facts

Active ingredients	Purpose
Avobenzone 3.0% (w/w)	Sunscreen
Dimethicone 2.0% (w/w)	Lip protectant
Homosalate 9.0% (w/w)	Sunscreen
Octisalate 4.4% (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.

Blistex DEEP RENEWAL

Deep Renewal is an advanced lip formula that delivers superb moisturization, softens and smooths lips to help them look and feel youthful, and promotes lips' vitality.

Deep Renewal utilizes best-in-class ingredients for beautifully cared-for lips.

- Coenzyme Q-10...a gold standard for moisturization and overall revitalization
- Hyaluronic filling spheres...help give lips a fuller appearance
- Vitamin & anti-oxidant complex...promotes lasting lip health

Drug Facts (continued)

Other information

- protect the product in this container from excessive heat and direct sun

Inactive ingredients

atelocollagen, beeswax, butylene glycol, dipalmitoyl hydroxyproline, ethylhexyl palmitate, flavors, jojoba esters, lanolin alcohol, microcrystalline wax, octyldodecanol, pentaerythrityl tetraistearate, pentylene glycol, petrolatum, phenoxyethanol, polybutene, ricinus communis (castor) seed oil, saccharin, silica, silica dimethyl silylate, sodium chondroitin sulfate, sodium hyaluronate, sorbic acid, squalane, tetrahydrodecyl ascorbate, tocopheryl acetate, ubiquinone

©2020 Blistex Inc., P.O. Box 5302, Oak Brook, IL 60522-5302 #C010195
 SATISFACTION GUARANTEED
 Blistex 0 41388 00204 0
 Card is 100% Recyclable.

DEEP RENEWAL BROAD SPECTRUM

dimethicone, avobenzone, homosalate, and octisalate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 157-1170
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
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECANOL (UNII: 461N1O614Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	

MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
CASTOR OIL (UNII: D5340Y2I9G)
YELLOW WAX (UNII: 2ZA36H0S2V)
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)
SQUALANE (UNII: GW89575KF9)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)
PENTAERYTHRITYL TETRAISO STEARATE (UNII: 9D7IK5483F)
CHONDROITIN SULFATE SODIUM, SHARK (UNII: Q75WVO004L)
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
SACCHARIN (UNII: FST467XS7D)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SORBIC ACID (UNII: X045WJ989B)
UBIDECARENONE (UNII: EJ27X76M46)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10157-1170-1	1 in 1 BLISTER PACK	09/09/2020	
1		3.69 g in 1 CYLINDER; Type 0: Not a Combination Product		
2	NDC:10157-1170-2	2 in 1 BLISTER PACK	09/09/2020	
2		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	09/09/2020	

Labeler - Blistex Inc (005126354)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc		005126354	MANUFACTURE(10157-1170)