

**BLISTEX ENHANCEMENT SERIES (DEEP RENEWAL AND SILK AND SHINE)-
avobenzone, dimethicone, octinoxate, octocrylene and oxybenzone**

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® Enhancement Series® (Deep Renewal® and Silk & Shine®)

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

SILK & SHINE®

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, flavors, hydrogenated polyisobutene, isostearoyl hydrolyzed silk, mica, microcrystalline wax, mineral oil, ozokerite, panthenyl ethyl ether, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxyethanol, phenyl trimethicone, polybutene, PPG-5-Ceteth-20, saccharin, titanium dioxide, tocopheryl acetate

PRINCIPAL DISPLAY PANEL - Kit Blister Pack

NDC 10157-9865-1

Blis tex®

LIP PROTECTANT/SUNSCREEN

ENHANCEMENT SERIES®

VALUE PACK

Anti-aging rejuvenation

Satiny smooth & light shine

BROAD SPECTRUM SPF 15

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

SPF 15



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 | 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 Purpose 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 | 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 tetraoctoate, petrolatum, phenoxethanol, polybutene, polyethylene, PTFE, ricinus communis (castor) seed oil, saccharin, silica dimethyl silylate, sodium chondroitin sulfate, sodium hyaluronate, sorbic acid, squalane, tetrahydroxyethyl ascorbate, tocopheryl acetate, ubiquinone |
| 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. | | |

SILK & SHINE. Enhances lips' natural radiance, leaves a smoother lip feel, and keeps lips hydrated...with real silk extracts and vitamins.

| | | |
|--|---|--|
| 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 polyacrylate-2, flavors, hydrogenated polyisobutene, isostearyl hydrolyzed silk, mica, microcrystalline wax, mineral oil, ozokerite, panthenyl ethyl ether, paraffin, pentaerythrityl tetraethylhexanoate, petrolatum, phenoxethanol, phenyl trimethicone, polybutene, PPG-5-Ceteth-20, saccharin, titanium dioxide, tocopheryl acetate |
| Active ingredients Purpose Dimethicone 2.0% (w/w) Lip protectant Octinoxate 7.5% (w/w) Sunscreen Oxybenzone 2.5% (w/w) Sunscreen | 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 | |
| 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 | Other information • protect the product in this container from excessive heat and direct sun | |

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SATISFACTION GUARANTEED
Blis tex

BLISTEX ENHANCEMENT SERIES (DEEP RENEWAL AND SILK AND SHINE)

avobenzone, dimethicone, octinoxate, octocrylene and oxybenzone kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10157-9865 |
|---------------------|----------------|---------------------------|----------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:10157-9865-1 | 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 DEEP RENEWAL

dimethicone, octinoxate, oxybenzone, avobenzone, and octocrylene 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 |
| Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX) | Avobenzone | 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 tetraisoostearate (UNII: 9D7IK5483F) | |
| petrolatum (UNII: 4T6H12BN9U) | |

| |
|---|
| 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) |
| CHONDROITIN 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 2 of 2

BLISTEX SILK AND SHINE

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) |
| arachidyl glucoside (UNII: 6JVV35JOOJ) |
| docosanol (UNII: 9G1OE216XY) |
| 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: 4T6H12BN9U) |
| phenoxyethanol (UNII: HIE492ZZ3T) |
| phenyl trimethicone (UNII: DR0K5NOJ4R) |
| PPG-5-Ceteth-20 (UNII: 4AAN25P8P4) |
| saccharin (UNII: FST467XS7D) |
| titanium dioxide (UNII: 15FIX9V2JP) |
| sandalwood (UNII: 3641YW25N2) |
| .alpha.-tocopherol acetate (UNII: 9E8X80D2L0) |
| Ceresin (UNII: Q1LS2UJO3A) |
| 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 | 11/01/2012 | |

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(10157-9865) |