

**NEOSTRATA ENLIGHTEN SKIN BRIGHTENER WITH SUNSCREEN BROAD SPECTRUM  
SPF 35- octinoxate, octisalate, and avobenzone cream**

**NeoStrata Company 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.*

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**NeoStrata® Enlighten Skin Brightener  
with Sunscreen Broad Spectrum SPF 35**

**Drug Facts**

**Active ingredients (w/w)**

Avobenzone 3%,  
Octinoxate 7.5%,  
Octisalate 5%

**Purpose**

Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

**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 product is swallowed, get medical help or contact a Poison Control Center right away

**Directions**

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply sunscreen at least every 2 hours
- **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 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: Ask a doctor

**Inactive ingredients**

Aqua/Water/Eau, Acetyl Glucosamine, Butyloctyl Salicylate, Dimethicone, C12-15 Alkyl Benzoate, Glycerin, Cyclopentasiloxane, Glyceryl Stearate, Butylene Glycol, Cyclohexasiloxane, Octyldodecyl Neopentanoate, Cetyl Alcohol, PEG-100 Stearate, Cetearyl Alcohol, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Extract, Tetrahydrodiferuloylmethane, 4-Butylresorcinol, Ceteth-20, PEG-75 Stearate, Propylene Glycol, Disodium EDTA, Steareth-20, Xanthan Gum, Ammonium Hydroxide, Sodium Bisulfite, Carbomer, Caprylyl Glycol, Phenoxyethanol, Chlorphenesin.

**Other information**

- Store at 15°C - 30°C (59°F - 86°F)
- Protect this product from excessive heat and direct sun

**Questions?**

**1-800-628-9904**

**PRINCIPAL DISPLAY PANEL - 40 g Tube Carton**

NEOSTRATA®

ENLIGHTEN

UNEVEN TONE AND  
DARK SPOTS

Skin Brightener  
with Sunscreen Broad  
Spectrum SPF 35

NET WT

40 g / 1.4 OZ

ENLIGHTEN

**Drug Facts / Information  
sur le médicament**

**Active ingredients /  
Ingrédients actifs**  
(w/w).....**Purpose / Utilité**  
Avobenzone 3%,  
Octinoxate 7.5%,  
Octisalate 5% }.....Sunscreen /  
Ecran solaire

**Uses / Usages** • Helps prevent sunburn / Aide à prévenir les coups de soleil • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun / Utilisé comme indiqué en association avec d'autres mesures de protection solaire (voir Mode d'emploi), diminue les risques de cancer de la peau et de photovieilissement cutané prématuré

**Warnings / Mises en garde**  
For external use only / Pour usage externe seulement

Do not use on damaged or broken skin / Ne pas utiliser sur une peau abîmée ou blessée

When using this product keep out of eyes. Rinse with water to remove. Lorsque vous utilisez ce produit éviter le contact avec les yeux. En cas d'application accidentelle, rincer à l'eau claire.

Stop use and ask a doctor if rash occurs / Cessez d'utiliser ce produit et consultez un médecin en cas d'éruption cutanée

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away / Garder hors de la portée des enfants. En cas d'ingestion, consulter immédiatement un médecin ou contacter un centre anti-poison.

**Directions / Mode d'emploi**  
• Apply liberally 15 minutes before sun exposure / Appliquer généreusement 15 minutes avant l'exposition au soleil  
• Use a water resistant sunscreen if swimming or sweating / Utiliser un écran solaire résistant à l'eau en cas de baignade ou de transpiration  
• Re-apply sunscreen at least every 2 hours / Renouveler l'application de l'écran solaire au minimum toutes les 2 heures  
• 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 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: Ask a doctor • Mesures de protection solaire. Passer du temps au soleil augmente les risques de cancer de la peau et de vieillissement cutané prématuré. Afin de réduire ces risques, appliquez régulièrement un écran solaire à large spectre FPS 15 ou supérieur, en association avec d'autres mesures de protection comme: • La limitation de votre temps d'exposition au soleil, en particulier entre 10 h et 14 h • Le port de vêtements à manches longues, de pantalons, de chapeaux et de lunettes de soleil • Enfants de moins de 6 mois: consulter un médecin

**Inactive ingredients /  
Ingrédients inactifs**  
Aqua/Water/Eau, Acetyl Glucosamine, Butyloctyl Salicylate, Dimethicone, C12-15 Alkyl Benzoate, Glycerin, Cyclopentasiloxane, Glyceryl Stearate, Butylene Glycol, Cyclohexasiloxane, Octyldodecyl Neopentanoate, Cetyl Alcohol, PEG-100 Stearate, Cetearyl Alcohol, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Extract, Tetrahydrodiferuloylmethane, 4-Butylresorcinol, Ceteth-20, PEG-75 Stearate, Propylene Glycol, Disodium EDTA, Steareth-20, Xanthan Gum, Ammonium Hydroxide, Sodium Bisulfite, Carbomer, Caprylyl Glycol, Phenoxyethanol, Chlorphenesin.

**Other information /  
Autres renseignements**  
• Store at 15°C - 30°C (59°F - 86°F) / Conserver entre 15°C et 30°C (59°F - 86°F) • Protect this product from excessive heat and direct sun / Protéger de la chaleur et des rayons directs du soleil

Questions? 1-800-628-9904

NEOSTRATA®

ENLIGHTEN

UNEVEN TONE AND  
DARK SPOTS

TEINT IRRÉGULIER ET  
TACHES BRUNES

Skin Brightener  
with Sunscreen Broad  
Spectrum SPF 35

Soin Eclat Parfait  
avec Écran Solaire à Large  
Spectre FPS 35

NET WT / POIDS NET  
40 g / 1.4 OZ

**Indications:** Uneven tone, dark spots, dull skin.  
**Mode of Action:** This antioxidant-enriched moisturizer combines NeoGlucosamine™, a gentle exfoliant, with B-Resorcinol, a known brightening agent, to reduce the look of age spots and provide a more even skin tone. With daily use, its Broad Spectrum SPF 35 protects against UV-induced skin aging.  
**Results:** Shown to diminish the appearance of dark spots and brighten overall skin tone while protecting skin against further signs of aging.

**Indications:** Teint irrégulier, ternes, taches brunes.

**Mode d'action:** Cet hydratant enrichi aux antioxydants associe la NeoGlucosamine™, un exfoliant doux, au B-Resorcinol, un agent éclaircissant reconnu, afin d'atténuer l'apparence des taches de vieillesse et d'uniformiser le teint. Utilisé quotidiennement, il protège également du vieillissement cutané lié aux UV grâce à son écran solaire à large spectre FPS 35.

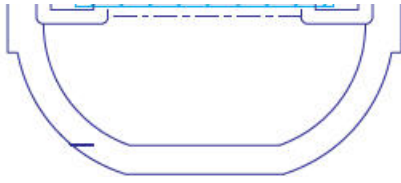
**Résultats:** Efficacité prouvée sur l'atténuation de l'apparence des taches brunes et l'éclaircissement général du teint, tout en prévenant l'apparition d'autres signes de vieillissement.

Mfd. for/Fabriqué pour NeoStrata Company, Inc., Princeton, NJ 08540, USA. Made in USA/Fabriqué aux États-Unis  
[www.neostrata.com](http://www.neostrata.com)



NO COATING FOR LOT/EXP  
DO NOT PRINT WARNISH BOX BORDERS

29F30131XA



# NEOSTRATA ENLIGHTEN SKIN BRIGHTENER WITH SUNSCREEN BROAD SPECTRUM SPF 35

octinoxate, octisalate, and avobenzone cream

## Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58414-0019 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 75 mg in 1 g |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE        | 50 mg in 1 g |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE        | 30 mg in 1 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>N-ACETYLGLUCOSAMINE</b> (UNII: V956696549)                                      |          |
| <b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)                                    |          |
| <b>DIMETHICONE 100</b> (UNII: RO266O364U)  |          |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)                                  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |          |
| <b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)   |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                                    |          |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)  |          |
| <b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)   |          |
| <b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)                               |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)  |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)   |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)                                      |          |
| <b>VITIS VINIFERA SEED</b> (UNII: C34U15ICXA)                                      |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                               |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)   |          |
| <b>4-BUTYLRESORCINOL</b> (UNII: 2IK4UQ3ZGA)  |          |
| <b>TETRAHYDRODIFERULOLMETHANE</b> (UNII: 00U0645U03)                               |          |
| <b>PEG-75 STEARATE</b> (UNII: OT38R0N74H)  |          |
| <b>STEARETH-20</b> (UNII: L0Q8IK9E08)  |          |
| <b>CETETH-20</b> (UNII: I835H2IHHX)  |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)   |          |
| <b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO) |          |

|  |  |
|--|--|
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)      |  |
| <b>SODIUM BISULFITE</b> (UNII: TZX5469Z6I) |  |
| <b>AMMONIA</b> (UNII: 5138Q19F1X)          |  |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)  |  |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)   |  |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)    |  |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58414-0019-1 | 1 in 1 CARTON                                     | 12/01/2018           |                    |
| 1 |                  | 40 g in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part352                                  | 12/01/2018           |                    |

**Labeler** - NeoStrata Company Inc. (605754829)

### Establishment

| Name                  | Address | ID/FEI    | Business Operations     |
|-----------------------|---------|-----------|-------------------------|
| Cosmetic Essence, LLC |         | 032565959 | MANUFACTURE(58414-0019) |

Revised: 6/2018

NeoStrata Company Inc.