

**NEOSTRATA SHEER HYDRATION SUNSCREEN BROAD SPECTRUM SPF 40-
octinoxate, octisalate, and avobenzone lotion
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.

**NeoStrata® Sheer Hydration
Sunscreen Broad Spectrum SPF 40**

Drug Facts

Active ingredients (w/w)

Avobenzone 3%, Octinoxate 7.5%, Octisalate 5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Broad Spectrum SPF 40
- 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
- Children under 6 months: Ask a doctor
- 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

Other information

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

Inactive ingredients

Water, Acetyl Glucosamine, Butyloctyl Salicylate, Cyclopentasiloxane, Dimethicone, C12-15 Alkyl Benzoate, Glycerin, Butylene Glycol, Glyceryl Stearate, Octyldodecyl Neopentanoate, Cetyl Alcohol, PEG-100 Stearate, Cetearyl Alcohol, Vitis Vinifera (Grape) Seed Extract, Melia Azadirachta Leaf Extract, Lecithin, Arctium Lappa Root Extract, DL-Alpha Tocopheryl Acetate, Dimethicone Crosspolymer, Propylene Glycol, PEG-75 Stearate, Steareth-20, Xanthan Gum, Ceteth-20, Ammonium Hydroxide, Carbomer, Disodium EDTA, Caprylyl Glycol, Phenoxyethanol, Chlorphenesin, Sodium Bisulfite.

Questions?

1-800-628-9904

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

NEOSTRATA®

DEFEND

Sheer Hydration
Sunscreen Broad
Spectrum SPF 40

Lotion
DIN 02482010

50 mL/1.7 FL OZ

DEFEND

before sun exposure • Use a water resistant sunscreen if swimming or sweating • Reapply sunscreen at least every 2 hours • Children under 6 months: Ask a doctor • 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 /
- Appliquer généreusement 15 minutes avant l'exposition au soleil
- Utiliser un écran solaire résistant à l'eau en cas de baignade ou de transpiration
- Renouveler l'application de l'écran solaire au minimum toutes les 2 heures
- Enfants de moins de 6 mois: consulter un médecin
- 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

Other information /

Autres renseignements

• Store at/Conserver entre 15°C-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

Inactive ingredients /
Ingrédients inactifs

Aqua/Water/Eau, Acetyl Glucosamine, Butyloctyl Salicylate, Cyclopentasiloxane, Dimethicone, C12-15 Alkyl Benzoate, Glycerin, ▶

Butylene Glycol, Glyceryl Stearate, Octyldodecyl Neopentanoate, Cetyl Alcohol, PEG-100 Stearate, Cetearyl Alcohol, Vitis Vinifera (Grape) Seed Extract, Melia Azadirachta Leaf Extract, Lecithin, Arotium Lappa Root Extract, DL-Alpha Tocopheryl Acetate, Dimethicone Crosspolymer, Propylene Glycol, PEG-75 Stearate, Steareth-20, Xanthan Gum, Ceteth-20, Ammonium Hydroxide, Carbomer, Disodium EDTA, Caprylyl Glycol, Phenoxyethanol, Chlorphenesin, Sodium Bisulfite.

Questions? 1-800-628-9904

Sheer Hydration

Sunscreen Broad Spectrum SPF 40 Oil-free daily protection

Cosmetic use: For all skin types, especially oily, blemish-prone skin, and uneven skin tone. **How it works:** This daily oil-free sunscreen is formulated with NeoGlucosamine, a gentle exfoliator that helps diminish the appearance of dark spots, and a botanical blend to target oiliness without irritation. **Results:** Provides skin with the hydration it needs without clogging pores or causing breakouts. Broad spectrum SPF 40 protection. Helps reduce the appearance of UV induced skin aging.

Hydratant Ultra-Léger

Écran Solaire à Large Spectre FPS 40 Protection quotidienne non grasse

Usage cosmétique: Pour tous types de peaux, en particulier les peaux grasses à imperfections et les teints irréguliers. **Comment ça fonctionne:** Cet écran solaire quotidien non gras associe la NeoGlucosamine, un exfoliant doux contribuant à atténuer l'apparence des taches de vieillisse, à une solution végétale réduisant la sécrétion de sébum sans irriter la peau. **Résultats:** Apporte à la peau l'hydratation nécessaire sans obstruer les pores ou causer d'éruption. Écran solaire à large spectre FPS 40. Aide à réduire les signes de vieillissement cutané lié aux UV.

Imported in Canada by/Importé au Canada par JOHNSON & JOHNSON INC., Markham, Canada L3R 5L2

Mfd. for/Fabriqué pour NeoStrata Company, Inc., Princeton, NJ 08540, USA Made in USA/Fabriqué aux États-Unis www.neostrata.com

NEOSTRATA®

DEFEND

Sheer Hydration
Sunscreen Broad Spectrum SPF 40

Hydratant Ultra-Léger
Écran Solaire à Large Spectre FPS 40

Lotion DIN 02482010

50 mL/1.7 FL OZ

Drug Facts / Information sur le médicament

Active ingredients (w/w) / Ingrédients actifs (p/p)	Purpose / Utilité
Avobenzone 3%, Octinoxate 7.5%, Octisalate 5%	Sunscreen / Écran solaire

Uses / Usages • Helps prevent sunburn / Aide à prévenir les coups de soleil • Broad Spectrum SPF 40 / à Large Spectre FPS 40 • 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 photoviellessement 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 si 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 ▶



29F30163XC



NEOSTRATA SHEER HYDRATION SUNSCREEN BROAD SPECTRUM SPF 40

octinoxate, octisalate, and avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58414-0020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CETETH-20 (UNII: I835H2IHHX)	
STEARETH-20 (UNII: L0Q8IK9E08)	
AMMONIA (UNII: 5138Q19F1X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SODIUM BISULFITE (UNII: TZ X5469Z 6I)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58414-0020-1	1 in 1 CARTON	02/01/2019	
1		50 mL in 1 BOTTLE, PUMP; 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	02/01/2019	

Labeler - NeoStrata Company Inc. (605754829)

Revised: 8/2023

NeoStrata Company Inc.