

**NEOSTRATA SHEER PHYSICAL PROTECTION SUNSCREEN BROAD SPECTRUM
SPF 50- titanium dioxide and zinc oxide 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 Physical Protection

Drug Facts

Active ingredients (w/w)

Titanium Dioxide 7%
Zinc Oxide 6%

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

- Shake vigorously for 15 seconds before each use
- 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

Inactive ingredients

Water, Dimethicone, Isododecane, C12-15 Alkyl Benzoate, Hydrogenated Polydecene, Butyloctyl Salicylate, Gluconolactone, Styrene/Acrylates Copolymer, Alumina, Ammonium Hydroxide, Lactobionic Acid, PEG-9 Polydimethylsiloxyethyl Dimethicone, Phenethyl Benzoate, Nylon-12, DL-Alpha Tocopheryl Acetate, Epigallocatechin Gallate, Polyhydroxystearic Acid, Ethylhexylglycerin, Tocopherol, Dimethicone/PEG-10/ 15 Crosspolymer, Hydrogen Dimethicone, Isohexadecane, Sodium Citrate, Distearidimonium Hectorite, Magnesium Sulfate, Dipropylene Glycol, Propylene Carbonate, Sodium Bisulfite, Triethoxycaprylsilane, Phenoxyethanol, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499).

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 - 50 mL Bottle Carton

NEOSTRATA®

DEFEND
PROTECTION AGAINST
ENVIRONMENTAL STRESSORS

Sheer Physical Protection
Sunscreen Broad Spectrum SPF 50
Matte-finish tinted sunscreen PA++++

50 mL / 1.7 FL OZ

DEFEND

Drug Facts

Active ingredients (w/w)....Purpose
Titanium Dioxide 7% }.....Sunscreen
Zinc Oxide 6% }

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
■ Shake vigorously for 15 seconds before each use
■ 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

Inactive ingredients
Water, Dimethicone, Isododecane, C12-15 Alkyl Benzoate, Hydrogenated Polydecene, Butyloctyl Salicylate, Gluconolactone, ▶

Drug Facts (Continued)

Styrene/Acrylates Copolymer, Alumina, Ammonium Hydroxide, Lactobionic Acid, PEG-9 Polydimethylsiloxyethyl Dimethicone, Phenethyl Benzoate, Nylon-12, DL-Alpha Tocopheryl Acetate, Epigallocatechin Gallate, Polyhydroxystearic Acid, Ethylhexylglycerin, Tocopherol, Dimethicone/PEG-10/15 Crosspolymer, Hydrogen Dimethicone, Isohexadecane, Sodium Citrate, Distearidimonium Hectorite, Magnesium Sulfate, Dipropylene Glycol, Propylene Carbonate, Sodium Bisulfite, Triethoxycaprylylsilane, Phenoxyethanol, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499).

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

NEOSTRATA®

DEFEND

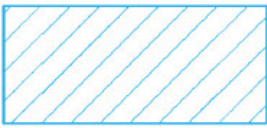
PROTECTION AGAINST ENVIRONMENTAL STRESSORS

Sheer Physical Protection
Sunscreen Broad Spectrum SPF 50
Matte-finish tinted sunscreen PA++++

50 mL / 1.7 FL OZ

Indications:
Mineral sunscreen protection for all skin types, including sensitive skin.
Mode of action:
Combines potent antioxidants with a Polyhydroxy Acid (PHA) complex to help protect skin's moisture barrier against environmental stressors.
Results:
Broad spectrum SPF 50 protection against the look of UVA/UVB-induced aging.

Mfd. For NeoStrata Company, Inc.
Princeton, NJ 08540,
USA Made in USA
www.neostrata.com



29F30164XA

NEOSTRATA SHEER PHYSICAL PROTECTION SUNSCREEN BROAD SPECTRUM SPF 50

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58414-0018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	70 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
AMMONIA (UNII: 5138Q19F1X)	
LACTOBIONIC ACID (UNII: 65R938S4DV)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
NYLON-12 (UNII: 446U8J075B)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EPIGALLOCATECHIN GALLATE (UNII: BQM438CTEL)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SODIUM BISULFITE (UNII: TZ X5469Z 6I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58414-0018-1	1 in 1 CARTON	09/01/2018	
1		50 mL in 1 BOTTLE, PLASTIC; 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	09/01/2018	

Labeler - NeoStrata Company Inc. (605754829)

Revised: 8/2023

NeoStrata Company Inc.