

**EXUVIANCE SKIN CARING BB FLUID WITH 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.*

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**Exuviance® Skin Caring BB Fluid**  
**with Sunscreen Broad Spectrum SPF 50**

***Drug Facts***

**Active ingredients**

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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- With first use or after a period of non-use, shake vigorously for at least 1 minute to achieve a uniform consistency. During periods of regular use, shake vigorously for at least 15 seconds before use. Apply liberally to face, neck and other exposed areas, 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating
- Reapply 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**

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, 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 or comments?**

Call toll-free 1-800-225-9411 (9am – 5pm ET)

### **PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton**

exuviance®

EMPOWER

SKIN CARING BB FLUID

WITH SUNSCREEN

BROAD SPECTRUM SPF 50 PA++++

Lightly hydrate,

even tone

Protect against

environmental

exposure

Universal tint

PHA/Bionic

Mineral Sunscreen

Green Tea

50 mL/1.7 fl oz

EMPOWER

exuviance®

EMPOWER

YOU, INTENTIONALLY

Exuviance is a skincare line with intention. A self-care tool. A means to be mindful. A precise solution. Exuviance was founded by globally recognized innovators in clinically developed, effective skincare, with a deep understanding of skin science at the molecular level. Exuviance expertly crafts formulas with the best ingredients, precisely chosen and optimally balanced for their proven benefit to specific skin conditions and concerns. Set your intention and practice a personalized skincare ritual created for you, intentionally.

SKIN CARING BB FLUID WITH SUNSCREEN BROAD SPECTRUM SPF 50 PA++++

Lightly hydrate, even tone, protect against environmental exposure. Universal tint, PHA/Bionic Mineral Sunscreen, Green Tea.

50 mL/1.7 fl oz

Mfd. for NeoStrata Co., Inc. Princeton, NJ 08540 USA. Made in USA. 1-800-225-9411 (U.S. Only) www.exuviance.com NeoStrata UG, DE-41470 Neuss ©NeoStrata Company, Inc. 2019

Drug Facts

Active ingredients: 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions: With first use or after a period of non-use, shake vigorously for at least 1 minute to achieve a uniform consistency. During periods of regular use, shake vigorously for at least 15 seconds before use. Apply liberally to face, neck and other exposed areas, 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply 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, Dimethicone, Isododecane, C12-15 Alkyl Benzoate, Hydrogenated Polydecene, Butyloctyl Salicylate, Gluconolactone, Styrene/Acrylates Copolymer, Alumina, Ammonium Hydroxide, Lactobionic Acid, PEG-9 Polydimethylsiloxylethyl Dimethicone, Phenethyl Benzoate, Nylon-12, Tocopheryl Acetate, Epigallocatechin Gallate, Polyhydroxystearic Acid, Ethylhexylglycerin, Tocopherol.

Drug Facts (continued)

Dimethicone/PEG-10/15 Cross-polymer, Hydrogen Dimethicone, Isohexadecane, Sodium Citrate, Disteardimonium 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 or comments? Call toll free 1-800-225-9411 (9am-5pm ET).

Empower skin's natural renewal with proven ingredients. This lightly hydrating fluid with a universal, virtually invisible tint, helps skin tone appear naturally beautiful and more even, while added skin caring ingredients provide daily renewal and protection benefits. Contains Polyhydroxy Acids (PHAs) to provide renewing hydration, while an ultra-fine mineral sunscreen, Vitamin E and Green Tea extract help protect against daily environmental aggressors. Designed for all skin types. Fragrance-free and oil-free. Non-acnegenic, non-comedogenic.



LOT/CODE AREA

29F20270XA

# EXUVIANCE SKIN CARING BB FLUID WITH SUNSCREEN BROAD SPECTRUM SPF 50

titanium dioxide and zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58414-0025
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>HYDROGENATED POLYDECENE TYPE I</b> (UNII: U333RI6EB7)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>LACTOBIONIC ACID</b> (UNII: 65R938S4DV)	
<b>PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: TYP81E471F)	
<b>PHENETHYL BENZOATE</b> (UNII: 0C143929GK)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>EPIGALLOCATECHIN GALLATE</b> (UNII: BQM438CTEL)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)	
<b>HYDROGEN DIMETHICONE (13 CST)</b> (UNII: 4QGR4P2YOI)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>SODIUM BISULFITE</b> (UNII: TZX5469Z6I)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

**FERROSOFERRIC OXIDE** (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58414-0025-1	1 in 1 CARTON	10/01/2019	
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	10/01/2019	

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

Revised: 9/2023

NeoStrata Company Inc.