

PRISMPPLUS BROAD-SPECTRUM SUNSCREEN SPF 43- octinoxate, octisalate, and zinc oxide lotion

Merz North America, 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.

Prism+ Broad-Spectrum Sunscreen SPF 43

Drug Facts

Active Ingredients

Octinoxate 7.5%

Octisalate 5.0%

Zinc Oxide 9.4%

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

- apply generously 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - 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 Broad-Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10am - 2pm
 - wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months of age: ask a doctor

Inactive Ingredients

Water, Caprylic/Capric Triglyceride, Octyldodecyl Neopentanoate, Butylene Glycol, Diatomaceous Earth, Diisopropyl Sebacate, Tocopheryl Acetate, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Cetyl Dimethicone, Isopropyl Palmitate, Carnosine, Melanin, Tocopherol, Hydrogenated Castor Oil, Beeswax, Ethylhexylglycerine, Sodium Chloride, Disodium EDTA, Triethoxycaprylylsilane, Neopentanoic Acid, Polyhydroxystearic Acid, Pentylene Glycol, Octyldodecanol, BHT, Phenoxyethanol

Other Information

- protect this product from excessive heat and direct sun

Questions?

1.844.469.6379

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

SUNSCREEN

PRISM+

Defense Cream

Broad-Spectrum Sunscreen SPF 43

Water Resistant (80 minutes)

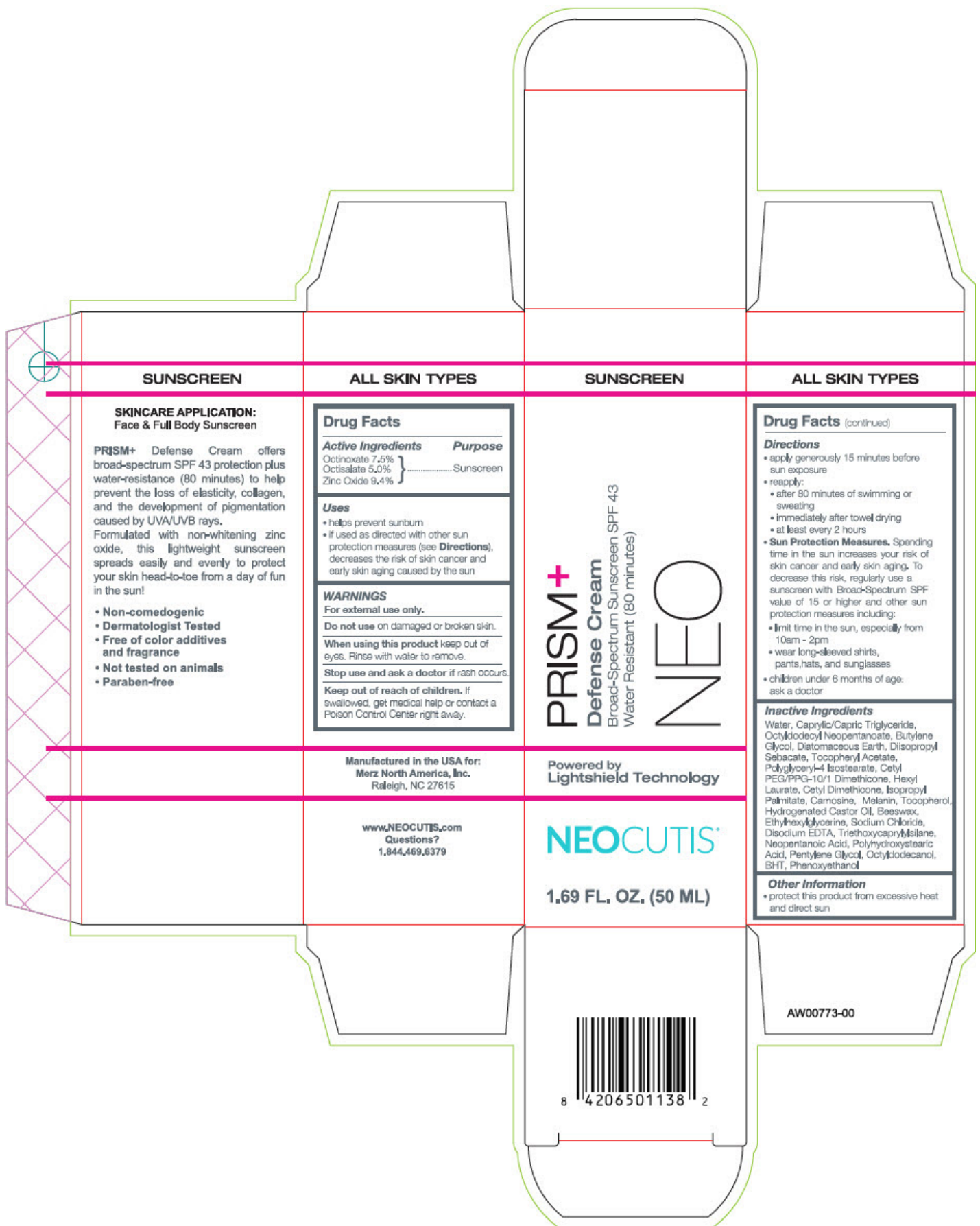
NEO

Powered by

Lightshield Technology

NEOCUTIS®

1.69 FL. OZ. (50 ML)



SUNSCREEN

ALL SKIN TYPES

SUNSCREEN

ALL SKIN TYPES

**SKINCARE APPLICATION:
Face & Full Body Sunscreen**

PRISM+ Defense Cream offers broad-spectrum SPF 43 protection plus water-resistance (80 minutes) to help prevent the loss of elasticity, collagen, and the development of pigmentation caused by UVA/UVB rays. Formulated with non-whitening zinc oxide, this lightweight sunscreen spreads easily and evenly to protect your skin head-to-toe from a day of fun in the sun!

- Non-comedogenic
- Dermatologist Tested
- Free of color additives and fragrance
- Not tested on animals
- Paraben-free

Drug Facts

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Zinc Oxide 9.4%	

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PRISM+
Defense Cream
Broad-Spectrum Sunscreen SPF 43
Water Resistant (80 minutes)

NEO

Drug Facts (continued)

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Other Information

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Manufactured in the USA for:
Merz North America, Inc.
Raleigh, NC 27615

Powered by
Lightshield Technology

www.NEOCUTIS.com
Questions?
1.844.469.6379

NEOCUTIS

1.69 FL. OZ. (50 ML)

AW00773-00



PRISMPLUS BROAD-SPECTRUM SUNSCREEN SPF 43

octinoxate, octisalate, and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46783-223
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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	94 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Diatomaceous Earth (UNII: 2RF6EJ0M85)	
Diisopropyl Sebacate (UNII: J8T3X564IH)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Cetyl PEG/PPG-10/1 Dimethicone (HLB 2) (UNII: V2W71V8T0X)	
Hexyl Laurate (UNII: 4CG9F9W01Q)	
Cetyl Dimethicone 25 (UNII: U4AS1BW4ZB)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Carnosine (UNII: 8HO6PVN24W)	
Melanin Synthetic (Tyrosine, Peroxide) (UNII: O0CV1RMR44)	
Hydrogenated Castor Oil (UNII: ZF94AP8MEY)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Sodium Chloride (UNII: 451W47IQ8X)	
Edetate Disodium (UNII: 7FLD91C86K)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Pivalic Acid (UNII: 813RE8BX41)	
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)	
Pentylene Glycol (UNII: 50C1307PZG)	
Octyldodecanol (UNII: 461N1O614Y)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46783-223-15	1 in 1 CARTON	06/01/2018	
1		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:46783-223-50	1 in 1 CARTON	06/01/2018	
2		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:46783-223-04	4 mL in 1 TUBE; Type 0: Not a Combination Product	06/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	06/01/2018	

Labeler - Merz North America, Inc (028147846)

Revised: 6/2019

Merz North America, Inc