NEOVA DNA DAMAGE CONTROL - EVERYDAY BROAD SPECTRUM SPF 44- octinoxate, octis alate, zinc oxide emulsion PhotoMedex, 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.

Neova DNA Damage Control - Everyday SPF 44 - Drug Facts

Active Ingredients

Octinoxate 6.5%, Octisalate 2.5% Zinc Oxide 8.5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed and with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin again 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 at least every 2 hours.
- Children under 6 months of age: 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

Allantoin, Ascorbyl Palmitate, Butylene Glycol, Cetearyl Glucoside, Citric Acid, Cyclopentasiloxane, Dimethicone, Ergothioneine, Ethyl Hexyl Isononanoate, Glycereth-26, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Iodopropynyl Butylcarbamate, Isopropyl Palmitate, Lecithin,

Micrococcus Lysate, Octyl Sterate, Oleth-3 Phosphate, Panthenol, PEG-7 Trimethylolprpopane Coconut Ether, Phenoxyethanol, Plankton Extract, Polyether-1, Polyisobutene, Purified Water, Retinyl Palmitate, Sodium Hyaluronate, Sodium Hydroxide, Tocopherol Acetate, Triethoxycaprylysilane.

Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-888-966-1010.

Neova DNA Damage Control Everyday SPF 44 2.5 fl. oz. (74mL) label and box

DNADamageControlEveryday2-5ozLabel.jpg









74 mL ← 2.5 fl. oz.

DNADamageControlEveryday2-5ozBox.jpg

SmartSunscreen Technology

 Triggers a repair that helps defend against the visible consequences of photodamage.

 Delivers high performance protection against the aging + burning effects of UVA/UVB rays. If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

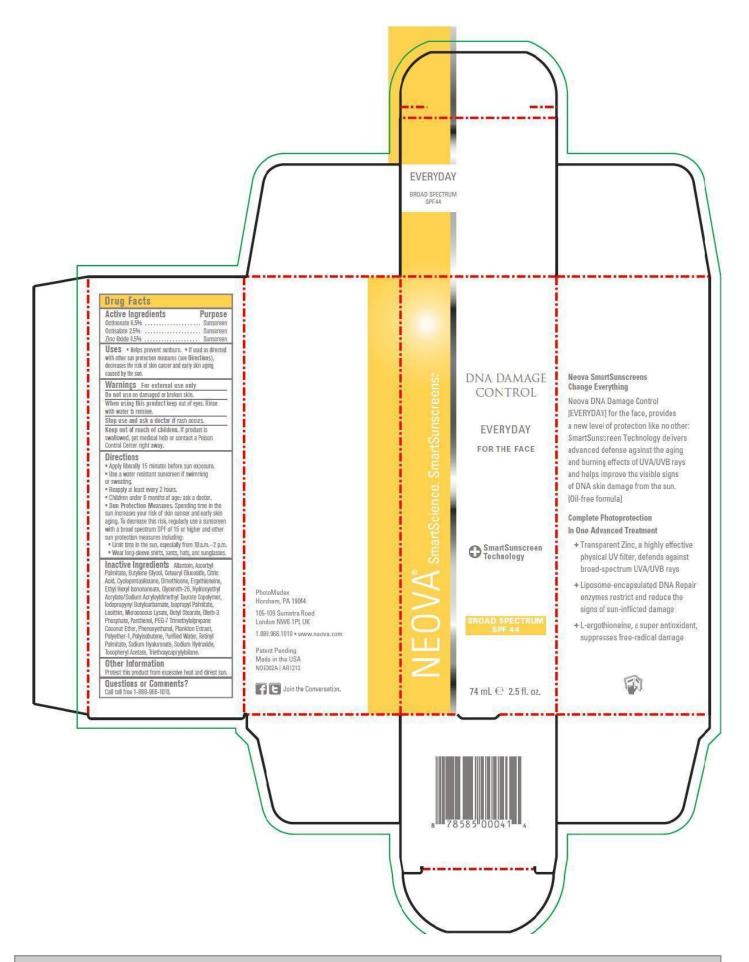
Directions: Apply every morning to face and neck. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours.

WARNINGS: For external use only. Avoid contact with eyes. Do not use on damaged or broken skin. Discontinue use if rash occurs. If rash persists, consult a doctor. Keep out of reach of children.

Active Ingredients: Octinoxate 6.5%, Octisalate 2.5%, Zinc Oxide 8.5%.

Key Performance Ingredients: DNA Repair Enzymes: Photolysomes, Endosomes; Antioxidant: L-ergothioneine.

PhotoMedex, Horsham, PA 19044 105-109 Sumatra Road, London NW6 1PL UK 1.888.966.1010 • www.neova.com Patent Pending NDE002A | AR1213 Made in the USA



octinoxate, octisalate, zinc oxide emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62362-159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	6.5 g in 100 mL	
Octisalate (UNII: 4X49 Y0596W) (Octisalate - UNII:4X49 Y0596W)	Octisalate	2.5 g in 100 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	8.5 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
Allantoin (UNII: 344S277G0Z)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Citric Acid Monohydrate (UNII: 2968 PHW8 QP)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone (UNII: 92RU3N3Y1O)	
Ergothioneine (UNII: BDZ3DQM98W)	
Ethylhexyl Isononanoate (UNII: 16KB4GE3K4)	
Glycereth-26 (UNII: NNE56F2N14)	
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Egg Phospholipids (UNII: 1Z74184RGV)	
Octyl Stearate (UNII: 772Y4UFC8B)	
Oleth-3 Phosphate (UNII: 8Q0Z18J1VL)	
Panthenol (UNII: WV9CM0O67Z)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Water (UNII: 059QF0KO0R)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Hyaluronate Sodium (UNII: YSE9 PPT4TH)	
Sodium Hydroxide (UNII: 55X04QC32I)	
.AlphaTocopherol Acetate (UNII: 9E8X80D2L0)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62362-159-01	1 in 1 BOX		
1 NDC:62362-159-74	74 mL in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	10/08/2012		

Labeler - PhotoMedex, Inc. (054503875)

Establishment			
Name	Address	ID/FEI	Business Operations
Photo Medex, Inc.		054503875	manufacture(62362-159)

Revised: 1/2014 PhotoMedex, Inc.