NEOVA DNA DAMAGE CONTROL - ACTIVE BROAD SPECTRUM SPF 43- octinoxate, 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 Active SPF 43 - Drug Facts

Active Ingredients

Octinoxate 7.5%, Zinc Oxide 9.0%

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.
- Reapply:
 - °After 80 minutes of swimming or sweating.
 - °Immediately after towel drying.
 - °At least every two 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

Ascorbyl Palmitate, Butylene Glycol, Citric Acid, Cyclopentasiloxane, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyldimethicone Crosspolymer, Ergothioneine, Ethyl Hexyl Isononanoate, Iodopropynyl Butylcarbamate, Lauryl PEG-9 Polymethylsiloxyethyl Dimethicone, Lecithin, Microcoous Lysate, Phenoxyethanol, Plankton Extract, Purified Water, Retinyl Palmitate, Sodium Chloride, Sodium Hydroxide, Triethanoxycaprylylsilane.

Other Information

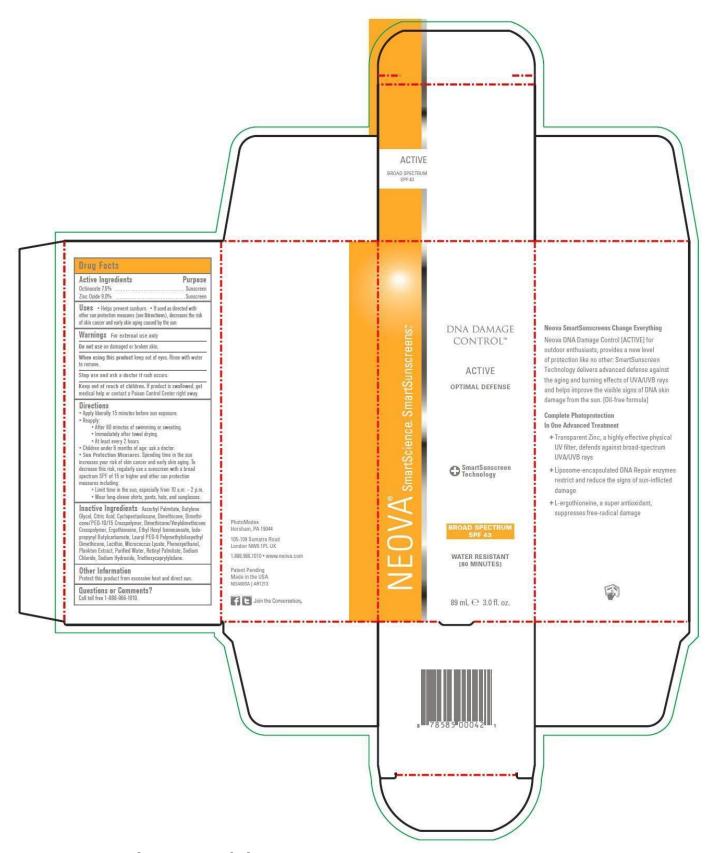
Protect this product from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-888-966-1010.

Neova DNA Damage Control Active SPF 43 3.0 fl. oz. (89mL)

DNADamageControl3ozActiveBox.jpg



DNADamageControl3ozActiveLabel.jpg



OPTIMAL DEFENSE



BROAD SPECTRUM SPF 43

WATER RESISTANT [80 MINUTES]

89 mL @ 3.0 fl. oz.

SmartSunscreen Technology

- DNA Repair enzymes inhibit and correct the consequences of photodamage
- · High-performance UVA/UVB protection

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 liberally 15 minutes before sun exposure. Reapply: After 80 minutes of swimming or sweating; immediately after towel drying; 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 7.5%, Zinc Oxide 9.0%.

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 NDA003A | ARI213 Made in the USA

NEOVA DNA DAMAGE CONTROL - ACTIVE BROAD SPECTRUM SPF 43

octinoxate, zinc oxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62362-179

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ASCORBYL PALMITATE (UNII: QN83US2B0N)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)			
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0R)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
ERGO THIO NEINE (UNII: BDZ3DQM98W)			
ETHYLHEXYL ISONONANOATE (UNII: 16 KB4GE3K4)			
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			
EGG PHO SPHO LIPIDS (UNII: 1Z74184RGV)			

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62362-179-01	1 in 1 BOX		
1	NDC:62362-179-89	89 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(62362-179)	

Revised: 1/2014 PhotoMedex, Inc.