NEOVA DNA DAMAGE CONTROL - ACTIVE BROAD SPECTRUM SPF 43- octinoxate, zinc oxide cream
PHARMA COSMETICS, 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

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, Micrococcus Lysate, Phenoxyethanol, Plankton Extract, Purified Water, Retinyl Palmitate, Sodium Chloride, Sodium Hydroxide, Triethanoxycaprylylsilane.

Other Information

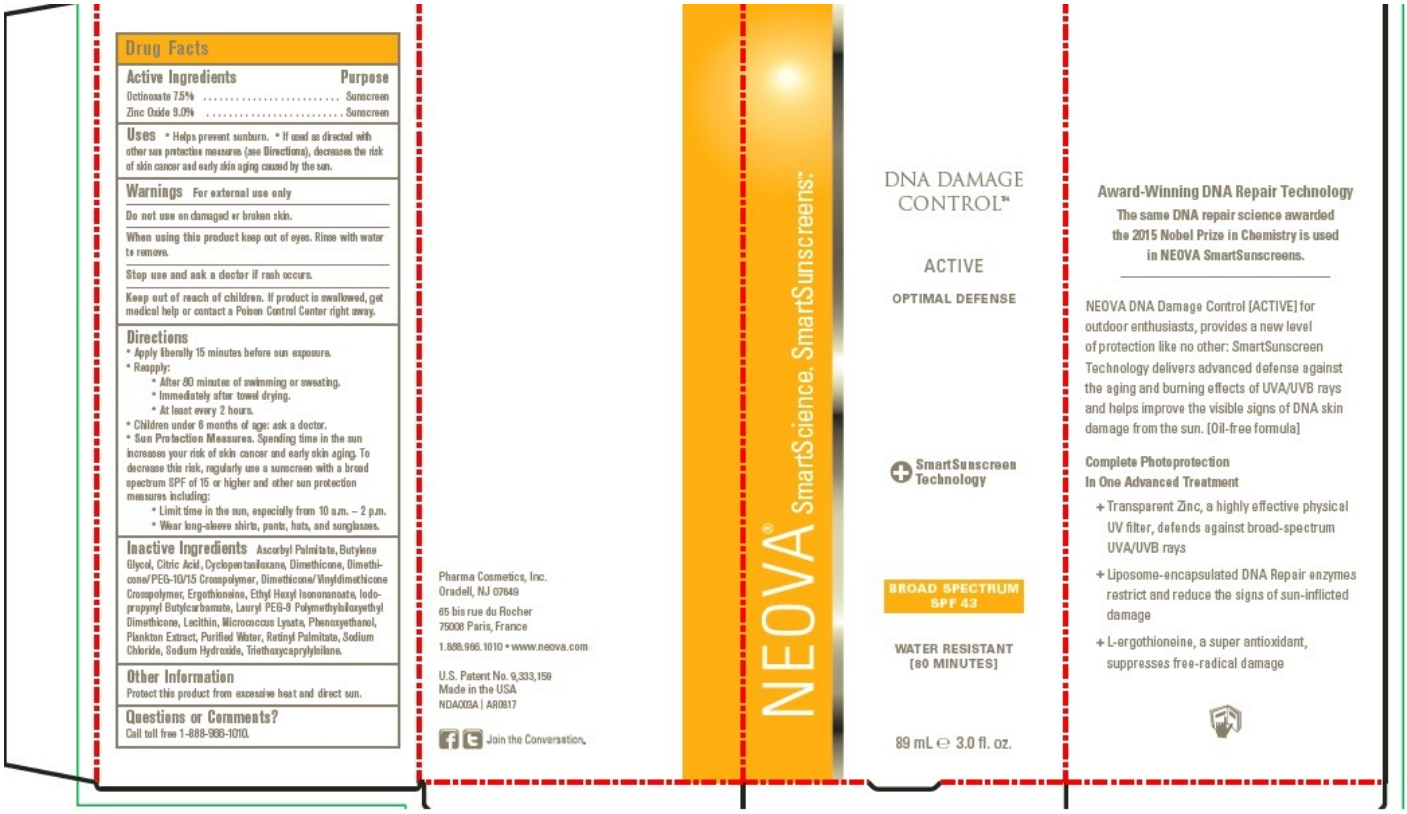
Protect this product from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-888-966-1010.

Priduct Label

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



NEOVA DNA DAMAGE CONTROL - ACTIVE BROAD SPECTRUM SPF 43

octinoxate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72251-003
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 MONOHYDRATE (UNII: 2968PHW8QP)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MICROCOCCUS LUTEUS (UNII: LV6L29Z6AX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72251-003-89	1 in 1 BOX	04/19/2018	
1		89 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

Labeler - PHARMA COSMETICS, INC (080622701)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(72251-003)