

NEOVA DNA DAMAGE CONTROL - ACTIVE SPF 45- zinc oxide, octinoxate, octisalate 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 45 - 2mL sample package insert

Directions for use:

Apply liberally to exposed skin every two hours. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Supplied

in a 3.0 fl. oz. / 89 mL tube.

Active Ingredients:

Zinc Oxide 8.0%, Octinoxate 7.5%, Octisalate 3.0%.

Inactive Ingredients:

Water (Aqua), Cyclopentasiloxane, Ethyl Hexyl Isononanoate, Micrococcus Lysate, Plankton Extract, L-ergothioneine, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Lauryl PEG-9 Polymethylsiloxylethyl Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Retinyl Palmitate, Ascorbyl Palmitate (Vitamin C), Sodium Chloride, Phenoxyethanol, Butylene Glycol, Iodopropynyl Butylcarbamate, Citric Acid, Sodium Hydroxide.

Image of package, pouch, and package insert

AmpuleActive.jpg

DNA Damage Control™
ACTIVE | SPF 45

PouchActive.jpg

DNA REPAIR 
TRANSPARENT ZINC

PhotoMedex, Inc.
Montgomeryville, PA 18936
7 Hawbridge Close
Shirley, Solihull
West Midlands B90 4SU UK
1.888.966.1010
www.neova.com
Patent Pending
Made in the USA
Reorder# NDA003S
REV 6/11

2 mL  0.07 fl. oz.

NEOVA®

SmartScience. SmartScreens.™

DNA Damage Control [Active | SPF 45] provides **complete photoprotection**, repairing tissue at the cellular level—where DNA damage occurs—while protecting the skin from additional UV insults.

- DNA Repair enzymes inhibit and correct the consequences of photodamage
- High-performance UVA/UVB protection
- Hyper antioxidant defense + highly water-resistant

Directions: Apply liberally to exposed skin every two hours. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

DNA DAMAGE CONTROL™
ACTIVE | SPF 45
HIGHLY WATER-RESISTANT

DNA DAMAGE CONTROL™

EVERYDAY | SPF 43
FOR THE FACE

ACTIVE | SPF 45
HIGHLY WATER-RESISTANT
SILK SHEER | SPF 45
PHOTO FINISH TINT

NEOVA®

Montgomeryville, PA 18936

Made in the USA

Patent Pending

1.888.966.1010

www.neova.com

EVERYDAY | SPF 43 Reorder# NDE002
ACTIVE | SPF 45 Reorder# NDA003
SILC SHEER | SPF 45 Reorder# NDS002

6/11

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- 1 Skin Care Foundation, www.skincancer.org, 2011.
- 2, 5, 8 Yarosh DB, Kibetel J, O'Connor A, et al. *DNA Repair Liposomes in Animutagenesis*. J Environ Pathol Toxicol Oncol. 1997;16:287-292.
- 3, 6, 9 Stege, H., L. Roza, A.A. Vink, M. Grewe, T. Ruzicka, S. Grether-Beck and J. Krutmann. *Enzyme Plus Light Therapy to Repair DNA Damage in Ultraviolet-B-Irradiated Human Skin*. Proc. Natl. Acad. Sci. USA, February 15, 2000, Vol. 97, No. 4.
- 4, 7 Obayashi, K., K. Kurihara, Y. Okano, H. Masaki and D.B. Yarosh. *L-Ergothioneine Scavenges Superoxide and Singlet Oxygen and Suppresses TNF and MMP-1 Expression in UV-Irradiated Human Dermal Fibroblasts*. J. Cosmet. Sci. 56:17-27, 2005.

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More Than Just Protection

UV-inflicted damage is cumulative; its wounding effects on the skin's DNA account for nearly all the visible signs of aging and contribute to 90% of non-melanoma skin cancers.¹ Basic sunscreens help to prevent skin injury, but do nothing to correct damage.

Neova® SmartSunscreens™ Change Everything
Neova DNA Damage Control sunscreens provide **complete photoprotection**, repairing tissue at the cellular level—where DNA damage occurs—while protecting the skin from additional UV insults.

DNA DAMAGE CONTROL EVERYDAY | SPF 43

Description

An elegant, lightweight moisturizing physical sunscreen designed especially for daily photoprotection of the face, neck, décolletage and back of hands.

- Offers superior protection + repair in one advanced treatment
- Defends against broad-spectrum UVA/UVB rays
- Restricts and corrects sun-inflicted DNA damage in cells
- Provides hyper antioxidant defense
- Delivers oil-free hydration

Active Ingredients

Zinc Oxide, 7.5%. Micronized zinc oxide applies light and transparent to the skin, offering highly effective, broad spectrum UVA/UVB protection.

Octinoxate, 7.5%, Octisalate, 2.5%. Provides broad spectrum UVA/UVB protection.

Key Performance Ingredients

Octinoxate, 7.5%, Octisalate, 3.0%. Provides broad spectrum UVA/UVB protection.

Key Performance Ingredients

Endosomes. A liposome encapsulated extract from the marine microbe, *Micrococcus lysate*. Extremely UV-resistant, the extract contains the enzyme UV-endonuclease which intensifies the skin's ability to repair sun-inflicted DNA damage, speeding recovery reaction, and reducing the appearance of post-sunburn peeling.⁵

Photolysomes. A liposome encapsulated DNA repair enzyme, Photolyase derived from plankton, is hyper-efficient in its defense against high doses of solar UV and unique in its ability to undo DNA damage in cells and prevent cell death caused by UV.⁶

L-ergothioneine. A powerful antioxidant that also blocks the activation of the two enzymes, elastase and matrix metalloproteinases (MMPs), which degrade collagen and elastin and destroy the skin's supporting structure, leading to wrinkle formation.⁷

Ascorbyl Palmitate (Vitamin C). An effective free radical-scavenging antioxidant which promotes skin health and vitality. It is also required for the manufacture of collagen, a protein that forms the basis of connective tissue—the most abundant tissue in the body.

Indications: DNA Damage Control [ACTIVE | SPF 45] is for guarding against broad spectrum UV rays and repairing the signs of photodamage.

Recommended for active lifestyles. Suitable for all skin types, even the most sensitive.

Directions for Use: Apply liberally to exposed skin every two hours. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Endosomes. A liposome encapsulated extract from the marine microbe, *Micrococcus lysate*. Extremely UV-resistant, the extract contains the enzyme UV-endonuclease which intensifies the skin's ability to repair sun-inflicted DNA damage, speeding recovery reaction, and reducing the appearance of post-sunburn peeling.²

Photolysomes. A liposome encapsulated DNA repair enzyme, Photolyase derived from plankton, is hyper-efficient in its defense against high doses of solar UV and unique in its ability to undo DNA damage in cells and prevent cell death caused by UV.³

L-ergothioneine. A powerful antioxidant that also blocks the activation of the two enzymes, elastase and matrix metalloproteinases (MMPs), which degrade collagen and elastin and destroy the skin's supporting structure, leading to wrinkle formation.⁴

Sodium Hyaluronate. A powerful humectant that deeply hydrates and binds up to 1,000 times its own weight in moisture, providing an immediate moisturizing boost.

Tocopheryl Acetate (Vitamin E). A natural antioxidant and moisturizer, reducing transdermal water loss and helping to maintain connective tissue. It is effective as a natural defense against harmful UV rays, preventing hyper-pigmentation and sun damage.

Ascorbyl Palmitate (Vitamin C). An effective free radical-scavenging antioxidant which promotes skin health and vitality. It is also required for the manufacture of collagen, a protein that forms the basis of connective tissue—the most abundant tissue in the body.

Indications: DNA Damage Control [EVERYDAY | SPF 43] is for guarding against broad spectrum UV rays and repairing the signs of photodamage.

Recommended daily, for all skin types, even the most sensitive.

Directions for Use: Apply every morning to face, neck and décolletage. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Supplied in a 2.5 fl. oz. / 74 mL tube.

Active Ingredients: Zinc Oxide 7.5%, Octinoxate 7.5%, Octisalate 2.5%.

Inactive Ingredients: Water (Aqua), Isopropyl Palmitate, Octyl Stearate, Ethyl Hexyl Isononanoate, Cyclopentasiloxane, Cetearyl Glucoside, Micrococcus Lysate, Plankton Extract, L-ergothioneine, Dimethicone, Glycereth-26, Sodium Hyaluronate, Panthenol, Allantoin, Tocopheryl Acetate, Ascorbyl Palmitate (Vitamin C), Oleth-3 Phosphate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, PEG-7 Trimethylolpropane Coconut Ether, Lecithin, Polyether-1, Phenoxyethanol, Butylene Glycol, Citric Acid, Iodopropynyl Butylcarbamate, Triethoxycaprylylsilane.

DNA DAMAGE CONTROL

ACTIVE | SPF 45

Description

A rapidly-absorbing, highly water-resistant physical sunscreen for the face and body, ideal for everyday use and ultra-active wear.

- Offers superior protection + repair in one advanced treatment
- Defends against broad-spectrum UVA/UVB rays

Supplied in a 3.0 fl. oz. / 89 mL tube.

Active Ingredients: Zinc Oxide 8.0%, Octinoxate 7.5%, Octisalate 3.0%.

Inactive Ingredients: Water (Aqua), Cyclopentasiloxane, Ethyl Hexyl Isononanoate, Micrococcus Lysate, Plankton Extract, L-ergothioneine, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Lauryl PEG-9 Polymethylsiloxethyl Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Retinyl Palmitate, Ascorbyl Palmitate (Vitamin C), Sodium Chloride, Phenoxyethanol, Butylene Glycol, Iodopropynyl Butylcarbamate, Citric Acid, Sodium Hydroxide.

DNA DAMAGE CONTROL

SILC SHEER | SPF 45

Description

A micronized physical sunscreen, with the cosmetic benefit of a skin-perfecting sheer tint for the face, that evens out skin tone. Perfect alone or as an under-makeup primer.

- Offers superior protection + repair in one advanced treatment
- Defends against broad-spectrum UVA/UVB rays
- Restricts and corrects sun-inflicted DNA damage in cells
- Residue-free, tinted matte finish
- Oil-free

Active Ingredients

Titanium Dioxide 3.5%. A highly effective physical sunscreen that defends against broad-spectrum UVA/UVB exposure.

Octinoxate 6.5%. Filters UVB rays.

Key Performance Ingredients

Endosomes. A liposome encapsulated extract from the marine microbe, *Micrococcus lysate*. Extremely UV-resistant, the extract contains the enzyme UV-endonuclease which intensifies the skin's ability to repair sun-inflicted DNA damage, speeding recovery reaction, and reducing the appearance of post-sunburn peeling.⁸

Photolysomes. A liposome encapsulated DNA repair enzyme, Photolyase derived from plankton, is hyper-efficient in its defense against high doses of solar UV and unique in its ability to undo DNA damage in cells and prevent cell death caused by UV.⁹

Antioxidant Complex. Green tea, Rosemary extracts and Lutein defend against free-radical damage.

Natural Aloe Vera Extract. Soothes skin while helping to hydrate and heal.

Indications: DNA Damage Control [SILC SHEER | SPF 45] is for guarding against broad spectrum UV rays and repairing the signs of photodamage.

Recommended daily, for all skin types, even the most sensitive.

Directions for Use: Apply evenly to face. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Supplied in a 2.5 fl. oz. / 74 mL bottle.

Active Ingredients: Titanium Dioxide 3.5%, Octinoxate 6.5%.

Inactive Ingredients: Camellia Sinensis Leaf Extract, Aloe Barbadensis Extract, Octyl Stearate, Cyclomethicone, Isopropyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Lauryl PEG-9 Polydimethylsiloxethyl

- Restricts and corrects sun-inflicted DNA damage in cells
- Provides hyper antioxidant defense
- Very water-resistant and sweat-resistant
- Oil-free

Active Ingredients

Zinc Oxide, 8.0%. Micronized zinc oxide applies light and transparent to the skin, offering highly effective, broad spectrum UVA/UVB protection.

Dimethicone, Micrococcus Lysate, Plankton Extract, Xanthophyll, Rosmarinus Officinalis (Rosemary) Leaf Extract, Squalane, Lecithin, Silica, Hydrated Silica, Microcrystalline Wax, Cetyl Dimethicone, Hydrogenated Castor Oil, Sodium Chloride, Phenoxyethanol, Iodo-propynyl Butylcarbamate, Melanin, Caramel, Iron Oxides, CI 77499, CI 77491, CI 77492.

NEOVA DNA DAMAGE CONTROL - ACTIVE SPF 45

zinc oxide, octinoxate, octisalate emulsion

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL	NDC:62362-129	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)			Zinc Oxide	8 mL in 100 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)			Octinoxate	7.5 mL in 100 mL
Octisalate (UNII: 4X49 Y0596 W) (Octisalate - UNII:4X49 Y0596 W)			Octisalate	3 mL in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
Water (UNII: 059QF0KO0R)				
Cyclomethicone 5 (UNII: 0THT5PCI0R)				
Ethylhexyl Isononanoate (UNII: I6KB4GE3K4)				
Micrococcus Luteus (UNII: LV6L29Z6AX)				
Ergothioneine (UNII: BDZ3DQM98W)				
Dimethicone (UNII: 92RU3N3Y1O)				
Vitamin A Palmitate (UNII: 1D1K0N0VVC)				
Ascorbyl Palmitate (UNII: QN83US2B0N)				
Sodium Chloride (UNII: 451W47IQ8X)				
Phenoxyethanol (UNII: HIE492ZZ3T)				
Butylene Glycol (UNII: 3XUS85K0RA)				
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)				
Citric Acid (UNII: 2968PHW8QP)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62362-129-03	1 in 1 POUCH		
1	NDC:62362-129-02	2 mL in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/06/2012	

Labeler - PhotoMedex, Inc. (054503875)

Establishment

Name	Address	ID/FEI	Business Operations
PhotoMedex, Inc.		054503875	manufacture

Revised: 1/2012

PhotoMedex, Inc.