

NAKED SKIN ONE AND DONE DARK- spf cream cream
Autumn Harp 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.

Naked Skin One and Done Dark

DRUG FACTS:

Active Ingredients:

Octinoxate 7.5%

Zinc Oxide 3.4%

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:

For sunscreen use: Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Use a water resistant sunscreen if swimming or sweating. 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 value 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 sleeved shirts, pants, hats, and sunglasses. Children under 6 months of age: Ask a doctor.

Other Information:

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients:

Water, Isododecane, Cyclopentasiloxane, Adipic Acid / Neopentyl Glycol Crosspolymer, Lauryl Dimethicone, Aloe Barbadensis Leaf Juice, Titanium Dioxide, Polyglyceryl-6 Polyricinoleate, Dimethicone/Vinyl Dimethicone Crosspolymer, Isononyl Isononanoate, Propylene Glycol, Hydrogenated Polyisobutene, Iron Oxide (CI 77492), Polyglyceryl-2 Isostearate, Glycerin,

Phenoxyethanol, Propanediol, Dimethicone Crosspolymer, Disteardimonium Hectorite, Isopropyl Myristate, Sodium Chloride, Glycyrrhiza Glabra (Licorice) Root Extract, Iron Oxides (CI 77491), Aspergillus Ferment, Xanthan Gum, Isoceteth-10, Iron Oxides (CI 77499), Silica, Isopropyl Titanium Triisostearate, Stearalkonium Hectorite, Triethoxycaprylylsilane, Evodia Rutaecarpa Fruit Extract, Ethoxydiglycol, Cyclotetrasiloxane, Propylene Carbonate, Dimethylcyclosiloxane, Polyhydroxystearic Acid, BHT, Sorbic Acid.

Questions or comments?

CALL TOLL FREE

1-800-784-8722(URBAN)

Package Display Panel

Image Contents

One step and you're done. Instantly blur imperfections and even out skin tone—for beautifully perfected, ultra-definition skin.

The best of both worlds, this hybrid complexion cream combines the benefits of a sheer foundation with the coverage of a tinted moist urizer—and our high-tech, weightless formula feels amazing on your skin. One & Done provides all-day wear and covers a wide range of skin tones. But the best part is how it transforms the look of your skin! Light-diffusing spheres immediately help make flaws seem to disappear. Over time, pores appear smaller and skin appears noticeably firmer and more radiant.

We loaded One & Done with so many nourishing ingredients (including peptides, vitamins and moisturizers), you'll be tempted to skip your skin treatment. Get online? Radiance—derived from the wu zhu yu plant—improves the look of radiance, tone and texture. And SPF 20 protects against sun damage.

Wear alone for gorgeous skin. For the perfect application, use our Optical Blurring Brush. For extra hydration, apply after your moisturizer.

Drug Facts

Active Ingredients
 Octinoxate 15%
 Zinc Oxide 1.6%

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

For sunscreen use:

- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- 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 value 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.
 - Children under 6 months of age: Ask a doctor.

Other information: protect the product from excessive heat and direct sunlight.

Inactive Ingredients

Water, coccolonic acid, cyclopentasiloxane, adipic acid, hexanoyl glycol acrylate, (silyl) dimethicone, polydimethylsiloxane, dimethicone/vinyl dimethacrylate copolymer, (sorbitol) sebacate, propylene glycol, hydrogenated polydecylene, polydimethylsiloxane, glycerin, phenoxyethanol, propylene glycol, caprylyl myristate, dimethicone crosspolymer, dibenzodioxane hexadecyl acrylate, glyceryl stearate (ceteareth-10), xanthan gum, silica, copoly (dimethyl siloxane), stearic acid, hexadecyl methacrylate, spermidine, sodium benzoate, (silyl) dimethicone, (silyl) dimethacrylate, ethylhexylglycerin, polyethylene glycol, ethylhexylglycerin, polyethylene glycol, stearyl alcohol, polyethylene glycol, polyethylene glycol, sodium benzoate, hexanoyl glycol acrylate, hexanoyl glycol acrylate.

Questions or comments?
 Call toll free: 800-394-URBANDAY

In a clinical study of NAKED SKIN ONE & DONE, a majority of participants had:

- An immediate improvement in the look of skin tone that lasted for up to 8 hours.
- A significant improvement in radiance after 12 weeks of use.
- Significantly firmer-feeling skin after 12 weeks of use.
- Visibly smaller-looking pores after 8 weeks of use.

NAKED
SKIN URBAN DECAY

one & done

HYBRID COMPLEXION
 PERFECTOR

BROAD SPECTRUM
 SPF 20

OPTICAL BLURRING
 LUMINOUS FINISH
 PARABEN FREE

40 ml / 1.3 fl. oz.

Manufactured by:
 Dist. by: Distributor:
 Urban Decay Cosmetics,
 Newport Beach, CA 92663, USA,
 106 rue Canton, 92300 Levallois-Perret,
 France, Tel: 100 07 - 89 657 6511
 CEDEP, Made in USA urbandecay.com



DRUG FACTS
Active Ingredients
OCTINOXATE 7.5%, ZINC OXIDE 3.4%

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.

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Other information: Protect the product in this container from excessive heat and direct sun.

QUESTIONS OR COMMENTS CALL TOLL FREE 1-800-794-8722 (URBAN)

one & done
Dist by Urban Decay® Cosmetics LLC, Newport Beach, CA 92663, USA, 455 Promenade des Anglais, 06206 Nice, France. Made in USA. urbandecay.com

NAKED SKIN ONE AND DONE DARK

spf cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0347
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.4 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGLYCERYL-2 MONOISOSTEARATE (UNII: 7B8OE71MQC)	
PROPANEDIOL (UNII: 5965N8W85T)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48)	

XANTHAN GUM (UNII: TTV12P4NEE)
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPA.S) (UNII: R9TPS68K19)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ISODODECANE (UNII: A8289P68Y2)
LAURYL TRISILOXANE (UNII: 5OHO78HI1D)
FERRIC OXIDE RED (UNII: 1K09F3G675)
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)
TETRADIUM RUTICARPUM FRUIT (UNII: Q413WWJ3X9)
SORBIC ACID (UNII: X045WJ989B)
ISOCETETH-10 (UNII: 1K92T9919H)
CYCLOMETHICONE 4 (UNII: CZ227117JE)
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
DIMETHICONE (UNII: 92RU3N3Y1O)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0347-1	40 g in 1 TUBE; Type 0: Not a Combination Product	02/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/04/2016	

Labeler - Autumn Harp Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp Inc		064187883	manufacture(51514-0347)

