

NAKED SKIN ONE AND DONE, MEDIUM 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, Medium 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)

Principle Display Panel

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 Purpose
 Octinoxate 15% Sunscreen
 Zinc Oxide 1.6% ↑

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 the 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:
 • Time in the sun, especially from 10 a.m. to 4 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, hexamethyl phosphoramide, dimethylmethoxy propyl dimethyl siloxane crosspolymer, polydimethylsiloxane, polybutene-1, polybutene-2, polybutene-3, polybutene-4, polybutene-5, polybutene-6, polybutene-7, polybutene-8, polybutene-9, polybutene-10, polybutene-11, polybutene-12, polybutene-13, polybutene-14, polybutene-15, polybutene-16, polybutene-17, polybutene-18, polybutene-19, polybutene-20, polybutene-21, polybutene-22, polybutene-23, polybutene-24, polybutene-25, polybutene-26, polybutene-27, polybutene-28, polybutene-29, polybutene-30, polybutene-31, polybutene-32, polybutene-33, polybutene-34, polybutene-35, polybutene-36, polybutene-37, polybutene-38, polybutene-39, polybutene-40, polybutene-41, polybutene-42, polybutene-43, polybutene-44, polybutene-45, polybutene-46, polybutene-47, polybutene-48, polybutene-49, polybutene-50, polybutene-51, polybutene-52, polybutene-53, polybutene-54, polybutene-55, polybutene-56, polybutene-57, polybutene-58, polybutene-59, polybutene-60, polybutene-61, polybutene-62, polybutene-63, polybutene-64, polybutene-65, polybutene-66, polybutene-67, polybutene-68, polybutene-69, polybutene-70, polybutene-71, polybutene-72, polybutene-73, polybutene-74, polybutene-75, polybutene-76, polybutene-77, polybutene-78, polybutene-79, polybutene-80, polybutene-81, polybutene-82, polybutene-83, polybutene-84, polybutene-85, polybutene-86, polybutene-87, polybutene-88, polybutene-89, polybutene-90, polybutene-91, polybutene-92, polybutene-93, polybutene-94, polybutene-95, polybutene-96, polybutene-97, polybutene-98, polybutene-99, polybutene-100.

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 La Colline-Parral,
 France. Tel: 1 800 07-8287. www.urbandecay.com





Image Content

NAKED SKIN ONE AND DONE, MEDIUM DARK			
spf cream cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0346
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
ISODODECANE (UNII: A8289P68Y2)			
LAURYL TRISILOXANE (UNII: 5OHO78HI1D)			
FERROSO FERRIC OXIDE (UNII: XM0M87F357)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
XANTHAN GUM (UNII: TTV12P4NEE)			
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KB11)			

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SORBIC ACID (UNII: X045WJ989B)
POLYGLYCERYL-2 MONOISOSTEARATE (UNII: 7B8OE71MQC)
WATER (UNII: 059QF0K00R)
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPA.S) (UNII: R9TPS68K19)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)
TETRADIUM RUTICARPUM FRUIT (UNII: Q413WWJ3X9)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)
CYCLOMETHICONE 4 (UNII: CZ227117JE)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)
PROPANEDIOL (UNII: 5965N8W85T)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
ASPERGILLUS FUMIGATUS (UNII: X88DF51T48)
ISOCETETH-10 (UNII: 1K92T9919H)
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)
DIETHYLENE GLYCOL MONOETHYL ETHER ACETATE (UNII: W5EIM81UBX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0346-0	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(51514-0346)

