

SHISEIDO URBAN ENVIRONMENT UV PROTECTION- octinoxate, octocrylene, and zinc oxide cream

SHISEIDO AMERICA 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.

SHISEIDO URBAN ENVIRONMENT UV PROTECTION

CREAM

Drug Facts

ACTIVE INGREDIENTS:	Purpose
OCTINOXATE 2.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 10.6%	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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **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
- children under 6 months: Ask a doctor

Inactive Ingredients

WATER, ISODODECANE, CYCLOMETHICONE, DIMETHICONE, BUTYLENE GLYCOL, SD ALCOHOL 40-B, POLYMETHYL METHACRYLATE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, GLYCERIN, DISTEARDIMONIUM HECTORITE, XYLITOL, METHYL GLUCETH-10, PEG/PPG-14/7 DIMETHYL ETHER, THIOTAURINE, SCUTELLARIA BAICALENSIS ROOT EXTRACT, ARGININE HCl, ONONIS SPINOSA ROOT EXTRACT, ECTOIN, SODIUM PCA, HYDROGENATED POLYDECENE, HYDROGEN DIMETHICONE, ISOSTEARIC ACID, BENZOPHENONE-3, TRISODIUM EDTA, SILICA, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, ALUMINA, TRIETHOXYCAPRYLYLSILANE, BHT, SYZYGIUM JAMBOS LEAF EXTRACT, TOCOPHEROL, PHENOXYETHANOL, FRAGRANCE, TITANIUM DIOXIDE,

Other information

- protect this product in this container from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-906-7503

SHISEIDO DIST. NEW YORK • PARIS • MILANO

PRINCIPAL DISPLAY PANEL - 50mL Tube Carton

SHI SEIDO

Anti-Aging UV Care

40

Urban Environment

UV Protection Cream

BROAD SPECTRUM

SPF 40

For Face/Body

WATER RESISTANT

(40 MINUTES)

SUNSCREEN

50mL NET WT. 1.9 OZ.

Urban Environment
UV Protection Cream

BROAD SPECTRUM
SPF 40

For Face/Body

Anti-Aging UV Care

SHISEIDO

40

Urban Environment
UV Protection Cream

BROAD SPECTRUM
SPF 40

For Face/Body

WATER RESISTANT
(40 MINUTES)

SUNSCREEN

Drug Facts
(continued)

Directions

■ children under 6 months: Ask
a doctor

Inactive ingredients

WATER • ISODODECANE • CYCLOMETHICONE •
DIMETHICONE • BUTYLENE GLYCOL •
SD ALCOHOL 40-B •
POLYMETHYL METHACRYLATE •
LAURYL PEG-8 POLYDIMETHYLSILOXYETHYL
DIMETHICONE •
GLYCERIN • DISTEARDIMONIUM HECTORITE •
XYLITOL • METHYL GLUCETH-10 •
PEG/PPG-14/7 DIMETHYL ETHER •
THIOTAURINE •
SCUTELLARIA BAICALENSIS ROOT EXTRACT •
ARGININE HCl •
ONONIS SPINOSA ROOT EXTRACT • ECTOIN •
SODIUM PCA • HYDROGENATED POLYDECENE •
HYDROGEN DIMETHICONE •
ISOSTEARIC ACID • BENZOPHENONE-3 •
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FRAGRANCE • TITANIUM DIOXIDE •

Other Information

■ protect this product in this
container from excessive
heat and direct sun.

Questions or Comments?

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SUNSCREEN

SHISEIDO URBAN ENVIRONMENT UV PROTECTION CREAM

50mL NET WT. 1.9OZ.

56X34.5X114.5 1 2 3 4 5 6 7 8 9 0

SHISEIDO
 URBAN ENVIRONMENT UV PROTECTION CREAM
 BROAD SPECTRUM
 SPF 40
 FOR FACE/BODY

Multi-Environment Defense. Comprehensive Skin Protection.

A feather-light daily sunscreen that provides exceptional hydration while protecting against external aggressors such as UV rays, dryness and air pollution for beautiful, healthy-looking skin.

- Exceptionally powerful formula effectively helps protect skin from harmful UVA/UVB rays that cause photo-aging.
 - Hydro-Restoring Complex contains moisturizing amino acids that naturally exist in skin. Provides long-lasting moisture for skin that is smooth to the touch.
 - Thiotaurine and Rose Apple Leaf Extract are synergistically effective in inhibiting oxidative damage in skin caused by the external environment*.
 - Scutellaria Baicalensis helps prevent UV damage to essential fibroblasts which produce collagen and elastin, the key elements to resilient, youthful-looking skin*.
 - Rose Apple Leaf Extract helps prevent DNA damage caused by UV rays*.
 - Invisible on skin. Can be used as a makeup base for a beautiful foundation finish. Easily removes with daily cleanser.
 - WATER RESISTANT (40 MINUTES).
 - NON-COMEDOGENIC.
 - DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED.
- *in vitro test

Drug Facts

Active ingredients

Purpose

Drug Facts
(continued)

Warnings

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

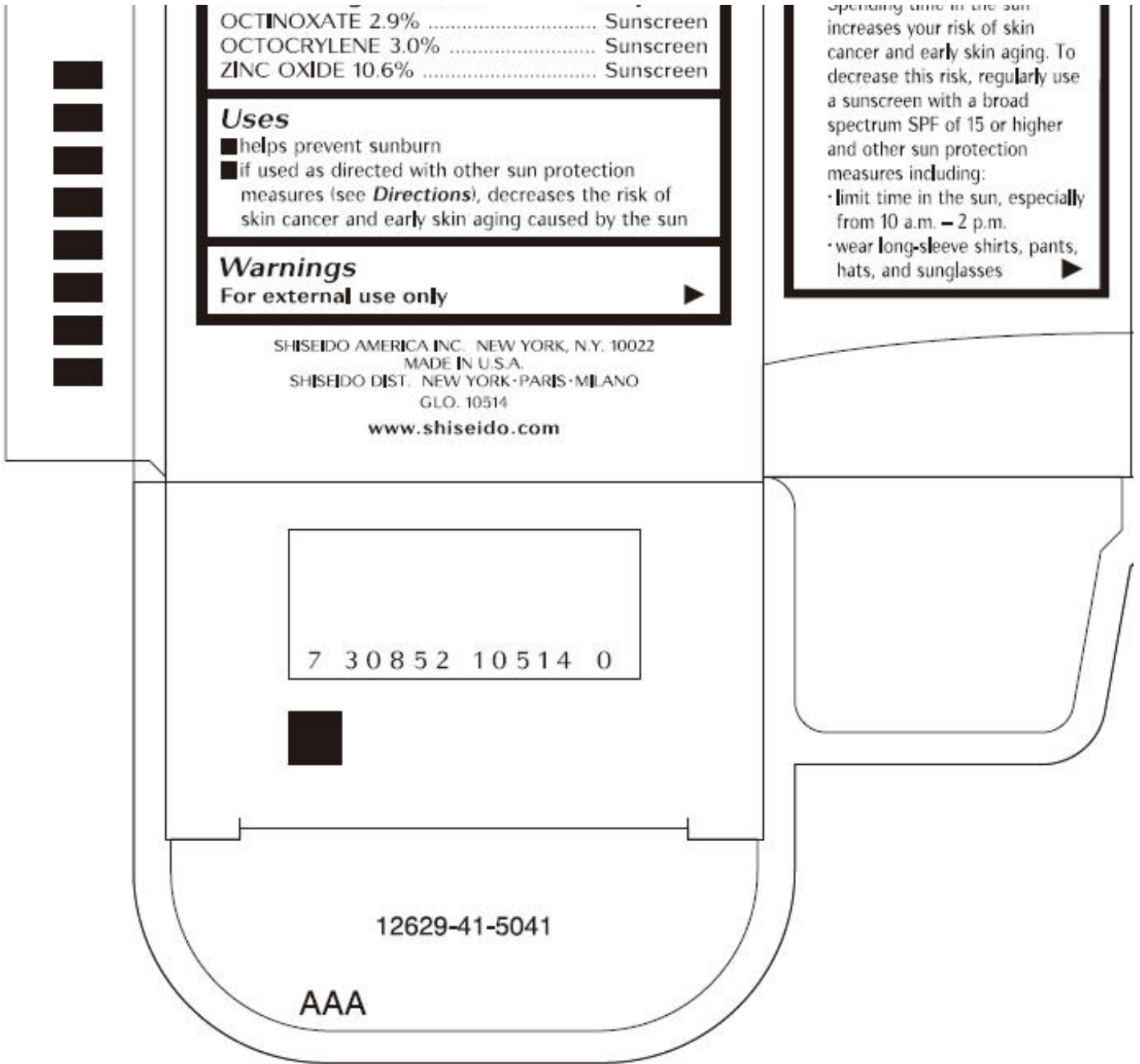
Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- Sun Protection Measures.
 - Spending time in the sun



SHISEIDO URBAN ENVIRONMENT UV PROTECTION

octinoxate, octocrylene, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-271
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1583 mg in 54.6 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1638 mg in 54.6 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5788 mg in 54.6 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
THIO TAURINE (UNII: NQZ2D7AO62)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ARGININE HYDRO CHLORIDE (UNII: F7LTH1E20Y)	
ONONIS CAMPESTRIS ROOT (UNII: FD2FMC53M1)	
ECTOINE (UNII: 7GXZ3858RY)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
ISO STEARIC ACID (UNII: X33R8U0062)	
OXYBENZONE (UNII: 95OOS7VE0Y)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-271-60	1 in 1 CARTON	10/01/2012	
1		54.6 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2012	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(52686-271) , analysis(52686-271)

