

SHISEIDO IBUKI PROTECTIVE MOISTURIZER- avobenzone, octinoxate, octocrylene, and oxybenzone emulsion

SHISEIDO AMERICAS CORPORATION

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 IBUKI PROTECTIVE MOISTURIZER

Drug Facts

<i>ACTIVE INGREDIENTS:</i>	<i>Purpose</i>
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 2.0%	Sunscreen
OXYBENZONE 1.0%	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
- use a water resistant sunscreen if swimming or sweating
- reapply 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, SD ALCOHOL 40-B, GLYCERIN, DIPROPYLENE GLYCOL, DIMETHICONE, ETHYLHEXYL PALMITATE, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, SILICA, TREHALOSE, BETAINE, GLYCYL GLYCINE, LAURYL BETAINE, PAEONIA ALBIFLORA

ROOT EXTRACT, HAMAMELIS VIRGINIANA (WITCH HAZEL) LEAF EXTRACT, LAMIUM ALBUM FLOWER EXTRACT, CITRUS JUNOS SEED EXTRACT, ZINGIBER AROMATICUS EXTRACT, PEG-20 GLYCERYL ISOSTEARATE, TRIISOSTEARIN, TRIETHANOLAMINE, ISOSTEARIC ACID, ALCOHOL, BUTYLENE GLYCOL, CARBOMER, BATYL ALCOHOL, BEHENYL ALCOHOL, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TRISODIUM EDTA, SODIUM METABISULFITE, BHT, PHENOXYETHANOL, SODIUM BENZOATE, BENZOIC ACID, FRAGRANCE, TITANIUM DIOXIDE, MICA,

Other information

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

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 75 mL Bottle Carton

SHI SEIDO

IBUKI

Protective Moisturizer

BROAD SPECTRUM

SPF 18

SUNSCREEN

75mL 2.5 FL. OZ.

Protective Moisturizer

SHISEIDO
IBUKI
PROTECTIVE MOISTURIZER
BROAD SPECTRUM
SPF 18

Correct imperfections. Resist future problems.

This multi-action daytime formula with soft reflecting powder intensively corrects the appearance of unevenness such as visible pores, breakouts/blemish marks and skin roughness. It renews the skin's surface, revealing an incredibly smooth, uniform texture, while providing lasting hydration.

- Formulated with PhytoResist Complex which boosts skin's strength* to resist problems.
- Protects skin from damaging factors such as dryness, UV rays and pollution.
- Gentle yet effective formula for all skin types including sensitive.
- NON-COMEDOGENIC.
- DERMATOLOGIST-TESTED.
- * In vitro test

SHISEIDO AMERICAS
CORPORATION DIST.
NEW YORK, NY 10022
MADE IN U.S.A.
GLO. 11112
www.shiseido.com

Drug Facts

Active ingredients	Purpose
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 2.0%	Sunscreen
OXYBENZONE 1.0%	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
- use a water resistant sunscreen if swimming or sweating
- reapply 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

SHISEIDO



IBUKI

Protective Moisturizer
BROAD SPECTRUM
SPF 18
SUNSCREEN

75mL 2.5 FL. OZ.

Drug Facts
(continued)

Inactive ingredients

WATER · SD ALCOHOL 40-8 · GLYCERIN ·
DIPROPYLENE GLYCOL · DIMETHICONE ·
ETHYLHEXYL PALMITATE ·
POLYBUTYLENE GLYCOL/PPG-8/1 COPOLYMER ·
SILICA · TREHALOSE · BETAINE ·
GLYCYL GLYCINE · LAURYL BETAINE ·
PAEDONIA ALBA FLORES EXTRACT ·
HAMAMELIS VIRGINIANA (WITCH HAZEL)
LEAF EXTRACT ·
LAMIUM ALBUM FLOWER EXTRACT ·
CITRUS JUNOS SEED EXTRACT ·
ZINCBER AROMATICUS EXTRACT ·
PEG-20 GLYCERYL ISOSTEARATE ·
TRISOSTEARIN · TRIETHANOLAMINE ·
ISOSTEARIC ACID · ALCOHOL ·
BUTYLENE GLYCOL · CARBOMER ·
BATYL ALCOHOL · BEHENYL ALCOHOL ·
ACRYLATES/C10-30 ALKYL ACRYLATE
CROSSPOLYMER ·
TRISODIUM EDTA · SODIUM METABISULFITE ·
BHT · PHENOXYETHANOL ·
SODIUM BENZOATE · BENZOIC ACID ·
FRAGRANCE · TITANIUM DIOXIDE · MICA

Other Information

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

Questions or Comments?

Call toll free 1-800-906-7503



7 30852 11112 7

11112-41-5040

AAA

47X46X157

1 2 3 4 5 6 7 8 9 0

SHISEIDO IBUKI PROTECTIVE MOISTURIZER

avobenzone, octinoxate, octocrylene, and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1903 mg in 76.12 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5633 mg in 76.12 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1522 mg in 76.12 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	761 mg in 76.12 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DIMETHICONE (UNII: 92RU3N3Y10)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TREHALOSE (UNII: B8WCK70T7I)	
BETAINE (UNII: 3SCV180C9W)	
DIGLYCINE (UNII: 10525P22U0)	
LAURYL BETAINE (UNII: Y4P927Q133)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
LAMIUM ALBUM FLOWER (UNII: 62IB9494JA)	
CITRUS JUNOS SEED (UNII: UY4301Q45N)	
PEG-20 GLYCERYL ISO STEARATE (UNII: ABV7KNA149)	
TRIOSTEARIN (UNII: 71503RH8KG)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISO STEARIC ACID (UNII: X33R8U0062)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BATILOL (UNII: 39YR661C4U)	
DOCOSANOL (UNII: 9G1OE216XY)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

MICA (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-10 1-10	1 in 1 CARTON	08/01/2013	
1		76.12 g in 1 BOTTLE; 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	08/01/2013	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-10 1) , analysis(58411-10 1)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION