

SHISEIDO BENEFIANCE WRINKLE SMOOTHING DAY- avobenzene, homosalate, octinoxate, octocrylene, and oxybenzone cream
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 BENEFIANCE WRINKLE SMOOTHING DAY CREAM

Drug Facts

Active ingredients	Purpose
AVOBENZONE 2.0%	Sunscreen
HOMOSALATE 5.0%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
OXYBENZONE 1.5%	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•GLYCERIN•DIPROPYLENE GLYCOL•BUTYLENE GLYCOL•BEHENYL ALCOHOL•SD ALCOHOL 40-

B•SILICA•DIMETHICONE•ISODODECANE•ISOHEXADECANE•SORBITOL•BEHENETH-20•MYRISTYL MYRISTATE•PHYTOSTERYL MACADAMIATE•ERYTHRITOL•XANTHAN GUM•TOCOPHERYL ACETATE•PEG/PPG-14/7 DIMETHYL ETHER•PEG/PPG-17/4 DIMETHYL ETHER•CAFFEINE•SAPINDUS MUKOROSI PEEL EXTRACT•ANGELICA KEISKEI LEAF/STEM EXTRACT•CAMELLIA SINENSIS LEAF EXTRACT•CITRUS JUNOS SEED EXTRACT•ZIZIPHUS JUJUBA FRUIT EXTRACT•EUCHEUMA SERRA/GRATELOUPIA SPARSA/SACCHARINA ANGUSTATA/ULVA LINZA/UNDARIA PINNATIFIDA EXTRACT•CURCUMA LONGA (TURMERIC) RHIZOME EXTRACT•POLYQUATERNIUM-51•SACCHARINA ANGUSTATA/UNDARIA PINNATIFIDA EXTRACT•CHLORELLA VULGARIS EXTRACT•PPG-17•STEARYL ALCOHOL•BEHENETH-30•ALCOHOL•CARBOMER•CELLULOSE GUM•TRISODIUM EDTA•HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER•SODIUM CITRATE•BHT•SODIUM METAPHOSPHATE•POTASSIUM HYDROXIDE•CITRIC ACID•TOCOPHEROL•PPG-3 DIPIVALATE•SODIUM METABISULFITE•PHENOXYETHANOL•FRAGRANCE•IRON OXIDES•

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 - 50 mL Jar Carton

SHISEIDO
GINZA TOKYO

Benefiance

Wrinkle Smoothing Day Cream

BROAD SPECTRUM
SPF 23
SUNSCREEN

ReNeura Technology+™

Wrinkles

50mL NET WT. 1.8 OZ.

Benefiance
Wrinkle Smoothing Day Cream



SHISEIDO
GINZA TOKYO

Benefiance
Wrinkle Smoothing Day Cream

BROAD SPECTRUM
SPF 23
SUNSCREEN

ReNeura Technology+™

Wrinkles
50mL NET WT. 1.8 OZ.

Drug Facts (continued)

Directions

■ children under 6 months: Ask a doctor.

Inactive ingredients

WATER - GLYCERIN - COPROPYLENE GLYCOL - BUTYLENE GLYCOL - BEHENYL ALCOHOL - SD ALCOHOL 40-9 - SILICA - DIMETHICONE - ISODODECANE - ISOHEXADECANE - SORBITOL - BEHENETH-20 - MYRISTYL MYRISTATE - PHYTOSTERYL MACADAMATE - ERYTHRITOL - XANTHAN GUM - TOCOPHERYL ACETATE - PEG/PPG-14/7 DIMETHYL ETHER - PEG/PPG-17/14 DIMETHYL ETHER - CAFFEINE - SAMOLIS MUKOROSSI PEEL EXTRACT - ANGELICA KEiskei LEAF/STEM EXTRACT - CAMELLIA SINENSIS LEAF EXTRACT - CITRUS JUNOS SEED EXTRACT - ZEPHUS JULLUBA FRUIT EXTRACT - EUCHUEMA SERRA/BRAPELOUPA SPARSA/SACCHARINA ANGUSTATA/ULVA LINZA/UNDARIA PINNATIFIDA EXTRACT - CURCUMA LONGA (TURMERIC) RHIZOME EXTRACT - POLYQUATERNIUM-51 - SACCHARINA ANGUSTATA/UNDARIA PINNATIFIDA EXTRACT - CHLORELLA VULGARIS EXTRACT - PPG-17 - STEARYL ALCOHOL - BEHENETH-30 - ALCOHOL - CARBOMER - CELLULOSE GUM - TRISODIUM EDTA - HDIMETHYLOL HEXYLLACTONE CROSSPOLYMER - SODIUM CITRATE - BHT - SODIUM METAPHOSPHATE - POTASSIUM HYDROXIDE - CITRIC ACID - TOCOPHEROL - PPG-3 DIMYRISTATE - SODIUM METABISULFITE - PHENOXYETHANOL - FRAGRANCE - IRON OXIDES

Other Information

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

Questions or Comments?

Call toll free 1-800-906-7503



<http://s1872.com/14951AA>
See our website for more information.

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SHISEIDO
 BENEHANCE
 WRINKLE SMOOTHING DAY CREAM
 BROAD SPECTRUM SPF 23

Reawaken your skin's sensors. Renew its inner vibrance.

Focus on the neuroscience of your skin's senses. With this silky smooth cream, ReNeura Technology+™ directs internal sensory signals, to make skin optimally responsive to the age-defying benefits of skincare. It visibly smoothes out wrinkles, plumps up lines, and delivers moisture. Capture a youthfully radiant look, and protect against hazards throughout the day.

- Apply in the morning, after cleanser.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.
- Avoid contact with eyes.

NON-COMEDOGENIC. DERMATOLOGIST-TESTED.

Drug Facts

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OCTOCRYLENE 3.0%	Sunscreen
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Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO AMERICAS CORPORATION DIST.
 NEW YORK, NY 10022
 MADE IN U.S.A.
 G.L.O. 14591
 www.shiseido.com

Drug Facts (continued)

Uses

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Directions

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- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours

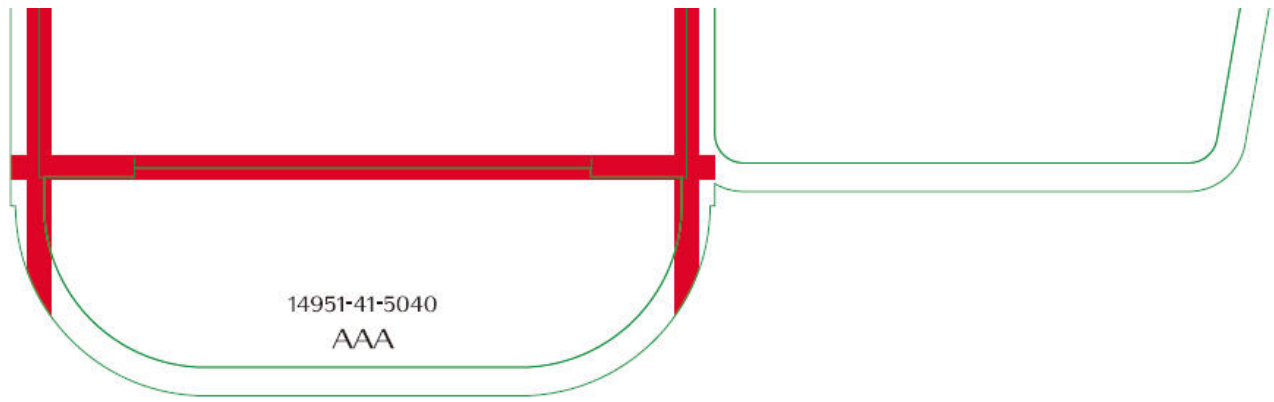
■Sun Protection Measures.

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.

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SHISEIDO BENEFIANCE WRINKLE SMOOTHING DAY

avobenzone, homosalate, octinoxate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-439
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1032 mg in 50 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2580 mg in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3818 mg in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1548 mg in 50 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	774 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DOCOSANOL (UNII: 9G10E216XY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
ISOHEXADECANE (UNII: 918X10UF1E)	
SORBITOL (UNII: 506T60A25R)	
BEHENETH-20 (UNII: BJ4GP2IFLN)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
ERYTHRITOL (UNII: RA96B954X6)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)	
CAFFEINE (UNII: 3G6A5W338E)	

SAPINDUS MUKOROSI FRUIT RIND (UNII: 3D1P12PN9U)
ANGELICA KEISKEI TOP (UNII: AP628M4TQO)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CITRUS JUNOS SEED (UNII: UY43O1Q45N)
JUJUBE FRUIT (UNII: G55HNL2C70)
TURMERIC (UNII: 856YO1Z64F)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
CHLORELLA VULGARIS (UNII: RYQ4R60M02)
PPG-17 (UNII: OV0Q322E0U)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
BEHENETH-30 (UNII: 21Z34J9KN8)
ALCOHOL (UNII: 3K9958V90M)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)
EDETATE TRISODIUM (UNII: 420IP921MB)
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-439-50	1 in 1 CARTON	06/01/2018	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/2018	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-439) , ANALYSIS(58411-439)