

SHISEIDO FUTURE SOLUTION LX INFINITE TREATMENT PRIMER- titanium dioxide, octinoxate, and ensulizole 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 FUTURE SOLUTION LX INFINITE TREATMENT PRIMER

Drug Facts

Active ingredients	Purpose
ENSULIZOLE 1.0%	Sunscreen
OCTINOXATE 3.9%	Sunscreen
TITANIUM DIOXIDE 4.1%	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 two 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•DIMETHICONE•BUTYLENE GLYCOL•GLYCERIN•ISOHEXADECANE•SD ALCOHOL 40-B•ZEA MAYS (CORN) STARCH•PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE•DIPHENYLSILOXY PHENYL TRIMETHICONE•SILICA•TRIISOSTEARIN•DISTEARDIMONIUM HECTORITE•CETYLETHYLHEXANOATE•XYLITOL•ERYTHRITOL•TRIMETHYLSILOXYSILICATE•TREHALOSE•TOCOPHERYL ACETATE•2-O-ETHYL ASCORBIC ACID•PRUNUS SPECIOSA LEAF EXTRACT•ANGELICA ACUTILOBA ROOT EXTRACT•SCUTELLARIA BAICALENSIS ROOT EXTRACT•CAMELLIA SINENSIS LEAF EXTRACT•SODIUM ACETYLATED HYALURONATE•ISODONIS JAPONICUS LEAF/STALK EXTRACT•HYDROLYZED CONCHIOLIN PROTEIN•ROSA ROXBURGHII FRUIT EXTRACT•GOLD•TRIETHANOLAMINE•ISOSTEARIC ACID•ALUMINUM HYDROXIDE•STEARIC ACID•DISODIUM EDTA•ALCOHOL•CALCIUM ALUMINUM BOROSILICATE•BHT•HYDROGEN DIMETHICONE•TOCOPHEROL•POLYSILICONE-

2•TRIETHOXYCAPRYLYLSILANE•SODIUM CITRATE•TIN OXIDE•BARIUM
SULFATE•CITRIC ACID•PHENOXYETHANOL•FRAGRANCE•TITANIUM
DIOXIDE•MICA•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 - 40 mL Tube Carton

SHISEIDO
GINZA TOKYO

FUTURE SOLUTION LX
Infinite Treatment Primer

SkingenecellEnmei

BROAD SPECTRUM
SPF 30
SUNSCREEN

40mL NET WT. 1.4 OZ.



SHISEIDO FUTURE SOLUTION LX INFINITE TREATMENT PRIMER

titanium dioxide, octinoxate, and ensulizole emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-657
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	1.77 g in 40 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	1.71 g in 40 mL
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)		ENSULIZOLE	0.428 g in 40 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIISOSTEARIN (UNII: 71503RH8KG)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
XYLITOL (UNII: VCQ006KQ1E)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
ERYTHRITOL (UNII: RA96B954X6)	
MICA (UNII: V8A1AW0880)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TREHALOSE (UNII: B8WCK70T7I)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ALCOHOL (UNII: 3K9958V90M)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
PRUNUS SPECIOSA LEAF (UNII: Q71D900FVU)	
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SODIUM ACETYLATED HYALURONATE (UNII: VN66R7GL93)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
GOLD (UNII: 79Y1949PYO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-657-10	1 in 1 CARTON	05/01/2021	
1		40 mL 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	05/01/2021	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

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