

NOEVIR RAYSELA UV SHIELD PRIMER- zinc oxide, octinoxate cream
Nippon Shikizai, 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.

NOEVIR RAYSELA
UV SHIELD PRIMER
RAYSELA Base Protection UV
BROAD SPECTRUM
SPF50+

Protects skins from the sun's harmful rays (UV-A, UV-B) to prevent sunburn, spots and premature signs of aging while keeping your skin hydrated.

- Broad Spectrum SPF50+ effectively shields UV rays while hydrating skin.
- Can be used as a makeup base throughout the year.
- Light-diffusing emulsion creates soft and smoother appearance.
- Deeply moisturizing without heaviness for youthful looking skin.
- Specially formulated emulsion provided light, pleasant finish while absorbing excess sebum.

Drug Facts

Active Ingredients

OCTINOXATE 6.99%

ZINC OXIDE 17.67%

Purpose

Sunscreen

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 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 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.

Other Information

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

Inactive ingredients

WATER, CYCLOPENTASILOXANE, BUTYLENE GLYCOL, DIPHENYLSILOXY PHENYL TRIMETHICONE, PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, POLYMETHYLSILSESQUIOXANE, DISTEARDIMONIUM HECTORITE, HYDROGEN DIMETHICONE, PENTYLENE GLYCOL, GLYCERIN, MAGNESIUM SULFATE, POLYHYDROXYSTEARIC ACID, SORBITAN SESQUIESTEARATE, TRIMETHYLSILOXYSILICATE, SILICA DIMETHYL SILYLATE, SODIUM CITRATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, TOCOPHEROL, SQUALANE, ALCOHOL, CELLULOSE ACETATE, ASCOPHYLLUM NODOSUM EXTRACT, SORBITOL, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, PHELLODENDRON AMURENSE BARK EXTRACT, BELAMCANDA CHINENSIS ROOT EXTRACT, VITIS VINIFERA (GRAPE) LEAF EXTRACT, CITRUS GRANDIS (GRAPEFRUIT) FRUIT EXTRACT, SPIRAEA ULMARIA FLOWER EXTRACT, PHENOXYETHANOL, FRAGRANCE

Principal Display Panel - Raysela UV Shield Primer Label**RAYSELA****UV Shield Primer**

Base Protection UV

**BROAD
SPECTRUM****SPF
50+****NOEVIR**

NET WT. 1.7 OZ. - 50g

RAYSELA

UV Shield Primer
Base Protection UV

Drug Facts (continued)

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NOEVIR CO., LTD.
6-13-1 PORT ISLAND,
KOBE, JAPAN
MADE IN JAPAN

BROAD
SPECTRUM

SPF
50+

NOEVIR

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Drug Facts (continued)

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NOEVIR RAYSELA UV SHIELD PRIMER

zinc oxide, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24509-0001
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	176.7 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	69.9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SQUALANE (UNII: GW89575KF9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
ROSEMARY (UNII: IJ67X351P9)	
ALCOHOL (UNII: 3K9958V90M)	
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
PUMMELO (UNII: ET1TN5W71X)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
IRIS DOMESTICA ROOT (UNII: T2MU9QFA87)	
VITIS VINIFERA LEAF (UNII: R1H893D80E)	
ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)	
SORBITOL (UNII: 506T60A25R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:24509-0001-1	1 in 1 BOX	04/10/2018	
1		50 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 final	part352	04/10/2018	

Labeler - Nippon Shikizai, Inc. (692572936)

Establishment

Name	Address	ID/FEI	Business Operations
Nippon Shikizai, Inc.		694869178	MANUFACTURE(24509-0001) , ANALYSIS(24509-0001)

Establishment

Name	Address	ID/FEI	Business Operations
Nippon Shikizai, Inc.		692076308	MANUFACTURE(24509-0001) , PACK(24509-0001) , LABEL(24509-0001) , ANALYSIS(24509-0001)

Revised: 4/2020

Nippon Shikizai, Inc.