

**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.*

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**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

NET WT. 1.7 OZ. - 50g

### Drug Facts (continued)

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## NOEVIR RAYSELA UV SHIELD PRIMER

zinc oxide, octinoxate cream

**Product Information**

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

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
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.		692076308	MANUFACTURE(24509-0001) , ANALYSIS(24509-0001) , PACK(24509-0001) , LABEL(24509-0001)

Revised: 1/2021

Nippon Shikizai, Inc.