

**RODERM PROTECTING SPF 28 SUNSCREEN- octinoxate, zinc oxide lotion**  
**Roman Health Ventures 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.*

-----  
**Roderm Protecting SPF Lotion**

**Drug Facts**

**Active ingredients**

Octinoxate 7%

Zinc Oxide 6%

**Purpose**

Sunscreen

**Use**

Helps prevent sunburn.

**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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age: ask a doctor
- **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 value 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-sleeved shirts, pants, hats and sunglasses

**Other information**

Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients**

Water, Isocetyl Stearate, Cetyl Dimethicone, Styrene/Acrylates Copolymer, Sorbitol, Ethyl

Macadamiate, Cetearyl Alcohol, Dimethicone, Acrylates/Dimethicone Copolymer, Phenoxyethanol, Glyceryl Stearate, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Cetareth-10, Ethylhexyl Salicylate, VP/Eicosene Copolymer, Xanthan Gum, Polymethyl Methacrylate, Caprylyl Glycol, Cocos Nucifera (Coconut) Oil, Ethylhexylglycerin, Vaccinium Vitis-Idaea Fruit Extract, Quercus Suber Bark Extract, Triethoxycaprylylsilane, Camellia Sinensis Leaf Extract, Disodium EDTA, Tocopheryl Acetate, Oak Root Extract, Centella Asiatica Extract, Polygonum Aviculare Extract, Citric Acid, Gluconolactone, Isomalt, Calcium Gluconate, Lecithin, Vitis Vinifera (Grape) Fruit Cell Extract, Sodium Benzoate, Lepidium Sativum Sprout Extract.

Distributed by:

Roman Health Ventures, Inc.

900 Broadway, Suite 706A

New York, NY 10003

**roderm**  
**Protecting SPF Lotion**

Broad Spectrum SPF 28 Sunscreen

**1.66 fl oz (50 mL)**

### Drug Facts

Active ingredients	Purpose
Octinoxate 7% Zinc Oxide 6% }	Sunscreen

### Use

Helps prevent sunburn

### 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 swallowed, get medical help or contact a Poison Control Center right away.

### Directions

- Apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age: ask a doctor
- **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 value 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-sleeved shirts, pants, hats, and sunglasses ▶

### Drug Facts (continued)

### Other information

Protect the product in this container from excessive heat and direct sun.

### Inactive ingredients

Water, Isocetyl Stearate, Cetyl Dimethicone, Styrene/Acrylates Copolymer, Sorbitol, Ethyl Macadamiate, Cetearyl Alcohol, Dimethicone, Acrylates/Dimethicone Copolymer, Phenoxyethanol, Glycerol Stearate, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Ceteareth-20, Ethylhexyl Salicylate, VP/Eicosene Copolymer, Xanthan Gum, Polymethyl Methacrylate, Caprylyl Glycol, Cocos Nucifera (Coconut) Oil, Ethylhexylglycerin, Vaccinium Vitis-Idaea Fruit Extract, Quercus Suber Bark Extract, Triethoxycaprylylsilane, Camellia Sinensis Leaf Extract, Disodium EDTA, Tocopheryl Acetate, Oak Root Extract, Centella Asiatica Extract, Polygonum Aviculare Extract, Citric Acid, Gluconolactone, Isomalt, Calcium Gluconate, Lecithin, Vitis Vinifera (Grape) Fruit Cell Extract, Sodium Benzoate, Lepidium Sativum Sprout Extract

Distributed by  
Roman Health Ventures, Inc.  
900 Broadway, Suite 706A  
New York, NY 10003

**roderm**

## Protecting SPF Lotion

Broad spectrum SPF 28  
Sunscreen

1.66 fl oz | 50 mL

## RODERM PROTECTING SPF 28 SUNSCREEN

octinoxate, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72484-203
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYGONUM AVICULARE WHOLE</b> (UNII: M990N03611)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>CETYL DIMETHICONE 150</b> (UNII: 5L694Y0T22)	
<b>ISOCETYL STEARATE</b> (UNII: 3RJ7186O9W)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>VACCINIUM VITIS-IDAEA FRUIT OIL</b> (UNII: 16Y54799WZ)	
<b>LEPIDIUM SATIVUM WHOLE</b> (UNII: 0FL88F2R2Q)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ETHYL MACADAMIATE</b> (UNII: ANA2NCS6V1)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)	
<b>QUERCUS SUBER BARK</b> (UNII: 8R5219271Q)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4)	
<b>OCTISALATE</b> (UNII: 4X49Y0596W)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>CALCIUM GLUCONATE</b> (UNII: SQE6VB453K)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>VITIS VINIFERA FRUIT OIL</b> (UNII: YQ5Q4Y2Z8U)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>QUERCUS SPP. WHOLE</b> (UNII: MF4E5I2OUQ)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1R98B0)	
<b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U)	
<b>ISOMALT</b> (UNII: S870P55O2W)	
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72484-203-01	1 in 1 CARTON	11/11/2021	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
	NDC: 72484			

2	NDC: 1484-203-02	1 in 1 CARTON	11/11/2021	
2		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part352		11/11/2021	

**Labeler** - Roman Health Ventures Inc. (081317350)

Revised: 11/2021

Roman Health Ventures Inc.