

ROMAN BROAD SPECTRUM SPF 28 SUNSCREEN FACE MOISTURIZER- 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.

Roman Sunscreen Face Moisturizer

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, Cetearth-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 Street, Suite #706

New York, NY 10003

roman

Weightless Face Moisturizer

Broad Spectrum SPF 28 Sunscreen

2 fl oz (60 mL)

getroman.com

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, Glyceryl Stearate, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Ceteareth-20, Ethylhexyl Salicylate, VP/Eicosane 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.

Weightless Face Moisturizer

Broad Spectrum SPF 28 Sunscreen

2 fl oz (60 mL)

Roman

Drug Facts

Active Ingredients	Purpose
Octinoxate 7%	Sunscreen
Zinc Oxide 6%	

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

ro

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

ROMAN BROAD SPECTRUM SPF 28 SUNSCREEN FACE MOISTURIZER

octinoxate, zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72484-201

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLYGONUM AVICULARE WHOLE (UNII: M990N03611)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
COCONUT OIL (UNII: Q9L0O73W7L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
WATER (UNII: 059QF0KO0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
VACCINIUM VITIS-IDAEA FRUIT OIL (UNII: 16Y54799WZ)	
LEPIDIUM SATIVUM WHOLE (UNII: 0FL88F2R2Q)	
SORBITOL (UNII: 506T60A25R)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
QUERCUS SUBER BARK (UNII: 8R5219271Q)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
OCTISALATE (UNII: 4X49Y0596W)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
VITIS VINIFERA FRUIT OIL (UNII: YQ5Q4Y2Z8U)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
QUERCUS SPP. WHOLE (UNII: MF4E5I2OUQ)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	

ISOMALT (UNII: S870P55O2W)

VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72484-201-03	1 in 1 CARTON	07/28/2020	
1		60 mL in 1 BOTTLE, PLASTIC; 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	07/28/2020	

Labeler - Roman Health Ventures Inc. (081317350)

Revised: 7/2020

Roman Health Ventures Inc.