ROSACLEAR SKIN BALANCING SUN PROTECTION BROAD SPECTRUM SPF 30 SUNCREEN- titanium dioxide and zinc oxide lotion OMP, 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.

ROSACLEAR® SKIN BALANCING SUN PROTECTION BROAD SPECTRUM SPF 30 SUNSCREEN LOTION

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 2.0%	Sunscreen
Zinc Oxide 15.5%	Sunscreen

Uses

helps prevent sunburn

Warnings

For external use only

Do not use

on damaged or broken skin

Stop use and ask a doctor

• if rash occurs

When using this product

• keep out of eyes. Rinse with water to remove.

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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: 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

Inactive ingredients

alumina, butylparaben, C12-15 alkyl benzoate, cetearyl alcohol, coco-glucoside, dipropylene glycol, ethylparaben, glycerin, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, iron oxides, isobutylparaben, isohexadecane, isopropyl titanium triisostearate/triethoxycaprylylsilane crosspolymer,

methylparaben, mica, PEG-6, phenoxyethanol, polyhydroxystearic acid, propylparaben, titanium dioxide, tocopheryl acetate, triethoxycaprylylsilane, water

Other information

- store at controlled room temperature: 15°C-25°C (59°F-77°F).
- protect this product from excessive heat and direct sun

Questions or comments?

1.800.636.7546

Monday-Friday 9 a.m.-4 p.m. Pacific Time

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Distributed by OMP, Inc., Long Beach, CA 90806

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www.obagi.com Made in USA 10726414Z 7264 Rev. 12/13

PRINCIPAL DISPLAY PANEL - 85 g Bottle Label

OBAGI® MEDICAL

rosaclear®

· NON-COMEDOGENIC · NON-COMEDOGENIC

SKIN BALANCING SUN PROTECTIONBROAD SPECTRUM SPF 30
SUNSCREEN LOTION

Net wt. 3 oz. (85 g)

Skin Bajancing Sun Protection Broad Spectrum SPF 30 contains reflective agents that help reduce the appearance of redness and biotchiness. Dermatologist Tested | Allergy Tested

Active ingredients

Purpose

Titanium Dioxide 2% _____ __Sunscreen Zinc Oxide 15.5%.....

Use ■ helps prevent sunburn

Warnings

For external use only

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

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 ■ use a water

resistant sunscreen if swimming or sweating reapply at least every 2 hours children under 6 months: 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 from 10 a,m,-2 p,m. wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients

alumina, butylparaben, C12-15 alkyli benzoate, cetearyl alcohol, coco-glucoside, dipropylene glycol, ethylparaben, glycerin, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, iron oxides, isobutylparaben, isohexadecane, isopropyl titanium triisostearate/triethoxycaprylylsilane crosspolymer, methylparaben, mica, PEG-6, phenoxyethanol, polyhydroxystearic acid, propylparaben, titanium dioxide, tocopheryl acetate, triethoxycaprylylsilane, water

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The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen







SUNSCREEN LOTION



Net wt. 3 oz. (85 g)

ROSACLEAR SKIN BALANCING SUN PROTECTION BROAD SPECTRUM SPF **SUNCREEN** 30

titanium dioxide and zinc oxide lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62032-072

Route of Administration TOPICAL

A -+:-- T---- J:---- / A -+:-- N/ -:-

Active Ingredient/Active Molety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	20 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	155 mg in 1 mL	

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0KO0R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCO GLUCOSIDE (UNII: ICS790225B)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	
ISO HEXADECANE (UNII: 918 X10 UF1E)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	
GLYCERIN (UNII: PDC6 A3C0 O X)	

Product Characteristics			
Color	GRAY	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:62032-072-64	88 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	0 1/0 1/20 0 9	

Labeler - OMP, Inc. (790553353)

Establishment				
Name	Address	ID/FEI	Business Operations	
Swiss-American Products		611921669	MANUFACTURE(62032-072)	

Revised: 10/2014 OMP, Inc.