REDNESS RELIEF PRIMER SPF20- titanium dioxide and zinc oxide lotion Dermalogica, 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.

Redness Relief Primer SPF20

Drug Facts

Active ingredients

Titanium Dioxide (3.0%), Zinc Oxide (8.5%).

Purpose

Sunscreen

Use

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see **Directions**), helps decrease 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 30 minutes before sun exposure.
- Reapply at least every two 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 help 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 from excessive heat and direct sun.

Inactive ingredients

Cyclopentasiloxane, Isododecane, Caprylic/Capric Triglyceride, Dimethicone Crosspolymer, Caprylyl Methicone, Lauryl PEG-10 Tris (Trimethylsiloxy) Silylethyl Dimethicone, Dimethicone/Bis-Isobutyl PPG-20 Cross polymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Water/Aqua/Eau, Polyhydroxystearic Acid, Avena Sativa (Oat) Kernel Oil, Bisabolol, Saccharomyces Lysate Extract, Zingiber Officinale (Ginger) Root Extract, Boerhavia Diffusa Root Extract, Melia Azadirachta Seed Extract, Melia Azadirachta Leaf Extract, Avena Sativa (Oat) Kernel Extract, Amber Powder, Coccinia Indica Fruit Extract, Solanum Melongena (Eggplant) Fruit Extract, Ocimum Basilicum (Basil) Leaf Extract, Curcuma Longa (Tumeric) Leaf Extract, Pearl Powder, Dodecene, Hydroxyphenyl Propamidobenzoic Acid, Silica Dimethyl Silylate, Dimethicone, Butylene Glycol, Pentylene Glycol, Glycerin, Alumina, PEG-10, Stearic Acid, Triethoxycaprylylsilane, Ethylhexylglycerin, Ascorbyl Palmitate, Potassium Sorbate, Phenoxyethanol, Iron Oxides CI 77492, CI 77499.

Questions or comments?

Call toll free **1-800-831-5150** in the US

PRINCIPAL DISPLAY PANEL - 22 mL Tube Carton

redness relief primer

spf 20

broad spectrum

UVA medium protection

UltraCalming TM

0.75 US FL OZ / 22 mL e

dermalogica®

redness relief primer

redness relief primer



broad spectrum

Redness-reducing, Broad Spectrum primer for sensitized skin. Counteract telltale skin redness and balance skin tone with this soothing, translucent primer tinted with natural green botanical extracts. Velvety silicones smooth the skin and strengthen barrier protection while physical sunscreens shield the skin from irritating UV rays. Oat Extracts and Oat Kemel Oil help soothe and condition the skin. After applying moisturizer, smooth over entire face or use on areas of redness. Can be worn alone or underneath foundation to extend wear. Contains our exclusive *UltraCalming*™ *Complex*, which helps soothe and strengthen the skin. Slide on the included tube dispenser to help get the most product out of the tube.

Formulated without artificial fragrances, colors or parabens. Product guaranteed when professionally recommended.



Made in the USA

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Drug Facts

Active

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Purpose Sunscreen

- Helps prevent sunburn.■ If used as directed with other sun protection measures (see **Directions**), helps decrease the risk of skin cancer and early skin aging caused by the sun.

Warnings For external use only.

- on damaged or broken
- 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 30 minutes before sun exposure.
 Reapply at least every two hours.
- Use a water resistant sunscreen if swimming or sweating.
- sweating.

 Sun Protection Measures.
 Spending time in the sun increases your risk of skin cancer and early skin aging. To help decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun higher and other sun protection measures
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broad spectrum Drug Facts (continued)

Other information

■ Protect this product from and direct sun.

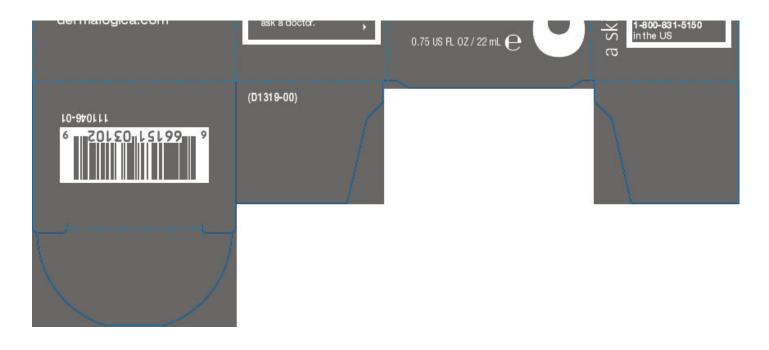
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(UVA) medium protection

UltraCalming™

Questions or comments?



REDNESS RELIEF PRIMER SPF20

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	30 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	85 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Cyclomethicone 5 (UNII: 0THT5PCI0R)		
Isododecane (UNII: A8289P68Y2)		
Medium-Chain Triglycerides (UNII: C9H2L21V7U)		
Caprylyl Trisiloxane (UNII: Q95M2P1KJL)		
Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer (UNII: O4I3UFO6ZF)		
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)		
Water (UNII: 059QF0KO0R)		
Polyhydroxystearic Acid (2300 MW) (UNII: YXH47AOU0F)		
Oat Kernel Oil (UNII: 3UVP41R77R)		
Levomenol (UNII: 24WE03BX2T)		
Saccharomyces Lysate (UNII: R85W246Z1C)		
Ginger (UNII: C5529G5JPQ)		
Boerhavia Diffusa Root (UNII: KROSRO9KYL)		
Azadirachta Indica Seed (UNII: P1NV46V59R)		
Azadirachta Indica Leaf (UNII: HKY915780T)		

Oat (UNII: Z6J799EAJK)	
Amber (UNII: 70J9Z0J26P)	
Coccinia Grandis Fruit (UNII: VLJ6WOT3K5)	
Eggplant (UNII: W5K7RAS4VK)	
Basil (UNII: 2U0KZP0FDW)	
Curcuma Longa Leaf (UNII: H2HC4RY52C)	
Pearl (Hyriopsis Cumingii) (UNII: A75L5FZ40U)	
Dodecene (UNII: WYE669F3GR)	
Hydroxyphenyl Propamidobenzoic Acid (UNII: 25KRT26H77)	
Silica Dimethyl Silylate (UNII: EU2PSP0G0W)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Pentylene Glycol (UNII: 50C1307PZG)	
Glycerin (UNII: PDC6A3C0OX)	
Aluminum Oxide (UNII: LMI26O6933)	
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

F	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:68479-009-02	1 in 1 CARTON			
1		22 mL in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:68479-009-00	2 mL in 1 POUCH; 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	03/21/2014	

Labeler - Dermalogica, Inc. (177698560)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		790530976	MANUFACTURE(68479-009)

Establishment			
Name	Address	ID/FEI	Business Operations
Diamond Wipes		16 110 4729	MANUFACTURE(68479-009)

Revised: 11/2015 Dermalogica, Inc.