# OCLIPSE SUNSCREEN PLUS PRIMER BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION- titanium dioxide and zinc oxide lotion ZO Skin Health, 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.

-----

#### OCLIPSE® Sunscreen + Primer Broad-Spectrum SPF 30 UVA/UVB Protection

#### **Drug Facts**

Active ingredients	Purpose	
Titanium Dioxide 10.2%	Sunscreen	
Zinc Oxide 3.7%	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.

**Stop 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.
- Apply to all skin exposed to the sun.

#### Other information

- Protect the product in this container from excessive heat and direct sunlight.
- You may report a serious adverse reaction to: 1 Technology Dr. B123, Irvine, CA 92618

#### **Inactive ingredients**

Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone

Crosspolymer, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Melanin, Tribehenin, Calcium Behenate, Sorbitan Isostearate, Myristoyl Pentapeptide-8, Dimethiconol, Alumina, PEG-10 Dimethicone, Methicone, Iron Oxides.

#### **DIST BY**

ZO Skin Health, Inc. Irvine, CA 92618

### PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

**ZO® SKIN HEALTH** 

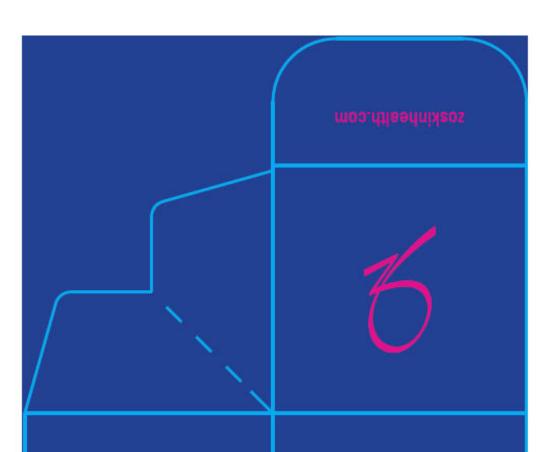
**BY ZEIN OBAGI, MD** 

 $\mathbf{OCLIPSE}^{\circledR}$ 

SUNSCREEN + PRIMER BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION

beverly hills

30 mL / 1 Fl. Oz.



## Drug Facts (continued)

### Other information

- Protect the product in this container from excessive heat and direct sunlight.
   You may report a serious adverse reaction to: 1 Technology Dr. B123, Irvine, CA 92618

Inactive ingredients
Cyclopentasiloxane, Cyclotetrasiloxane,
Dimethicone Crosspolymer, Dimethicone/
Vinyl Dimethicone Crosspolymer, Methyl
Methacrylate/Glycol Dimethacrylate
Crosspolymer, Melanin, Tribehenin,
Calcium Behenate, Sorbitan Isostearate,
Myristoyl Pentapeptide-8, Dimethiconol,
Alumina, PEG-10 Dimethicone,
Methicone, Iron Oxides.









# OCLIPSE SUNSCREEN PLUS PRIMER BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION

titanium dioxide and zinc oxide lotion

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	102 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	37 mg in 1 mL

Inactive Ingredients			
Strength			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:42851-051-03	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, PUMP		
2	NDC:42851-051-01	15 mL in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 1/0 1/20 12	

# Labeler - ZO Skin Health, Inc. (826468527)

Establishment				
Name	Address	ID/FEI	Business Operations	
Owen Biosciences, Inc.		790003045	MANUFACTURE(42851-051)	

Revised: 9/2013 ZO Skin Health, Inc.