

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

OCLIPSE[®]

SUNSCREEN + PRIMER

BROAD-SPECTRUM SPF 30

UVA/UVB PROTECTION

beverly hills

30 mL / 1 Fl. Oz.

zoskinhealth.com



Drug Facts (continued)

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ZO[®] SKIN HEALTH

BY ZEIN OBAGI, MD



CLIPSE[®]

SUNSCREEN + PRIMER

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

beverly hills

30 mL / 1 Fl. Oz.

"ZO" is a registered trademark
of ZO Skin Health, Inc.



Using titanium dioxide and zinc oxide—two physical sunscreens—this sunscreen provides full spectrum UV protection. Melanin, nature's best protectant, works to neutralize free radicals generated by sunlight. A tint and a silky matte finish help the

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and a silky matte finish help and sunscreen reduce the appearance of skin imperfections and create the perfect primer for makeup application.



Scan for more information about this product

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DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

MADE IN USA 060800

zoskinhealth.com

NO COATING

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				
Ingredient Name				Strength
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)				
CYCLOMETHICONE 4 (UNII: CZ227117JE)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)				
TRIBEHENIN (UNII: 8OC9U7TQZ0)				
CALCIUM BEHENATE (UNII: J5VFA9V6YG)				
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)				
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)				
ALUMINUM OXIDE (UNII: LM26O6933)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
METHICONE (20 CST) (UNII: 6777U11MKT)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	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	01/01/2012		

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

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