

ZO SKIN HEALTH SUNSCREEN PLUS PRIMER BROAD-SPECTRUM SPF 30-
titanium dioxide and zinc oxide cream
ZO Skin Health, Inc.

ZO ® Skin Health Sunscreen + Primer Broad-Spectrum SPF 30

National Drug Codes: 42851-060-15, 42851-060-30, and 42851-060-75

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Titanium Dioxide 1.0%	Sunscreen
Zinc Oxide 20.0%	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.

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 and as needed.
- 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.

Other Information

- Protect this product from excessive heat and direct sun.

Inactive Ingredients

Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, PEG-10 Dimethicone, Phenyl Trimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Glycyrrhiza Uralensis (Licorice) Root Extract, Helianthus Annuus (Sunflower) Seed Oil, Centella Asiatica Extract, Ecllonia Kurome Extract, Glycine Soja (Soybean) Seed Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Hexyl Laurate, Polyglyceryl-4 Isostearate, Tribehenin, Bisabolol, Cetyl PEG/PPG-10/1 Dimethicone, Water, Glycerin, Squalane, Polymethyl Methacrylate, Dimethiconol, Caprylic/Capric Triglyceride, Stearic Acid, Alumina, Caprylyl Glycol, Behenyl Behenate, Melanin, Tocopheryl Acetate, Ethyl Ferulate, Triethoxycaprylylsilane, Ascorbic Acid, Retinyl Palmitate, Ethylhexylglycerin, Tocopherol, Myristoyl Pentapeptide-8, Pentylene Glycol, Phenoxyethanol, Chlorphenesin, 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

NDC 42851-060-30

SUNSCREEN + PRIMER

BROAD-SPECTRUM

SPF 30

ZOX 12[™]

30 mL / 1 Fl. Oz.



ZO SKIN HEALTH By ZEIN OBAGI MD	
PRODUCT Sunscreen + Primer SPF 30, UC	
CATEGORY:	Protect
FORMULA NO.:	ZO-004-67 Rev. 1
CLASSIFICATION:	OTC
ITEM TYPE:	Component
SIZE:	Full - 30mL
PART NO.:	221300
UPC:	810866012136
REGION GBL US INTL US+INTL CN CHINA	
VENDOR K1	TEMPLATE 11390A5
COLORS	
	Spot White
	Pantone Blue 072 C
	Black
SUBSTRATE	
	18pt Silver Foil SBS C1S

GRADE/A		FINAL 1 05.10.23
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FILE NAME Sunscreen_Primer_30mL_Sac_US_ZO5337_MECH_F1		
NOTES: created 04.25.23 kj; Revised copy and added barcode 04.27.23 kj; Revised slug and released final file 05.10.23 kj		

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titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SOYBEAN (UNII: L7HT8F1ZOD)	
ROSEMARY (UNII: IJ67X351P9)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIBEHENIN (UNII: 80C9U7TQZ0)	
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)
SQUALANE (UNII: GW89575KF9)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
STEARIC ACID (UNII: 4ELV7Z65AP)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
BEHENYL BEHENATE (UNII: K8NU647RJ0)
ETHYL FERULATE (UNII: 5B8915UELW)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
TOCOPHEROL (UNII: ROZB2556P8)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CHLORPHENESIN (UNII: I670DAL4SZ)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
LEVOMENOL (UNII: 24WE03BX2T)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
FERRIC OXIDE RED (UNII: 1K09F3G675)
ALUMINUM OXIDE (UNII: LMI26O6933)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
DIMETHICONE (UNII: 92RU3N3Y1O)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
GLYCYRRHIZA URALENSIS (UNII: 42B5YD8F0K)
SUNFLOWER OIL (UNII: 3W1JG795YI)
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)
ECKLONIA KUROME (UNII: 802YF989GT)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-060-15	1 in 1 CARTON	10/31/2019	
1		15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:42851-060-30	1 in 1 CARTON	10/31/2019	
2		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:42851-060-75	1 in 1 CARTON	10/31/2019	
3		75 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug M020

10/31/2019

Labeler - ZO Skin Health, Inc. (826468527)

Revised: 10/2024

ZO Skin Health, Inc.