

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, Ecklonia 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,

Dist. by ZO Skin Health, Inc. Irvine, CA 92618

ZO[®] SKIN HEALTH

NDC 42851-060-30

SUNSCREEN + PRIMER

BROAD-SPECTRUM

ZOX 12™

30 mL / 1 Fl. Oz.

titanium dioxide and zinc oxide cream

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

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
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)	
SOYBEAN (UNII: L7HT8F1ZOD)	
ROSEMARY (UNII: IJ67X351P9)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
WATER (UNII: 059QF0K00R)	
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: R0ZB2556P8)	
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)	

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
OTC Monograph Drug	M020	10/31/2019	

Labeler - ZO Skin Health, Inc. (826468527)

