

ZO SKIN HEALTH SUNSCREEN PLUS POWDER BROAD-SPECTRUM SPF 45- zinc oxide powder
ZO Skin Health, Inc.

ZO ® Skin Health Sunscreen + Powder Broad-Spectrum SPF 45 (Medium)
National Drug Code 42851-068-27

Drug Facts

Active Ingredients

<i>Active Ingredients</i>	<i>Purpose</i>
Zinc Oxide 25.0%	Sunscreen

Purpose Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides high protection against 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
- Reapply: at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- Children under 6 months of age: 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

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- Protect the product in this container from excessive heat and direct sun.
- You may report a serious adverse reaction to: 9685 Research Dr., Irvine, CA 92618

Inactive Ingredients

Mica, Hydroxyapatite, Polymethyl Methacrylate, HDI/Trimethylol Hexyllactone Crosspolymer, Simmondsia Chinensis (Jojoba) Butter, Bronze Powder, Simmondsia Chinensis (Jojoba) Seed Oil, Iron Oxides, Triethoxycaprylylsilane, Bisabolol, Ethyl Ferulate, Ethylhexylglycerin, Melanin, Pentylene Glycol, Water, Silica, Tocopheryl Acetate, Ascorbic Acid, Retinyl Palmitate, Phenoxyethanol.

Principal Display Panel

ZO® SKIN HEALTH
BY ZEIN OBAGI MD

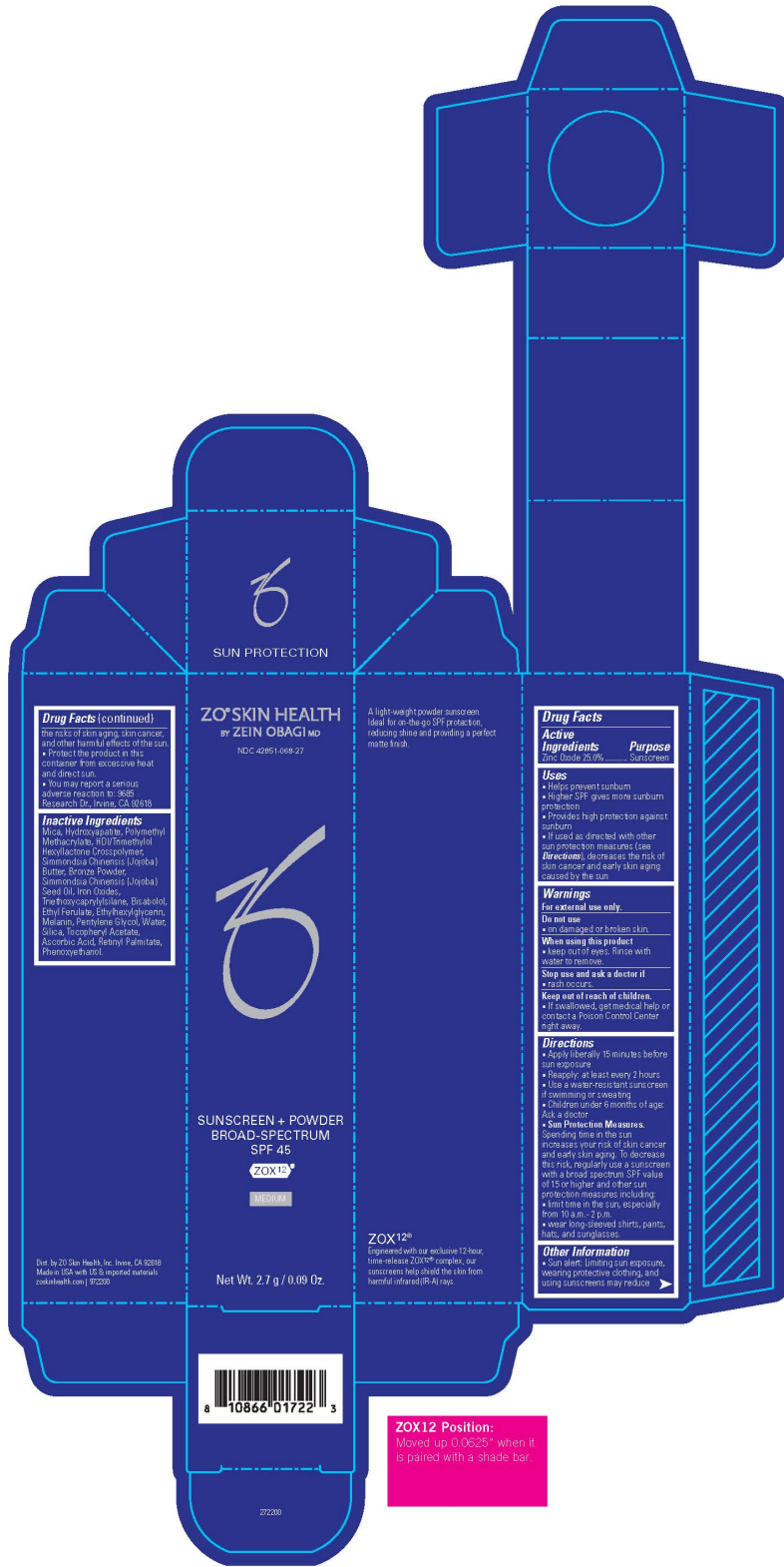
NDC 42851-068-27

SUNSCREEN + POWDER
BROAD-SPECTRUM
SPF 45

ZOX12®

MEDIUM

Net Wt. 2.7 g / 0.09 Oz.



ZO° SKIN HEALTH BY ZEIN OBAGI MD	
PRODUCT Powder + Sunscreen Broad Spectrum SPF 45 Medium	
CATEGORY:	Protect
FORMULA NO.:	ZO-004-109B
CLASSIFICATION:	Over-the-Counter Drug
ITEM TYPE:	Component
SIZE:	Full
PART NO.:	272200
UPC:	810866017223
REGION GBL US INTL US+INTL CN CHINA	
VENDOR K1	TEMPLATE Z2563A3 STE W FALSE TOP
COLORS	
	Spot White
	Pantone Blue 072 C
	Black
SUBSTRATE 18pt Silver Foil SBS C1S	

GRADE / A DSGN / INSP-1, • PREM• QLTY FOR SKN DTL, PREP. BY 11/20/16/166/755/425 GRADE A DESIGN • DDT • COM	FINAL 1 02.09.21
FILE NAME SunscreenPowder_2_7g_SEC_US_Medium_ZOS127_MECH_F1	
NOTES: created 01.29.21 bf; revised copy 02.03.21 kj RELEASED FILE 02.09.21 bf	

ZO SKIN HEALTH SUNSCREEN PLUS POWDER BROAD-SPECTRUM SPF 45
zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-068
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.675 mg in 2.7 g

Inactive Ingredients

Ingredient Name	Strength
JOJOBA BUTTER (UNII: XIA46H803R)	
COPPER (UNII: 789U1901C5)	
JOJOBA OIL (UNII: 724GKU717M)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
ETHYL FERULATE (UNII: 5B8915UELW)	
MICA (UNII: V8A1AW0880)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-068-27	1 in 1 CARTON	02/09/2021	
1		2.7 g in 1 JAR; 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	02/09/2021	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
Bentley Laboratories, LLC		068351753	manufacture(42851-068)

Revised: 12/2023

ZO Skin Health, Inc.