

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

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

***Drug Facts***

***Active Ingredients***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
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

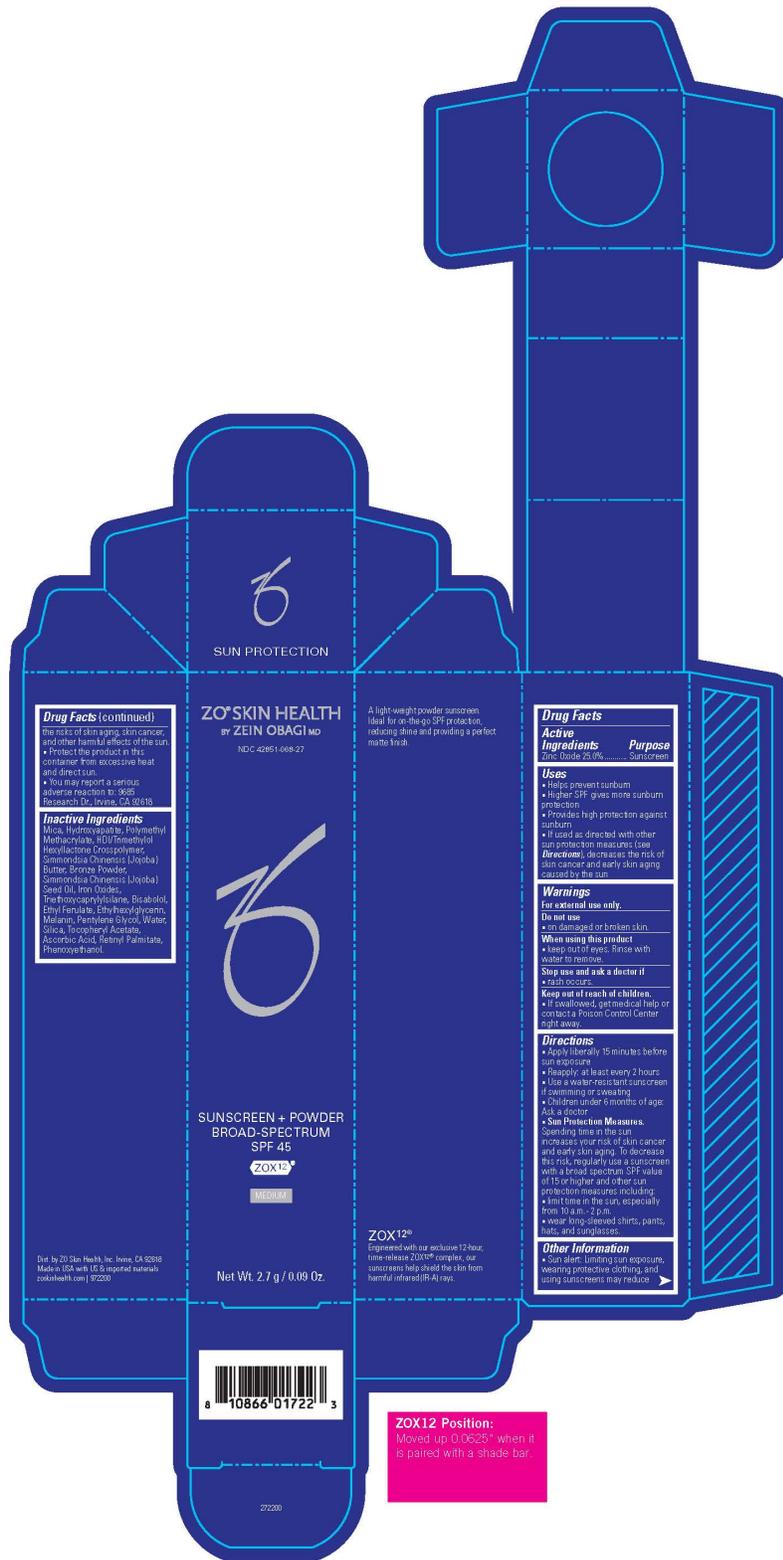
NDC 42851-068-27

SUNSCREEN + POWDER  
BROAD-SPECTRUM  
SPF 45

ZOX12®

MEDIUM

Net Wt. 2.7 g / 0.09 Oz.



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

<b>GRADE / A</b> DSGN / INSP-1, • PREM• QLTY FOR SKN DTL, PREP. FOR: 11/20/14 646755-0235 GRADE A DESIGN • DDT• COM	<b>FINAL</b> <b>1</b> 02.09.21
<b>FILE NAME</b> SunscreenPowder_2_7g_SEC_US_Medium_ZOS127_MECH_F1	
<b>NOTES:</b> 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**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
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)	
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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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: 11/2024

ZO Skin Health, Inc.