

ZEALIOS SUN BARRIER SPF 45- zinc oxide, octinoxate, and octisalate cream
Personal Best Products Inc. dba Zealios

Zealios Sun Barrier SPF 45

Drug Facts

Active Ingredients:	Purpose
Zinc Oxide 8.00%	Sunscreen
Octinoxate 7.50%	Sunscreen
Octisalate 3.00%	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 use 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 Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 80 minutes of swimming or sweating.
 - Immediately after towel drying.
 - 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 am – 2 pm.
 - Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Ascorbyl Palmitate, Butylene Glycol, Cyclopentasiloxane, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Ethyl Hexyl Isononanoate, Iodopropynyl Butylcarbamate, Lauryl PEG-9 Polymethylsiloxyethyl Dimethicone, Phenoxyethanol, Purified Water, Retinyl Palmitate, Sodium Chloride, Triethoxycaprylsilane

Other Info

Protect this product from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL - 88 ml Tube Label

SPORT PERFORMANCE

SUN BARRIER

SPF 45

BROAD SPECTRUM

8% Micronized Zinc Oxide

DRIES

CLEAR

Water Restant (80 min.)

Oil & Fragrance Free

Non-Greasy Sunscreen

3 fl oz (88 ml)

2X4mm

Stay sun protected through the hottest days,
sweatiest adventures & toughest elements.

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zealios

SPORT PERFORMANCE

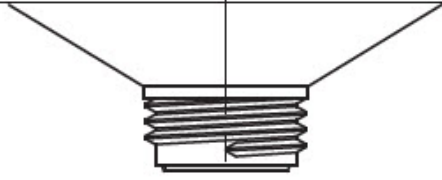
SUN BARRIER

SPF 45
BROAD SPECTRUM
8% Micronized Zinc Oxide



Water Resistant (80 min.)
Oil & Fragrance Free
Non-Greasy Sunscreen

PRINTABLE WIDTH 121mm 3 fl oz (88 ml)



ZEALIOS SUN BARRIER SPF 45

zinc oxide, octinoxate, and octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83326-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83326-001-01	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/08/2015	
2	NDC:83326-001-02	88 mL in 1 TUBE; Type 0: Not a Combination Product	07/08/2015	
3	NDC:83326-001-03	10 mL in 1 PACKET; Type 0: Not a Combination Product	07/08/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M020	07/08/2012	

Labeler - Personal Best Products Inc. dba Zealios (075619252)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss American CDMO		080170933	MANUFACTURE(83326-001)

Revised: 12/2023

Personal Best Products Inc. dba Zealios