

**PURA VIDA SUNSCREEN- zinc oxide, octinoxate, octisalate, and oxybenzone lotion
R & R Lotion, Inc**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pura Vida Sunscreen

Drug Facts

Active Ingredients	Purpose
Octinoxate 5.9%	Sunscreen
Octisalate 3.8%	Sunscreen
Oxybenzone 4.7%	Sunscreen
Zinc Oxide 6.4%	Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer & 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 a rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure reapply:
 - after 80 minutes of swimming or sweating
 - immediatly after towel drying
 - every 2 hours

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 of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10am-2pm
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

Purified DI Water, Octyl Stearate/Octyl Palmitate/Dioctyl Adipate, Propylene Glycol, Glyceryl Stearate & Peg 100, Cetearyl Alcohol & Cetareth 20, Xanthan Gum, Imidazolidinyl Urea, Methyl Paraben, Propyl Paraben, Crodafos N3N, and Vitamin E.

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?

1-888-860-7424

PRINCIPAL DISPLAY PANEL - 236 ML Bottle Label

*for the
Life
of
Your Skin*

***Pura
Vida***

Sunscreen
SPF 30+
protector solar

Zinc Oxide

BROAD SPECTRUM
80 MINUTE WATER RESISTANCE

8 FL. OZ. (236ML) e

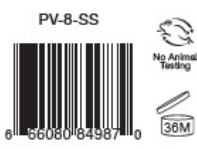
- Physical Barrier Technology
- Water Resistant 80 Minutes
- Fragrance Free
- PA+++ (UVA)
- ISO24444 / ISO24442
- ASTM D120 Compliant

Clear Zinc Oxide Sunscreen provides a Physical Barrier against the Sun, by acting like a million tiny mirrors reflecting both harmful UVA & UVB Rays.

Un protector solar de oxido de zinc transparente que proporciona una barrera fisica contra el sol. Al actuar como un millon de pequeños espejos reflejando los rayos nocivos UVA y UVB.

FDA Registered Manufacture
Made in the USA

Comments/Questions?
1547 N. 77th Street
Scottsdale, AZ 85260
1-888-860-7424



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59555-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	64 mg in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	59 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	38 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	47 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Xanthan Gum (UNII: TTV12P4NEE)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Methylparaben (UNII: A218C7H9T)	
Diethylhexyl Adipate (UNII: MBY1SL921L)	

Ethylhexyl Palmitate (UNII: 2865993309)	
Ethylhexyl Stearate (UNII: EG3PA2K3K5)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
.Alpha.-Tocopherol (UNII: H4N855PNZ1)	
Imidurea (UNII: M629807ATL)	
Diethanolamine Oleth-3 Phosphate (UNII: Y67NX5905E)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Peg-100 Stearate (UNII: YD01N1999R)	
Propylparaben (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59555-106-03	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/21/2015	
2	NDC:59555-106-11	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/21/2015	
3	NDC:59555-106-08	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/21/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/21/2015	

Labeler - R & R Lotion, Inc (062979000)