

BRIGHT GUARD SPORT SPF- zinc spf lotion
RENU LABORATORIES, 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.

Bright Guard Sport SPF 30

Bright Guard Sport SPF 30

sunscreen is broad spectrum, water
resistant (80 minutes), free of parabens
and made for all skin types

Active Ingredients

Octyl Methoxy Cinnamate 7.00% Sunscreen

Titanium Dioxide 1.25% Sunscreen

Zinc Oxide 1.25% Sunscreen

Octyl Salicylate 1.00% Sunscreen

Purpose

Octyl Methoxy Cinnamate 7.00% Sunscreen

Titanium Dioxide 1.25% Sunscreen

Zinc Oxide 1.25% Sunscreen

Octyl Salicylate 1.00% 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.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and consult physician** if irritation or rash develops.
- **Keep out of reach of children.**
- If product is swallowed, get medical attention or contact poison control center immediately.

DIRECTIONS

- Apply generously 15 minutes before sun exposure
- Reapply after 80 minutes of swimming or sweating.
- reapply immediately after towel drying.
- Reapply at least 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 sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including
- Limited time in the sun, especially between 10am and 2pm.
- Wear long sleeve shirts, pants, hats and sunglasses.
- For children under 6 months, consult a physician.

OTHER INGREDIENTS

Aloe Barbadensis (Aloe Vera) Leaf Juice, Caprylyl Glycol, Carbopol, Deionized Water, Cetareth-20, Cetearyl Alcohol, Dimethicone, Isocetyl Stearate, Polyester-7, Neopentyl Glycol, Diheptanoate, Sorbitol, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethanolamine.

Other information

- Protect this product from excessive heat and direct sunlight.
- May stain some fabrics.

Questions or Comments?

Visit www.BrightGuard.com or call (310) 589-4116

Pouch Label

brightguard

Bright Guard Sport SPF 30 Sunscreen is broad spectrum, water resistant (80 minutes) free of parabens and made for all skin types

DRUG FACTS

Active Ingredients

Cetyl Methoxy Cinnamate	7.00%	Sunscreen
Titanium Dioxide	1.25%	Sunscreen
Zinc Oxide	1.25%	Sunscreen
Octyl Salicylate	1.0%	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 contact a physician** if irritation or rash develops. **Keep out of reach of children.**
- If product is swallowed, get medical attention or contact a poison control center immediately .

Directions:

- Apply generously 15-minutes before sun exposure • Reapply: after 80 minutes of swimming or sweating • reapply immediately after towel drying • Reapply at least every two hours • **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including: • Limited time in the sun, especially between 10 am and 2pm. • Wear long sleeve shirts, pants, hats and sunglasses. • For children under 6 months , consult a physician

Other Ingredients: Deionized water, Water (aqua), Isocetyl Stearate, Sorbitol, Cetareth-20, cetaryl Alcohol, Dimethicone, Stearic Acid, Tocopheryl Acetate (vitaminE), Aloe Barbadensis (Aloe Vera) Leaf Juice, Carbopol, Polyester-7, Neopentyl Glycol Diheptanoate Triethanoamine, Capryl Glycol, Methylisothiazolinone

Other Information: • Protect this product from excessive heat and direct sunlight • may stain some fabrics.

Questions or Comments? Visit www.BrightGuard.com or call (310) 5894116

BRIGHT GUARD SPORT SPF 30 POUCH LABEL

BRIGHT GUARD SPORT SPF

zinc spf lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-675
--------------	----------------	--------------------	---------------

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.5 g in 1000 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 g in 1000 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	10 g in 1000 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	12.5 g in 1000 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CARBOMER 934 (UNII: Z135WT9208)	
WATER (UNII: 059QF0KO0R)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-675-01	1000 g in 1 POUCH; Type 0: Not a Combination Product	07/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/01/2021	

Labeler - RENU LABORATORIES, INC. (945739449)

Registrant - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-675)

Revised: 7/2021

RENU LABORATORIES, INC.