

BARUNU SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion
Prime Enterprises, 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.

Barunu Sun Broad Spectrum SPF 50 Sunscreen Lotion

Active ingredients

Avobenzone 3 %, Homosalate 10 %, Octisalate 5 %, Octocrylene 5 %,

Purpose

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

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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 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
 - immediately after towel drying
 - 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 a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hyaluronate, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

Other information

- protect this product from excessive heat and direct sun
- avoid contact with fabrics - could cause discoloration

Questions or comments?

www.barunu.com



FACIAL

**DAILY URBAN
FACE DEFENSE**

BROAD SPECTRUM SPF 50

SUNSCREEN LOTION

50+

- **HYALURONIC ACID**
- **ALOE VERA HYDRATION**
- **VERY HIGH PROTECTION**

UVB + UVA

- *Fragrance Free*
- *Water Resistant*
- *Non Greasy*

2.5 Fl. Oz. (74 mL)

DAILY URBAN FACE DEFENSE SPF 50+ is a lotion designed for the daily defense of facial skin against sun rays, environmental damage and premature aging. Contains **ALOE VERA** and **HYALURONIC ACID** which gives deep hydration and moisture to your skin, rich in vitamins, antioxidants and maintains broad spectrum **UVA** and **UVB** protection during the day. This lotion is fragrance free, water resistant, quick drying and non greasy.

Drug Facts

Active ingredients	Purpose
Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 5%	Sunscreen

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Directions

- apply liberally 15 minutes before sun exposure and rub into skin
- reapply:
 - after 80 minutes of swimming or sweating
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- **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:
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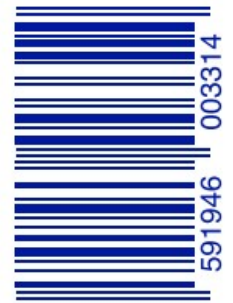
www.barunu.com



MADE IN USA
FROM US AND IMPORTED INGREDIENTS
DISTRIBUTED BY:
BARUNU INTERNACIONAL
Miami, FL, 33172



@poderdelasabila



BARUNU SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0577
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.89 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	96.3 mg in 1 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.15 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0577-3	74 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	05/11/2022	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0577) , pack(58443-0577) , manufacture(58443-0577) , analysis(58443-0577)

Revised: 9/2022

Prime Enterprises, Inc.