

PANAMA JACK SPF 8- avobenzone, 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.

Panama Jack 8 SPF 8 Sunscreen Lotion

Active Ingredients

Avobenzone 2%

Octocrylene 2%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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 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
- children under 6 months: Ask a doctor

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Cetyl Alcohol, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, Isopropylphthalimide, PEG-100 Stearate, Phenoxyethanol, Polyethylene, Propylene Glycol, Sodium Hydroxide, Stearyl Alcohol, Tocopheryl

Acetate, Ubiquinone, Water, Xanthan Gum

Other information

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

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack 8 SPF 8 Sunscreen Lotion



Take your place in the sun and take us with you.
Panama Jack. For All Sunkind.™

- Reef-Friendly
- Cruelty Free
- PABA Free
- Gluten Free
- Paraben Free
- Retinyl Palmitate Free
- Octinoxate Free
- Oxybenzone Free

| Drug Facts | |
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0-45336-05108-1

Distributed by: Panama Jack, Inc. Orlando, FL 32801 www.panamajack.com
Made in USA from US and Imported ingredients.

| PANAMA JACK SPF 8 | | | |
|--------------------------------|----------------|--------------------|----------------|
| avobenzone, octocrylene lotion | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58443-0282 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 19.68 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 19.68 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| N-BUTYLPHthalimide (UNII: 5TH1DKT35E) | |
| CARBOMER 980 (UNII: 4Q93RCW27E) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| UBIDECARENONE (UNII: EJ27X76M46) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| ISOPROPYLPHthalimide (UNII: 1J1MM83329) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58443-0282-4 | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/15/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 02/15/2019 | |

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---|
| Prime Enterprises Inc. | | 101946028 | pack(58443-0282) , manufacture(58443-0282) , label(58443-0282) , analysis(58443-0282) |

Revised: 1/2021

Prime Enterprises Inc.