

PANAMA JACK BROAD SPECTRUM SPF 30- 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.

Panama Jack Sport Broad Spectrum SPF 30 Sunscreen Lotion 30

Active Ingredients

Avobenzone 3%

Homosalate 7.5%

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

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 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, Cetyl Alcohol, Cetyl Phosphate, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, PEG-100 Stearate, Phenoxyethanol, Phenyl Trimethicone, Polyethylene, Propylene Glycol, Silica, Sodium Hydroxide, Stearyl Alcohol, Tocopheryl Acetate, Ubiquinone, Water

Other information

- may stain some fabrics
- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack Sport Broad Spectrum SPF 30 Sunscreen Lotion 30

Panama Jack

Sport

Broad Spectrum SPF 30 Sunscreen Lotion

30

UVA / UVB Protection
Paraben Free • PABA Free • Non-Greasy
Water Resistant (80 Minutes)

REEF FRIENDLY

3 FL OZ (89 mL)

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

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

Drug Facts

| Active Ingredients | Purpose |
|--------------------|-----------|
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| Octocrylene 5% | |

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REEF FRIENDLY

0 45336 08230 6

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

PANAMA JACK BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58443-0284 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 29.94 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 49.9 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 49.9 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 74.85 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| STEARYL ALCOHOL (UNII: 2KR89I4HIY) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| UBIDECARENONE (UNII: EJ27X76M46) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CETYL PHOSPHATE (UNII: VT07D6X67O) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:58443-0284-3 | 89 mL in 1 TUBE; Type 0: Not a Combination Product | 03/28/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 03/28/2019 | |

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---|
| Prime Enterprises Inc. | | 101946028 | pack(58443-0284) , manufacture(58443-0284) , label(58443-0284) , analysis(58443-0284) |

Revised: 1/2021

Prime Enterprises Inc.