PANAMA JACK BROAD SPECTRUM 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.

Panama Jack 50 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

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, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, PEG-100 Stearate, Phenoxyethanol, Polyethylene, Propylene Glycol, Sodium Hydroxide, Stearyl Alcohol, Tocopheryl Acetate, Ubiquinone, Water, Xanthan Gum

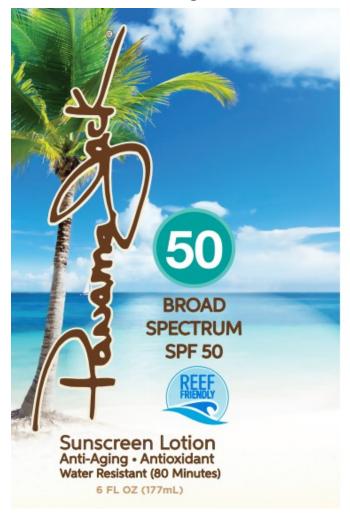
Other information

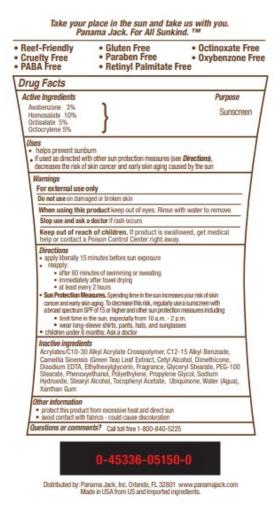
- protect this product from excessive heat and direct sun
- avoid contact with fabrics could cause discoloration

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack 50 Broad Spectrum SPF 50 Sunscreen Lotion





PANAMA JACK BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0288
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.67 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	49.45 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.45 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	98.9 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR8914H1Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
UBIDECARENO NE (UNII: EJ27X76 M46)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PEG-100 STEARATE (UNII: YD0 1N1999R)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0288-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/06/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		10 19 46 0 28	pack(58443-0288), manufacture(58443-0288), label(58443-0288), analysis(58443-0288)

Revised: 1/2021 Prime Enterprises Inc.