

PANAMA JACK SPF 4- octinoxate oil

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.

Active ingredients

Octinoxate 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
 - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Extract, Arachis Hypogaea (Peanut) Oil, Citrus Medica Limonum (Lemon) Peel Oil, Cocos Nucifera (Coconut) Oil, Fragrance, Mineral Oil, Olea Europaea (Olive) Fruit Oil, Propylparaben, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Theobroma Cacao (Cocoa) Seed Butter

Other information

- protect this product from excessive heat and direct sun

Questions or Comments?

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label


Dark Tanning Oil SPF 4

Drug Facts

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Questions or comments?
Call toll free 1-800-840-5225 www.panamajack.com

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Formulated with Love, Care and Pride since 1974

Questions or Comments? Email us at info@panamajack.com
Distributed by: Panama Jack, Inc. Orlando, FL 32801 Made in USA

Panama jack

SPF 4

Dark

Tanning Oil

Exotic Natural Oils

Fruit & Nut Extracts

Light Sunscreen Formula

8 FL OZ (237 mL)

PANAMA JACK SPF 4

octinoxate oil

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0066	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	16.8 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
PEANUT OIL (UNII: 5TL50QU0W4)				
LEMON OIL (UNII: I9GRO824LL)				
MINERAL OIL (UNII: T5L8T28FGP)				
COCONUT OIL (UNII: Q9L0O73W7L)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
ALMOND OIL (UNII: 66YXD4DKO9)				
COCOA BUTTER (UNII: 512OYT1CRR)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0066-3	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/24/2013	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		01/24/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0066) , pack(58443-0066) , manufacture(58443-0066) , analysis(58443-0066)

