

**PANAMA JACK SPF 45 FLAVORLESS LIP BALM- avobenzone, homosalate, octinoxate, octisalate, petrolatum stick
Panama Jack**

Drug Facts

Active ingredient

Avobenzone 3.0%, Homosalate 3.0%, Octinoxate 7.5%, Octisalate 5.0%.....Sunscreen, Petrolatum 40.0%.....Skin Protectant

Purpose

Sunscreen, Skin Protectant

Keep Out of Reach of Children

If swallowed get medical help or contact a Poison Control Center right away.

Uses

Prevents Sunburns. Helps prevent wind burned and chapped lips.

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 to prevent sunburn, skin cancer and/or early aging.

For external use only: Stop use and ask a doctor: if rash or irritation develops and lasts.

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 the 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

C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Mineral Oil, Ozokerite, Phenyl Trimethicone, Tocopherol

Package/Label Principal Display Panel

SEALED • SAFETY SEALED • SEALED • SAFETY SEALED • SEALED • SAFETY SEALED

Drug Facts (Continued)

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 swallowed get medical help or contact a Poison Control Center right away.

Directions:

- Apply liberally 15 minutes before sun exposure and as needed.
- 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 the 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: C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Mineral Oil, Ozokerite, Phenyl Trimethicone, Tocopherol.

LAB-2719 LCSNOFN45

Drug Facts

Active ingredients:	Purpose
Avobenzone (3.0%), Homosalate (3.0%)	Sunscreen
Octinoxate (7.5%), Octisalate (5.0%)	Sunscreen
Petrolatum (40.0%)	Skin Protectant

Uses:

- Helps prevent sunburn. Helps prevent and temporarily protects dry, chapped lips.
- 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.

Questions or Comments? 1.800.848.5225

Distributed by: Panama Jack, Inc. Orlando, FL 32801
 Made in USA www.panamajack.com



0 45336 00602 9

PANAMA JACK.

45 FLAVORLESS LIP BALM

**Broad Spectrum
SPF 45**



Net Wt. 0.15 oz (4.25g)
 ▼ Lift for Drug Facts Continued ▼

PANAMA JACK SPF 45 FLAVORLESS LIP BALM

avobenzone, homosalate, octinoxate, octisalate, petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87449-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	30 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	400 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	122 mg in 1 g
CERESIN (UNII: Q1LS2UJO3A)	170 mg in 1 g

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87449-200-01	4.25 g in 1 CONTAINER; Type 0: Not a Combination Product	02/26/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	352	02/26/2026	

Labeler - Panama Jack (098368566)**Registrant** - OraLabs (801824756)**Establishment**

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	manufacture(87449-200) , label(87449-200) , analysis(87449-200)