

CARE ONE ORIGINAL SPF 4 LIP BALM- padimate o, petrolatum stick
American Sales Company

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.

Drug Facts

Active ingredient

Padimate O, Petrolatum

Purpose

Sunscreen, Skin Protectant

Keep Out of Reach of Children

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

Uses

Helps prevent sunburn. Helps prevent and temporarily protects dry, chapped or windburned 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 only to prevent sunburn, not skin cancer or early aging.

For external use only

Stop use and ask a doctor: If rash or irritation develops and lasts.

Directions

Apply liberally before sun exposure and as needed.

Children under 6 months of age: Ask a doctor before use.

Inactive Ingredients

Mineral Oil, Ozokerite, Microcrystalline Wax, Phenyl Trimethicone, Lanolin, Copercicia (Carnauba) Wax, Isopropyl Myristate, Cetyl Alcohol, Euphorbia Cerifera (Candelilla) Wax, Flavor, Camphor, Methylparaben, Titanium Dioxide (CI 77891), Yellow 5 Lake (CI 19140), Red 6 Lake (CI 15850).

Package/Label Principal Display Panel



CARE ONE ORIGINAL SPF 4 LIP BALM

padimate o, petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-979
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	44.0 mg in 1 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	3.00 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	1 mg in 1 g
CERESIN (UNII: Q1LS2UJO3A)	17.30 mg in 1 g
CARNAUBA WAX (UNII: R12CBM0EIZ)	1 mg in 1 g
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	2.23 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	27.50 mg in 1 g

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-979-02	1 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/15/2013	

Labeler - American Sales Company (809183973)**Registrant** - American Sales Company (809183973)**Establishment**

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(41520-979) , LABEL(41520-979)

Revised: 3/2013

American Sales Company