

CARE ONE MEDICATED LIP BALM IN A POT- petrolatum ointment
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

Petrolatum

Purpose

Skin Protectant

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center immediately. Do not induce vomiting before contacting a Poison Control Center.

Uses

Helps prevent and temporarily protect dry and chapped lips.

Warnings

For external use only: When using this product: avoid contact with eyes. Rinse with water to remove. Stop use and consult a doctor if: condition worsens or lasts more than 7 days. Do not induce vomiting before contacting a Poison Control Center. For adults and children over 2 years of age.

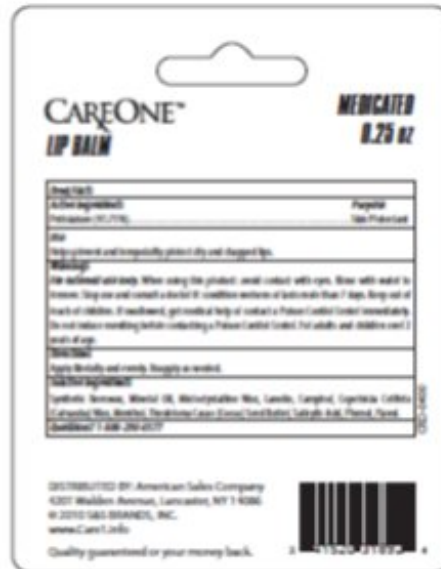
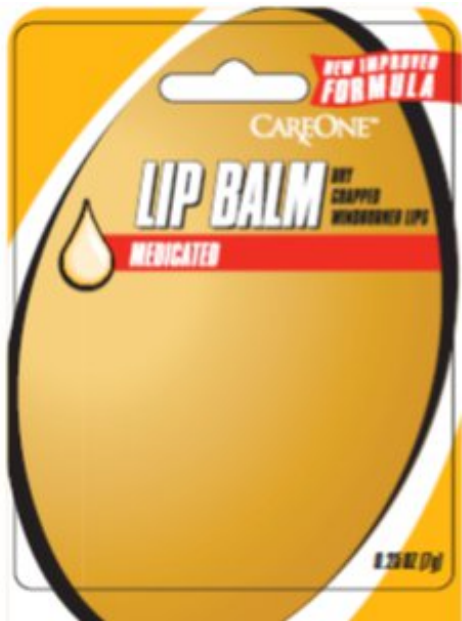
Directions

Apply liberally and evenly. Reapply as needed.

Inactive Ingredients

Synthetic Beeswax, Mineral Oil, Microcrystalline Wax, Lanolin, Camphor, Copernicia Cerifera (Carnauba) Wax, Menthol, Theobroma Cacao (Cocoa) Seed Butter, Salicylic Acid, Phenol, Flavor

Package/Label Principal Display Panel



CARE ONE MEDICATED LIP BALM IN A POT

petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-976
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	43.75 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WHITE WAX (UNII: 7G1J5DA97F)	15.65 mg in 1 g
MINERAL OIL (UNII: T5L8T28FGP)	15.5 mg in 1 g
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	12 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	8 mg in 1 g
3-BROMOCAMPHOR, (+/-)- (UNII: NAY429URSN)	1.7 mg in 1 g
CARNAUBA WAX (UNII: R12CBM0EIZ)	.85 mg in 1 g
COCOA BUTTER (UNII: 512OYT1CRR)	.70 mg in 1 g
MENTHOL (UNII: L7T10EIP3A)	.70 mg in 1 g
2-BUTANOYLOXYBENZOIC ACID (UNII: K60ASJ7Z6N)	.5 mg in 1 g
PHENOL (UNII: 339NCG44TV)	0.4 mg in 1 g

Product Characteristics

Color		Score	
Shape		Size	

Flavor	MENTHOL		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-976-03	1 g in 1 CONTAINER		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	03/12/2013		

Labeler - American Sales Company (809183973)

Registrant - American Sales Company (809183973)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(41520-976) , LABEL(41520-976)

Revised: 3/2013

American Sales Company