

CARE ONE MEDICATED LIP BALM- 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

Petrolatum

Purpose

Skin Protectant

Keep Out of Reach of Children

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

Uses

Helps heal severely dry, chapped lips.

Warnings

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

Directions

Apply to lips not more than 3 – 4 times daily. Children under six months of age: Ask doctor before use.

Inactive Ingredients

Beeswax, Camphor, Cetyl Alcohol, Flavor, Ispropyl Myristate, Lanolin, Menthol, Methylparaben, Mineral Oil, Octyldodecanol, Oleyl Alcohol, Ozokerite, Phenol, Phenyl Trimethicone, Propylparaben, Stearyl Alcohol, Water

Package/Label Principal Display Panel

Front of Card 3.5in x 3.875in

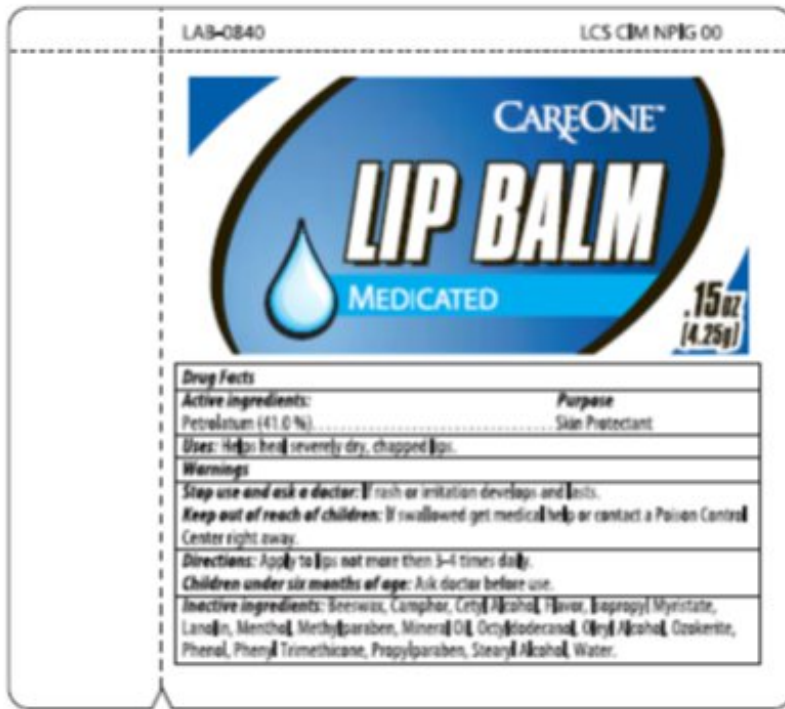


Back of Card



2.375in

label



2.125in

CARE ONE MEDICATED LIP BALM

petrolatum stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-975

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	41 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	16 mg in 1 g
APIS CERANA WORKER SECRETION (UNII: PRG8653U8K)	6 mg in 1 g
OLEYL ALCOHOL (UNII: 172F2WN8DV)	6 mg in 1 g
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	5 mg in 1 g
OCTYLDODECANOL (UNII: 461N1O614Y)	9 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	4 mg in 1 g
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	3 mg in 1 g
CETYL ALCOHOL (UNII: 936JST6JCN)	3 mg in 1 g
LIGHT MINERAL OIL (UNII: N6K5787QVP)	3 mg in 1 g
MENTHOL (UNII: L7T10EIP3A)	.60 mg in 1 g

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-975-02	4.25 g in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/11/2013	

Labeler - American Sales Company (809183973)

Registrant - American Sales Company (809183973)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(41520-975) , LABEL(41520-975)

