

CHAPICE MEDICATED BALM- camphor, menthol gel
OraLabs

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

Camphor (1.7%), Menthol (0.7%)

Purpose

External Analgesic, External Analgesic

Keep Out of Reach of Children

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

Uses

Helps to provide relief of the symptoms of cold sores and dry chapped lips.

Warnings

For external use only. When using this product: avoid contact with eyes. Stop use and ask a doctor if irritation and rash occur.

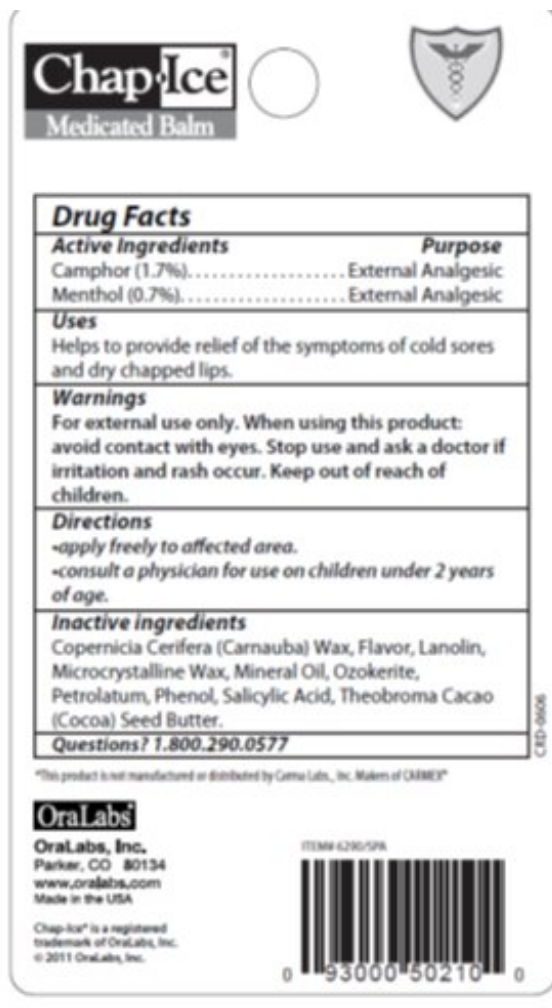
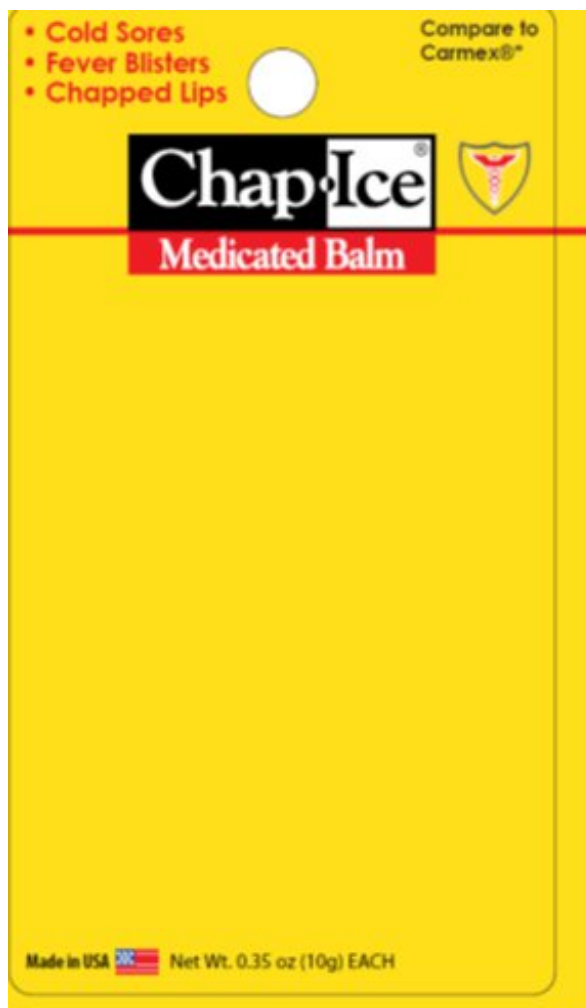
Directions

Apply freely to affected area. Consult a physician for use on children under 2 years of age.

Inactive Ingredients

Copernicia Cerifera (Carnauba) Wax, Flavor, Lanolin, Microcrystalline Wax, Mineral Oil, Ozokerite, Petrolatum, Phenol, Salicylic Acid, Theobroma Cacao (Cocoa) Seed Butter.

Package/Label Principal Display Panel



CHAPICE MEDICATED BALM			
camphor, menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63645-161
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)		CAMPHOR (SYNTHETIC)	1.700 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	0.700 mg in 1 g
Inactive Ingredients			
Ingredient Name		Strength	
LIGHT MINERAL OIL (UNII: N6K5787QVP)		1.053 mg in 1 g	
PHENOL (UNII: 339NCG44TV)		0.400 mg in 1 g	
EUCALYPTUS OIL (UNII: 2R04ONI662)		0.500 mg in 1 g	

PETROLATUM (UNII: 4T6H12BN9U)	83.947 mg in 1 g
CERESIN (UNII: Q1LS2UJO3A)	1.000 mg in 1 g
LANOLIN (UNII: 7EV65EAW6H)	8.000 mg in 1 g

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63645-161-04	1 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/15/2013	

Labeler - OraLabs (801824756)

Registrant - OraLabs (801824756)

Establishment

Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(63645-161) , LABEL(63645-161)

Revised: 8/2013

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