LEADER CAMPHOR PHENOL GEL- camphor, phenol gel Cardinal Health (Leader)

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 (10.8%), Phenol (4.7%)

Purpose

Pain reliever/antiseptic

Keep Out of Reach of Children

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

Uses

For the temporary relief of pain and itching associated with cold sores and fever blisters. First aid to help prevent infection.

Warnings

For external use only. Do not use over large areas of the body or with a bandage. Ask a doctor before use if you have a deep or puncture wound. Animal bites. Serious burns. When using this product do not use near the eye. If contact occurs, rinse eyes thoroughly with water and obtain medical attention.

Directions

Adults and children 2 years or over: clean the affected area. Apply directly to the cold sore or fever blister 1 to 3 times daily. Do not bandage. Children under 2 years: ask a doctor.

Inactive Ingredients

Eucalyptus, Glycerin, Mineral Oil, Silica.

Package/Label Principal Display Panel

OraLabs







(LEADER®)

Cold Sore Treatment

"This product is not manufactured or distributed by Bayer HealthCare, owner of the registered trademark Campho-Phenique".

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017 CIN 455847 WWW.myleader.com All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund



Inactive ingredients: Eucalyptus, Glycerin, Mineral Oil, Silica. crose cover trightly after each use Other information do not bandage
children under 2 years: ask a doctor apply directly to the cold sore or fever blister 1 to 3 times daily dean the affected area Do not induce vomiting before contacting medical help or a Poison Control Center. Center right away. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Stop use and ask a doctor if - condition worsens - symptoms persist for more than 7 days or dear up and occur again within a few days with water and obtain medical attention a deep or puncture wound - animal blees - serious burns
When using this product do not use near the eyes. If contact occurs, rinse eyes thorou Ask a doctor before use if you have over large areas of the body - with a bandage Do not use erateild reveal bins sense bloo rithw bateloozes gnirbti bins nisq to telegon ynsoognes and tever blisters (27%), Phenol (4.7%), Phenol (4.7%). Active ingredients Drug Facts



camphor, phenol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-751
Doute of Administration	TO DIC A I		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	10.8 mg in 1 g		
PHENOL (UNII: 339 NCG44TV) (PHENOL - UNII:339 NCG44TV)	PHENOL	4.7 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	77.75 mg in 1 g	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	5.75 mg in 1 g	
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mg in 1 g	
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.500 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:37205-751-23	1 g in 1 CONTAINER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/15/2013	

Labeler - Cardinal Health (Leader) (097537435)

Registrant - Cardinal Health (Leader) (097537435)

Establishment				
Name	Address	ID/FEI	Business Operations	
OraLabs, Inc.		801824756	MANUFACTURE(37205-751), LABEL(37205-751)	

Revised: 4/2014 Cardinal Health (Leader)