

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.

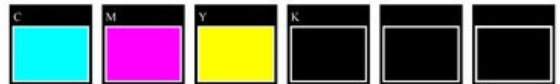
Inactive Ingredients

Eucalyptus, Glycerin, Mineral Oil, Silica.

Package/Label Principal Display Panel



Imprint Color(s)



camphor, phenol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-751
Route of Administration	TOPICAL		

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: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	4.7 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	77.75 mg in 1 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	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)

