CHAPICE CAMPHOR PHENOL GEL- camphor, phenol 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 10.8%, Phenol 4.7%

Purpose

External Analgesic

Keep Out of Reach of Children

If swallowed, get medical help or contact a Poison Control Center immediately. Do not induce vomiting before contacting medical help or a Poison Control Center. For adults and children over 2 years of age.

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 puncture wound, animal bites, or serious burns.

When using this product: avoid contact with eyes. Rinse with water to remove. Seek medical help or contact a Poison Control Center.

Stop use and consult a doctor if: conditions worsen or last more than 7 days, or if it clears up and returns again in a few days.

Directions

Adults and children over 2 years clean the affected area and apply directly to a cold sore or fever blister 1 to 3 times daily. Do not bandage.

Inactive Ingredients

Colloidal Silicon Dioxide, Eucalyptus Oil, Glycerin, Light Mineral Oil

Package/Label Principal Display Panel

CHAPICE CAMPHOR PHENOL GEL

camphor, phenol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63645-160
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:63645-160-04	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(63645-160) , LABEL(63645-160)

Revised: 7/2013 OraLabs