SHOPKO CAMPHOR PHENOL GEL- camphor, phenol gel Shopko

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 immediately. 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 puncture wound, animal bites, or serious burns.

When using this product: do not use near the eyes. If contact occurs, rinse eyes thoroughly with water and obtain medical attention.

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

Directions

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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. Children under 2 years: ask a doctor.

Inactive Ingredients

Eucalyptus Globulus Leaf Oil, Glycerin, Mineral Oil, Silica

Package/Label Principal Display Panel



Net Wt. 0.23 oz (6.5g)

SHOPKO Cold Sore Treatment

Camphor + Phenol

SHOPKO CAMPHOR PHENOL GEL

camphor, phenol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37012-734

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active wrotety			
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:37012-734-04	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 - Shopko (023252638)

Registrant - Shopko (023252638)

Establishment			
Name	Address	ID/FEI	Business Operations
OraLabs		801824756	MANUFACTURE(37012-734), LABEL(37012-734)

Revised: 7/2013 Shopko