PREMIER VALUE COLD SORE TREATMENT- camphor cream
Premier Value

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 ingredients

Benzalkonium chloride 0.13%

Camphor 3.0%

Purpose

Cold sore/fever blister treatment/first aid antiseptic

Uses

- for treatment of cold sores/fever blisters on the face or lips
- temporarily relieves the symptoms of itching and pain associated with cold sores/fever blisters
- first aid to help protect against infection in minor cuts, scrapes, burns, and sores

Warnings

For external use only: Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites or serious burns, consult a physician.

Allergy Alert: Do not use if you are allergic to any of the ingredients in this product.

When using this product avoid contact with eyes. Use only as directed.

Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions

- clean the affected area
- apply a small amount of this product to the affected area 1 to 3 times daily
- rub in gently
- may be covered with a sterile bandage
- wash hands before and after applying cream
- do not share this product with anyone
- **children under 12 years of age**: ask a doctor

Other information
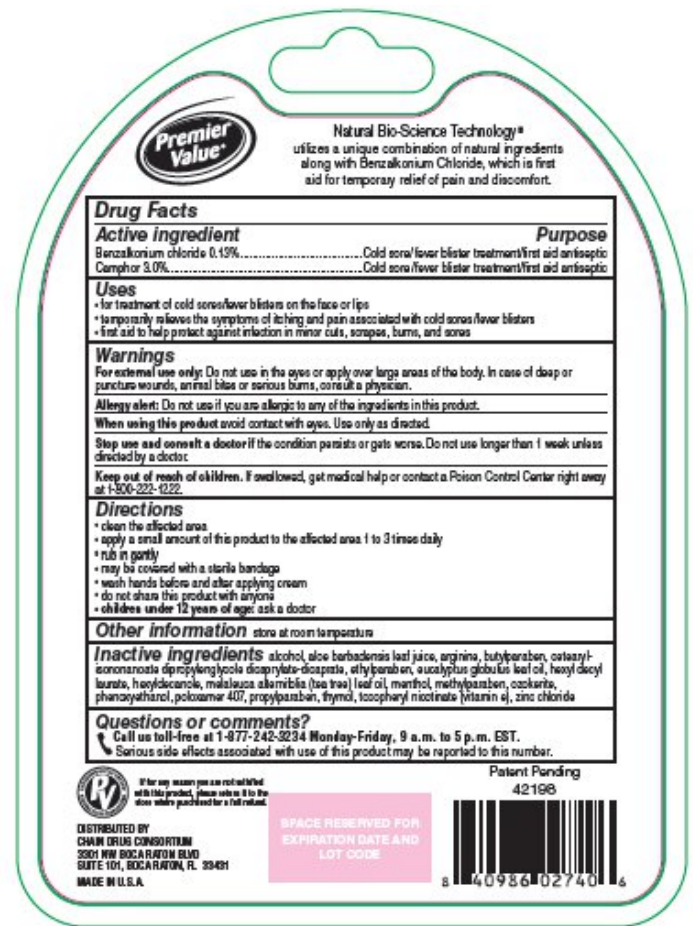
store at room temperature

Inactive ingredients

alcohol, aloe barbadensis leaf juice, arginine, butylparaben, cetearyl isononanoate, dipropylene glycol dicaprylate/dicaprate, ethylparaben, eucalyptus globulus leaf oil, hexyl decyl laurate, hexyldecanole, melaleuca alternifolia (tea tree) leaf oil, menthol, methylparaben, ozokerite, phenoxyethanol, poloxamer 407, propylparaben, thymol, tocopheryl nicotinate (vitamin e), zinc chloride

Questions or Comments?

Call us toll-free at 1-877-242-3234 Monday-Friday, 9 a.m. to 5 p.m. EST.
Serious side effects associated with use of this product may be reported to this number.

FPO TUBE BACK

PREMIER VALUE COLD SORE TREATMENT			
camphor cream			

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-407
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	1.3 mg in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Arginine (UNII: 94ZLA3W45F)	
Butylparaben (UNII: 3QPI1U3FV8)	
Ceresin (UNII: Q1LS2UJO3A)	
Cetearyl Isononanoate (UNII: P5O01U99NI)	
Corymbia Citriodora Leaf Oil (UNII: M63U6N96EB)	
Dipropylene Glycol Caprate/Caprylate Diester (UNII: R6G12EY23X)	
Ethylparaben (UNII: 14255EXE39)	
Hexyldecanol (UNII: 151Z7P1317)	
Hexyldecyl Laurate (UNII: 0V595C1P6M)	
Levomenthol (UNII: BZ1R15MTK7)	
Methylparaben (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Propylparaben (UNII: Z8IX2SC1OH)	
Tea Tree Oil (UNII: VIF565UC2G)	
Thymol (UNII: 3J50XA376E)	
TOCOPHERYL NICOTINATE, D-.ALPHA. (UNII: WI1J5UCY5C)	
Zinc Chloride (UNII: 86Q357L16B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-407-01	1 in 1 PACKAGE		
1		2 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/16/2013	

Labeler - Premier Value (101668460)

Registrant - Ranir LLC (364567615)

Establishment

Name	Address	ID/FEI	Business Operations
Ranir LLC		364567615	REPACK(68016-407) , RELABEL(68016-407)

Revised: 4/2013   Premier Value