AVERTEAX- benzyl alcohol cream Camellix, LLC

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.

AVERTEX Benzyl Alcohol

Active ingredient Purpose

Benzyl Alcohol (1.0%) Cold Sores & Fever blisters

PURPOSE:

Treats cold sores and fever blisters, a vesicle that occurs at the junction of the mucous membrane and the skin on the lips or nose and is caused by the virus herpes simplex, type 1.

ASK DOCTOR:

If condition worsens or does not improve after regular use of the product as directed, consult a doctor. If swallowed, contact a doctor.

WARNINGS:

For external use only.

DIRECTIONS:

For the temporary relief of pain and itching of cold sores and fever blisters, apply AverTeaX ointment directly on the affected area throughout the day as needed. To achieve best result, apply at the frist sign of symptons (redness, tingling, tightness, or itching.)

STOP USE:

If illergic to any ingridient of the product.

INDICATIONS & USAGE:

Indications are for pain and itching associated with fever blisters and cold sores.

For the temporary Relief of Pain and itching associated with fever blisters and cold sores.

DO NOT USE:

If allergic to any ingredient of the product.

KEEP OUT OF REACH OF CHILDREN:

- Keep out of reach of children.
- If swallowed, contact a doctor.

INACTIVE INGREDIENT

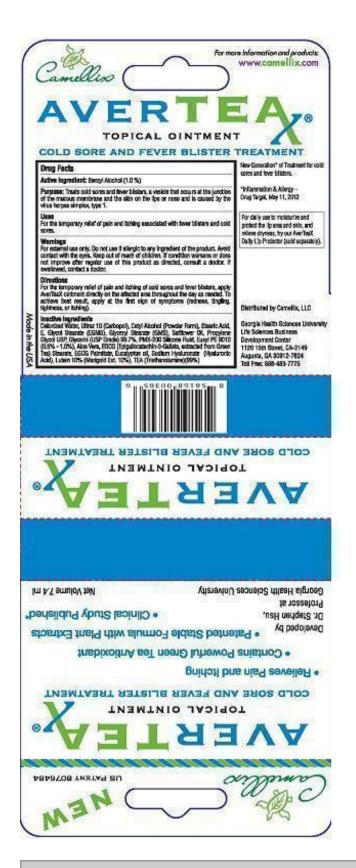
Ultrez 10 (Carbopol), Cetyl Alcohol (Powder Form), Stearic Acid, E. Glycol Stearate (EGMS),

Glyceryl Stearate (GMS), Safflower Oil, Propylene Glycol USP, Glycerin (USP Grade) 99.7%, PMX-200 Silicone Fluid, Euxyl PE 9010 (0.5% - 1.0%), Aloe Vera, EGCG (Epigallocatechin-3-Gallate, Extracted from Green Tea) Stearate, EGCG Palmitate, Eucalyptus oil, Sodium Hyaluronate (Hyaluronic Acid), Lutein 10% (Marigold Ext. 10%), TEA (Triethanolamine)(99%).

AVERTEAX TOPICAL OINTMENT COLD SORES AND FEVER BLISTERS TREATMENT DISTRIBUTED BY CAMELLIX MADE IN USA

Principal display panal





AVERTEAX

benzyl alcohol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54866-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
Safflower Oil (UNII: 65UEH262IS)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
EPIGALLO CATECHIN GALLATE STEARATES (UNII: MGB2NQG22C)	
EPIGALLO CATECHIN GALLATE PALMITATES (UNII: M213AC47MB)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
Hyaluronic Acid (UNII: S270N0TRQY)	
LUTEIN (UNII: X72A60C9MT)	
CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:54866-002-01	1 in 1 PACKAGE			
1	7.4 g in 1 TUBE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	0 1/0 1/20 14		

Labeler - Camellix, LLC (968429386)

Establishment				
Name	Address	ID/FEI	Business Operations	
Star Health and Beauty, LLC		013506838	manufacture(54866-002)	

Revised: 3/2014 Camellix, LLC