# AVERTEAX- zinc oxide and cocoa butter ointment 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.

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# AVERTEX Zinc Oxide & Cocoa Butter

# Active ingredient Purpose

Zinc Oxide (0.015%) Cold Sores & Fever blisters Cocoa Butter(0.25%) Cold Sores & Fever blisters

# **PURPOSE:**

Treatment for 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:**

Apply daily as a lip moisturizer and protector for dryness, cold sores, or fever blisters. To achieve best results, apply at the first sign of symptoms (dryness, cracking) directly on the lip and affected area as needed.

#### OTHER INFORMATION:

During an outbreak, also use AverTeaX Topical Ointment for temporary relief of pain and itching.

#### STOP USE IF:

Do not use if allergic to any ingredient of the product.

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

# **INDICATIONS & USAGE:**

Indications are for relief of dryness, cold sores and fever blisters.

For relief of dryness, soften cold sores and fever blisters.

#### 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.

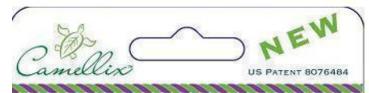
# **INACTIVE INGREDIENT:**

Sweet Almond Oil, Grape Seed Oil, Bees Wax, Shea Butter, Aloe Vera Extract, Royal Jelly, EGCG (Epigallocatechin-3-Gallate, Extracted from Green Tea) Stearate, EGCG Palmitate, Vitamin E, Eucalyptus oil.

AVERTEAX DAILY LIP PROTECTOR FOR DRYNESS, COLD SORES & FEVER BLISTERS DISTRIBUTED BY CAMELLIX MADE IN USA

# Principal display panal





# DAILY LIP PROTECTOR

FOR DRYNESS, COLD SORES & FEVER BLISTERS

- Relieves Dryness
  - Softens Cold Sore and Fever Blisters
    - Contains Powerful Green Tea Antioxidant

Developed by Dr. Stephen Hsu, Professor at

Patented Stable Formula with Plant Extracts

Clinical Study Published\*

Georgia Health Sciences University

Net Weight 4.2 g (0.15 oz)



FOR DRYNESS, COLD SORES & FEVER BLISTERS



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Active Ingredients: Zinc Oxido (0.015%), Cocos Buttor (0.25%)

Drug Facts

Georgia Health Sciences University Distributed by Camerix, LLC

TOT Free: 888-483-7775

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FOR DRYNESS, COLD SORES & FEVER BLISTERS



www.camellix.com For more information and products: zinc oxide and cocoa butter ointment

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:54866-003 |
| Route of Administration | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                                    |                   |                |  |
|--|-------------------|----------------|--|
| Ingredient Name  | Basis of Strength | Strength       |  |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)       | ZINC OXIDE        | 0.15 mg in 1 g |  |
| COCOA BUTTER (UNII: 5120 YT1CRR) (COCOA BUTTER - UNII:5120 YT1CRR) | COCOA BUTTER      | 2.5 mg in 1 g  |  |

| Inactive Ingredients                                    |          |
|---|----------|
| Ingredient Name   | Strength |
| ALMOND OIL (UNII: 66 YXD4DKO9)                          |          |
| GRAPE SEED OIL (UNII: 930 MLC8 XGG)                     |          |
| YELLOW WAX (UNII: 2ZA36H0S2V)                           |          |
| SHEA BUTTER (UNII: K49 155WL9 Y)                        |          |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)                    |          |
| Royal Jelly (UNII: L497I37F0C)                          |          |
| EPIGALLO CATECHIN GALLATE STEARATES (UNII: MGB2NQG22C)  |          |
| EPIGALLO CATECHIN GALLATE PALMITATES (UNII: M213AC47MB) |          |
| .ALPHATOCOPHEROL (UNII: H4N855PNZ1)                     |          |
| EUCALYPTUS OIL (UNII: 2R04ONI662)                       |          |

| Packaging          |                     |                      |                    |
|--------------------|---------------------|----------------------|--------------------|
| # Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:54866-003-01 | 1 in 1 PACKAGE      |                      |                    |
| 1                  | 4.2 g in 1 TUBE     |                      |                    |

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

# Labeler - Camellix, LLC (968429386)

| Establishment               |         |           |                        |  |
|-----------------------------|---------|-----------|------------------------|--|
| Name                        | Address | ID/FEI    | Business Operations    |  |
| Star Health and Beauty, LLC |         | 013506838 | manufacture(54866-003) |  |

Revised: 3/2014 Camellix, LLC