

HYVEE COLD SORE TREATMENT - benzalkonium chloride cream

Hyvee

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

Benzalkonium Chloride 0.13%

Purpose

Cold Sore/Fever Blister Treatment/First Aid Antiseptic

Uses

- For treatment of cold sores/fever blisters on the face or lips
- Helps relieve the symptoms of itching, burning and pain associated with cold sores/fever blisters in just one day
- Relieves dryness and softens cold sores and 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. (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
- 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, Camphor, Cetearylisononanoate, Dipropylenglycole Dicaprylate-Dicaprate, Ethylparaben, Eucalyptus Globulus Leaf Oil, Hexyldecanole, Hexyl Decyl Laurate, Menthol, Methylparaben, Ozokerite, Phenoxyethanol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Poloxamer 407, Propylparaben, Tocopheryl Nicotinate (Vitamin E), Thymol, 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.



Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

HYVEE COLD SORE TREATMENT

benzalkonium chloride cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42507-406 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|---------------|
| Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6 Y) | Benzalkonium Chloride | 1.3 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Alcohol (UNII: 3K9958V90M) | |
| Aloe Vera Leaf (UNII: ZY81Z83H0X) | |
| Arginine (UNII: 94ZLA3W45F) | |
| Butylparaben (UNII: 3QPIU3FV8) | |
| Camphor (Synthetic) (UNII: 5TJD82A1ET) | |
| Cetearyl Isononanoate (UNII: P5O01U99NI) | |
| Dipropylene Glycol Caprate/Caprylate Diester (UNII: R6G12EY23X) | |
| Ethylparaben (UNII: 14255EXE39) | |
| Corymbia Citriodora Leaf Oil (UNII: M63U6N96EB) | |
| Hexyldecanol (UNII: 151Z7P1317) | |
| Hexyldecyl Laurate (UNII: 0V595C1P6M) | |
| Levomenthol (UNII: BZ1R15MTK7) | |
| Methylparaben (UNII: A28C7H9T) | |
| Ceresin (UNII: Q1LS2UJO3A) | |
| Tea Tree Oil (UNII: VIF565UC2G) | |
| Poloxamer 407 (UNII: TUF2IVW3M2) | |
| Propylparaben (UNII: Z8IX2SC1OH) | |
| Alpha-Tocopherol (UNII: H4N855PNZ1) | |
| Thymol (UNII: 3J50XA376E) | |
| Zinc Chloride (UNII: 86Q357L16B) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42507-406-01 | 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 | part333A | 01/01/2012 | |

Labeler - Hyvee (006925671)

Registrant - Ranir LLC (364567615)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------|---------|-----------|---------------------|
| Ranir LLC | | 364567615 | label |