

EXCHANGE SELECT COLD SORE TREATMENT - benzalkonium chloride cream **Army + Air Force Exchange Service**

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.



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EXCHANGE SELECT COLD SORE TREATMENT

benzalkonium chloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5530 1-406
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: ZY8 1Z83H0 X)
Arginine (UNII: 94ZLA3W45F)
Butylparaben (UNII: 3QP1U3FV8)
Camphor (Synthetic) (UNII: 5TJD82A1ET)
Cetearyl Isononanoate (UNII: P5O0 1U99NI)
Dipropylene Glycol Caprate/Caprylate Diester (UNII: R6G12EY23X)
Ethylparaben (UNII: 14255EXE39)
Corymbia Citriodora Leaf Oil (UNII: M63U6N96EB)
Hexyldecanol (UNII: 151Z7P1317)
Hexyldecyl Laurate (UNII: 0 V595C1P6M)
Levomenthol (UNII: BZ1R15MTK7)
Methylparaben (UNII: A218C7HI9T)
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:55301-406-01	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	08/04/2011	

Labeler - Army + Air Force Exchange Service (001695568)

Registrant - Ranir LLC (364567615)

Establishment

Name	Address	ID/FEI	Business Operations
Ranir LLC		364567615	label