

## **COLD SORE TREATMENT - benzalkonium chloride tincture**

### **Cardinal Health**

*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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## **DRUG FACTS**

### **ACTIVE INGREDIENT**

Benzalkonium chloride, 0.13%

### **PURPOSE**

Cold Sore / Fever Blister Treatment; Topical Antiseptic

### **USES**

- Treat cold sores / fever blisters
- Help guard against infection

### **WARNINGS**

**For external use only. Flammable, keep away from fire or flame.**

#### **Do not use**

- in the eyes
- over large areas of the body
- if you are allergic to any ingredient in the product
- more than 3 times per day
- longer than one week unless directed by a doctor.

#### **Stop use and ask a doctor if**

- condition persists or worsens
- symptoms persist for more than 7 days

#### **Ask a doctor if**

- used to treat deep or puncture wounds, animal bites, or serious burns
- you are pregnant or nursing a baby

#### **When using this product**

you may feel a brief stinging sensation when applying it. The sting should go away in a short time.

#### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

### **DIRECTIONS**

**Adults and children over 2 years of age:**

- Clean the lip area of any lip preparations, lotions, ointments, residual beverages, or cosmetics including lipstick using warm water and a washcloth
- Remove the cardboard top from applicator and place onto the glass/plastic vial end - opposite the brush end of the product
- Squeeze the cardboard to break the inner glass vial open
- Saturate the applicator end with solution by holding the brush end down and squeezing the container until you can see liquid on the brush applicator
- For best results, massage the solution into the cold sore by rubbing. Rub firmly, but take care not to damage the tissue. The purpose of the rubbing is to deliver the drug to the infection site. Hold the vial so the solution flows to the sore.
- To treat most cold sores, usually one treatment is enough.
- If your symptoms go away and then return later, apply another dose.
- Do not use more than 3 times per day
- Discard after use.

**Children under 2 years of age:** ask a doctor.

#### **OTHER INFORMATION**

- Store at room temperature: 15° - 30° C (59° - 86° F)
- The ingredients in toothpaste, softdrinks, and some fruit juices can de-activate the active ingredient. For best results, avoid brushing your teeth with toothpaste or drinking soft drinks or fruit juices for one hour after applying.

#### **INACTIVE INGREDIENTS**

isopropyl alcohol (70% v/v), water

#### **PACKAGE INFORMATION - TRIFOLD INNER**

##### **1. CLEAN**

Prior to treatment, clean the area to be treated preferably with a washcloth and warm water. A dry wipe may be sufficient. Do not use soap or other cleansers.

##### **2. BREAK**

Remove paper cap from vial, exposing applicator tip.  
 Replace cap on other end of vial, leaving applicator tip exposed.  
 Firmly pinch center of vial, close to edge of paper cap, until inner ampoule breaks.  
 Hold with the white applicator tip down, allowing medication to saturate the applicator.  
 If necessary: pinch vial gently until a drop of medication appears.

Prior to use: Remove vial from package

##### **3. RUB**

The key is to rub on the sore and the surrounding area. Gently dabbing is not effective.

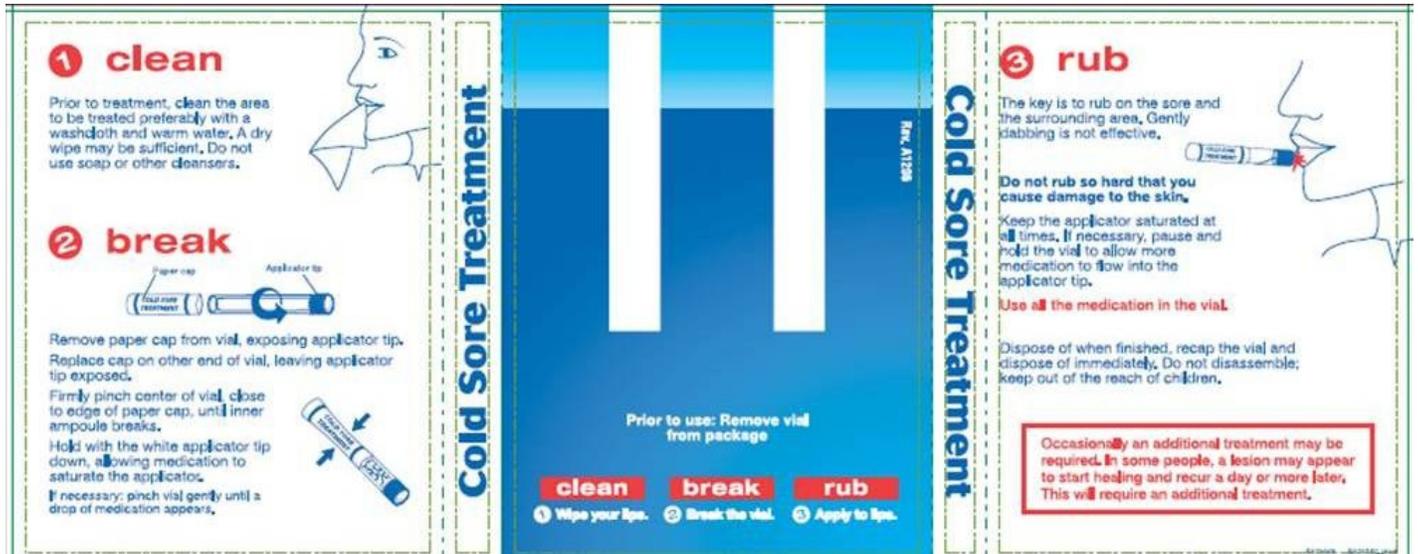
**Do not rub so hard that you cause damage to the skin.**

Keep the applicator saturated at all times. If necessary, pause and hold the vial to allow more medication to flow into the applicator tip.

Use all the medication in the vial.

Dispose of when finished, recap the vial and dispose of immediately. Do not disassemble; keep out of reach of children.

Occasionally an additional treatment may be required. In some people, a lesion may appear to start healing and recur a day or more later. This will require an additional treatment.



## PACKAGE INFORMATION - TRIFOLD OUTER

LEADER SATISFACTION GUARANTEED

NDC 37205-973-19

### Cold Sore Treatment

Cold Sore / Fever Blister Treatment  
Topical Antiseptic

Treats most cold sores in just ONE treatment  
Unique patented applicator eliminates need to touch sore with your fingers  
No messy creams or ointments left on the face  
Single use applicator

Compare to Viroxyn©

2 VIALS (0.6 ml EACH)

Fast Pain Relief

Distributed by Cardinal Health  
Dublin, OH 43017 CIN 3924091  
www.myleader.com MADE IN USA

All Leader Brand products are 100% satisfaction guaranteed or return to place of purchase for a full

refund.

US Patent No. 6,211,243B1

A patented new approach (US 6,211,243B1) to treating cold sores - rubbing the cold sore with the applicator tip delivers the germicidal medicine directly to the site of the infection.

Cold Sores and Fever Blisters are both caused by the Herpes Simplex virus (typically HSV-1) and are just different popular names for the HSV-caused lesions.

HERPES IS HIGHLY CONTAGIOUS.

A well-intentioned kiss can transfer the virus to another individual. Children are highly at risk.

After touching a cold sore:

- \* Wash your hands immediately with warm water and soap
- \* Do not touch your eyes
- \* Do not touch your genitals or other parts of the body. It is possible to transfer the virus to other parts of the body (autoinoculation)

Occasionally an additional treatment may be required. In some people, a lesion may appear to start healing and recur a day or more later. This will require an additional treatment.

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Occasionally an additional treatment may be required. In some people, a lesion may appear to start healing and recur a day or more later. This will require an additional treatment.

**Drug Facts**  
**Active Ingredient** Benzalkonium Chloride, 1.15% **Purpose** Cold Sore / Fever Blister Treatment; Topical Antiseptic  
**Uses** ■ Treat cold sores / fever blisters ■ Help guard against infection  
**Warnings**  
For external use only. Flammable. Keep away from fire or flames. Do not use ■ in the eyes ■ near large areas of the body ■ if you are allergic to any ingredient in this product. ■ more than 3 times per day ■ longer than one week unless directed by a doctor. Stop use and ask a doctor if ■ redness persists or worsens ■ symptoms persist for more than 7 days. Ask a doctor if ■ used to treat deep or puncture wounds, animal bites, or serious burns ■ you are pregnant or nursing a baby. When using this product you may feel a stinging sensation when you apply it. The stinging should go away in a short time. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.  
**Directions** Adults and children over 2 years of age:  
■ Clean the lip area of any lip preparations, lotions, emollients, residual beverages, or cosmetics including lipstick using warm water and a washcloth. ■ Remove the cardboard top from applicator and place into the glass plastic vial end - separate the brush end of the product. ■ Squeeze the cardboard to break the inner glass vial open. ■ Saturate the applicator and with motion by rubbing the brush end down and squeezing the container until you can see liquid on the brush applicator. ■ For best results, massage the solution into the cold sore by rubbing. Rub firmly, but take care not to damage the blisters. The purpose of the rubbing is to deliver the drop to the infection site, not the vial on the solution. Move to the sore. ■ To treat most cold sores, usually one treatment is enough. If your symptoms go away and then return later, apply another dose. ■ Do not use more than 3 times per day. ■ Discard after use.  
Children under 2 years of age: ask a doctor.  
**Other information**  
■ Store at room temperature: 15°-30° C (59°-86° F) ■ The ingredients in benzalkonium chloride, soft drink, and some fruit flavors can deactivate the active ingredients. For best results, avoid brushing your teeth with toothpaste or drinking soft drinks or fruit juices for one hour after applying.  
**Inactive ingredients** Proprietary blend (70% v/v), water.  
Distributed by Cardinal Health  
Dublin, OH 43017 **SKU 2024001**  
MADE IN USA  
All LEADER brand products are 100% antiseptic guaranteed or return to date of purchase for a \$100 refund.  
US Patent No. 6,211,243B1

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Cold Sore / Fever Blister Treatment & Topical Antiseptic  
Treats most cold sores in just ONE treatment  
Unique patented applicator eliminates the need to touch the sore with your fingers  
No messy creams or ointments left on the face  
Single use applicator  
2 VIALS (0.6 mL EACH)  
Fast Pain Relief

## COLD SORE TREATMENT

benzalkonium chloride tincture

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-973
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
Benzalkonium chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)		Benzalkonium chloride	0.13 mL in 1 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
isopropyl alcohol (UNII: ND2M416302)				
water (UNII: 059QF0K00R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-973-19	2 in 1 PACKAGE		
1		0.6 mL in 1 VIAL, PATENT DELIVERY SYSTEM		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/20/2007		

**Labeler** - Cardinal Health (097537435)

Revised: 12/2009

Cardinal Health