COLD SORE TREATMENT - benzalkonium chloride tincture
H and P Industries, Inc. dba Triad Group

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; 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.

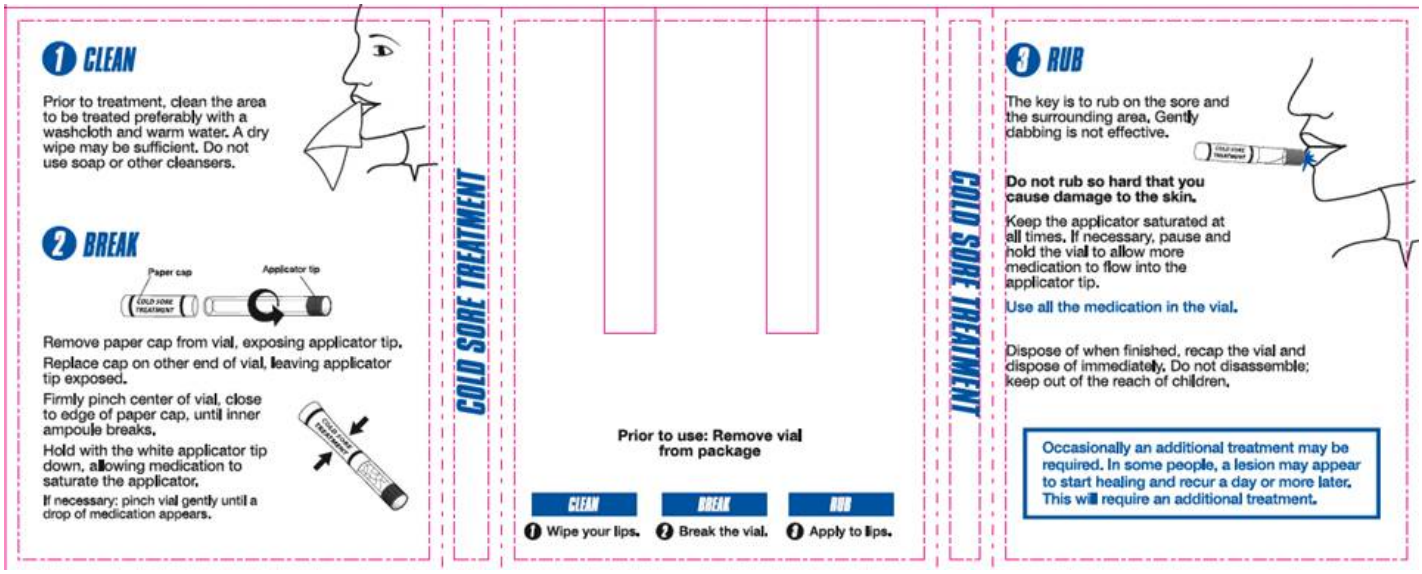
Prior to use: Remove vial from package

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

NDC 50730-1001-1

CARE ONE

1 DAY, 1 DOSE AND HEALING BEGINS
COLD SORE
TREATMENT
Benzalkonium Chloride, 0.13%

COLD SORE/FEVER BLISTER TREATMENT

Treats most cold sores in just one treatment
Patented applicator eliminates need to touch sore with fingers
No Messy creams or ointments left on the face
Instrucciones en espanol incluido

2 Vials
0.6 ml each

US Patent No's 6,211,243B1 and 6,322,243 and 6,410,599 and 6,414,032 and 6,423,750 and 6,759,434

*Viroxyn is a registered trademark of Quadex Pharmaceuticals LLC.

Distributed by: American Sales Company
4201 Walden Avenue

Lancaster, NY 14086
S and S Brands, Inc.
www.Care1.info

Quality Guaranteed or your money back.
Made in U.S.A.

A patented new approach 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 Simples 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)

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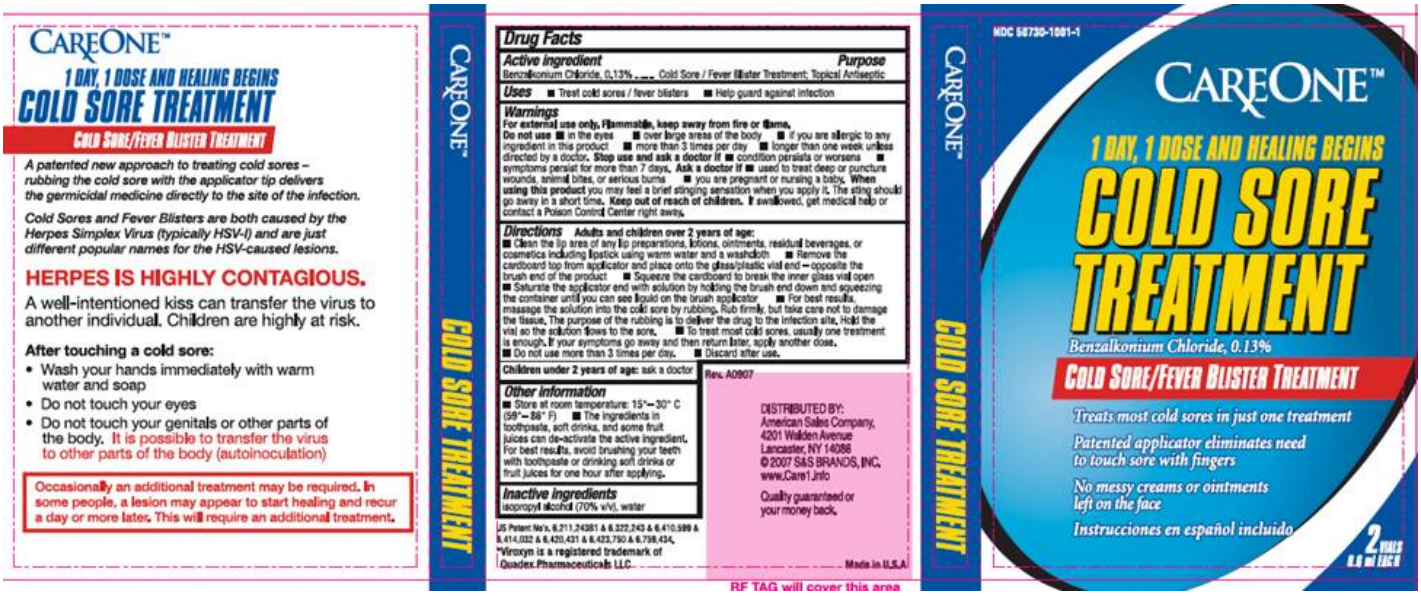

COLD SORE TREATMENT

benzalkonium chloride tincture

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50730-1001
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

Inactive Ingredients

Ingredient Name	Strength
isopropyl alcohol (UNII: ND2M416302)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50730-1001-1	2 in 1 PACKAGE		
1		0.6 mL in 1 VIAL, PATENT DELIVERY SYSTEM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2007	

Labeler - H and P Industries, Inc. dba Triad Group (050259597)

Revised: 12/2009

H and P Industries, Inc. dba Triad Group