

**VIROXYN PROFESSIONAL USE- benzalkonium chloride and benzocaine liquid**  
**Quadex Pharmaceuticals 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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**Viroxyn® Professional Use**

**Drug Facts**

<b>Active Ingredients:</b>	<b>Purposes:</b>
Benzalkonium Chloride 0.3%	Cold Sore/Fever Blister Treatment
Benzocaine 7.5%	Pain Relief During Application

**Uses**

- To treat cold sores/fever blisters.

**Warning**

- For external use only.
- Flammable; keep away from fire or flame

**Do not use**

- In the eyes
- Longer than one week, unless directed by a doctor
- If you are allergic to any ingredient in this product
- Over large areas of the body
- More than 3 times a day

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

- Condition persists or worsens
- Symptoms persist for more than 7-10 days

**Ask a doctor if:**

- You are pregnant or nursing a baby

**When using this product** you may feel a brief stinging sensation when you apply 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**

- Using only warm water and a washcloth, clean the lip area of any lip preparations, lotions, ointments, residual beverages, or cosmetics, including lipstick.
- Remove the cardboard cap from the applicator end and place the cardboard cap on to the glass/plastic vial end, opposite the brush end of the product.
- Squeeze the cardboard cap to break open the inner glass vial.
- 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.

- Touch the cold sore with the wet applicator and allow the numbing agent a few moments to numb your lip. Then begin actual treatment.
- For best results, message 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 you symptoms go away and then return later, apply another dose for the second cold sore.
- Do not use more than 3 times a day.
- Children under 2 years of age – ask a doctor or dentist.
- Discard after use.

### **Other Information**

Store at room temperature. The ingredients in toothpaste, soft drinks, and some fruit juices can deactivate the active ingredient in Viroxyn Professional Use®. For best results, avoid brushing your teeth with toothpaste or drinking sodas or fruit juices for at least one hour after applying the drug. Some people may notice a thin white powder on the lips after treatment. This is benzocaine that did not get absorbed into the lip and is normal.

### **Inactive Ingredients**

**Isopropyl alcohol (70 % v/v), water**

**Questions or to report an adverse event: 1-877-825-7153**

Quadex Labs  
6975 Union Park Center #300  
Salt Lake City, Utah 84047  
**www.viroxyn.com**  
**1-877-825-7153**

### **PRINCIPAL DISPLAY PANEL - 2 Vial Carton**

NDC 66774-1003-2

Professional Use  
Cold Sore Treatment

**Viroxyn®**  
**PROFESSIONAL USE**  
**WITH 7.5%**  
**BENZOCAINE**

Cold Sore Treatment

Relieves Pain  
Starts Healing  
Just One Dose

Available **ONLY** through medical professionals.

Contents: 2 Vials (0.6 ml)

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Cold Sore/Fever Blister Treatment

Quacker Labs  
6975 Union Park Center #300  
Cottonwood Heights, Utah 84047

Made in the U.S.A.

www.viroxyn.com

**Did You Know:**

"Cold sore" or "fever blister" are just different popular names for the same lesion, which is caused by a virus.

**Cold sores are highly contagious:**

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

**If you accidentally touch your cold sore:**

- Immediately wash your hands with warm water and soap
- Do not touch your eyes
- Do not touch other parts of the body. It is possible to transfer the virus to other parts of your body.

**Additional Treatments:**

Occasionally a lesion will start healing and then appear to recur. This is typically caused by a new viral release, and will require an additional treatment for the second lesion.

Deactivation of the active ingredient, caused by toothpaste, mouthwash, soft drinks, soaps, detergents, and some fruit juices, may require an additional treatment.

**How It Works:**

Viroxyn Professional Use<sup>®</sup> is a patented approach to treating cold

Cold Sore/Fever Blister Treatment

Quacker Labs  
6975 Union Park Center #300  
Cottonwood Heights, Utah 84047

Made in the

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**Ask a doctor if:**

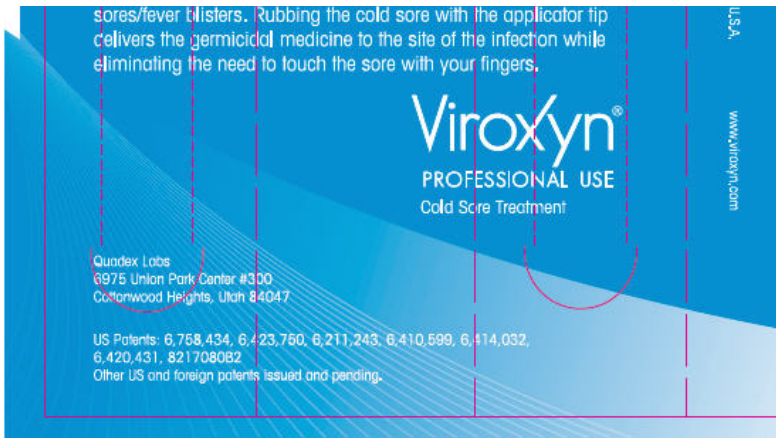
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- Rub the cold sore with the applicator tip above the numbing agent a few minutes to numb your lip. Then begin actual treatment.
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## VIROXYN PROFESSIONAL USE

benzalkonium chloride and benzocaine liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66774-1003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzalkonium chloride</b> (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)	Benzalkonium chloride	1.14 mg in 1 mL
<b>Benzocaine</b> (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	65.775 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Isopropyl Alcohol</b> (UNII: ND2M416302)	
<b>Water</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66774-1003-2	2 in 1 BLISTER PACK		
1		0.6 mL in 1 AMPULE		
2	NDC:66774-1003-3	3 in 1 BLISTER PACK		
2		0.6 mL in 1 AMPULE		
3	NDC:66774-1003-4	6 in 1 BOX		
3		0.6 mL in 1 AMPULE		
4	NDC:66774-1003-5	12 in 1 BLISTER PACK		
4		0.6 mL in 1 AMPULE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC MONOGRAPH NOT FINAL	part348	10/22/2012	
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**Labeler** - Quadex Pharmaceuticals LLC (090438909)

**Establishment**

Name	Address	ID/FEI	Business Operations
Quadex Pharmaceuticals LLC		090438909	MANUFACTURE(66774-1003)

Revised: 11/2012

Quadex Pharmaceuticals LLC