TRICLARA- benzalkonium chloride liquid Nightingale Pharmaceuticals, Inc.

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.

TriClara Antiseptic Cold Sore Treatment

Drug Facts

Active Ingredient

Benzalkonium Chloride (0.13%)

Purpose

Antiseptic - First Aid

Uses

- treatment of cold sore / fever blister
- effective relief of symptoms of cold sore / fever blister
- protects against infections in sores, burns, cuts and scrapes

Warnings

- **For external use only:** Do not use in or around eyes or ears. Consult a physician before using on puncture wounds, serious burns or animal bites.
- **Allergy alert:** Do not use if you are allergic to any ingredients in this product.

Stop use and consult a doctor if the condition persists or gets worse.

Keep out of reach of children. If swallowed, get medical help or contact poison control at 1-800-222-1222.

Directions

- clean the affected area with soap and water and thoroughly dry the area.
- for best results apply a small quantity with a rubbing motion 8 times (once every 2 hours while awake) daily at onset of symptoms until cleared.
- wash hands after applying.
- do not share this product with others.
- retain these directions for help with use.
- for use on children under 12 years: ask a doctor.

Other information

- Store at 15 to 25°C (59 to 77°F), in a dry place, away from heat, humidity and direct sunlight
- Discard 30 days after removeal from vauumed pouch.

Inactive ingredients

glycerin, water, N-acetyl cysteine, sodium hydroxide (for pH), ascorbic acid

TriClara ® ON & GONE

New

Antiseptic Cold Sore Treatment

0.13% Benzalkonium Chloride

FAST

CLEAR

EFFECTIVE

BETTER APPEARANCE + SOOTHING RELIEF

Cold Sore / Fever Blister Antiseptic

NET WT 3.5G / .12 OZ

Distributed by:

Nightingale Pharmaceuticals, Inc.

Santee, CA 92071

www.triclara.com

RETAIN CARTON FOR COMPLETE PRODUCT INFORMAITON



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RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

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TRICLARA

benzalkonium chloride liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72518-001

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TOPICAL

	Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength	
l	BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
ACETYLCYSTEINE (UNII: WYQ7N0BPYC)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
ASCORBIC ACID (UNII: PQ6CK8PD0R)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:72518-001-00	3.5 g in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/14/2019		

Labeler - Nightingale Pharmaceuticals, Inc. (081338827)

Revised: 1/2019 Nightingale Pharmaceuticals, Inc.