

EYEWASH STATION ADDITIVE CONCENTRATE- chlorhexidine gluconate and propylene glycol liquid

Encon Safety Products, 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.

HYDROSEP POTABLE WATER ADDITIVE

Product Information

Ingredients

Chlorhexidine gluconate 1% w/v Purified Water, Propylene Glycol

Purpose

Preservative

Use

A preservative for use in potable self-contained emergency eyewash stations

Warnings

For external use only. In case of contact with eye in undiluted form, flush with clean water

Do not use

- in full strength

When using this product

- do not change dilution or use with other chemicals
- do not reuse

Stop use and ask a doctor if you have any of the following

- changes in vision
- eye pain
- condition worsens or persists
- continued redness or irritation of the eye

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wear protective eyewear and gloves
- clean potable eyewash station and rinse with potable water
- partially fill station with potable water
- remove tamper evident seal and cap of bottle
- add entire contents of the bottle to the eyewash station container
- fill the station to the manufacturer's required level
- date and initial inspection tag

- station should be cleaned and refilled every 120 days when using this product
- in advance of emergency, add the concentrate to potable water to have a solution available

Other information

- lot number is printed on the bottle
- store at 20° to 25° C [68° to 77° F]
- for your protection, this bottle has an imprinted white seal with black printing "TAMPER EVIDENT SEAL"
- do not use if this seal is missing or broken
- use before expiration date marked on bottle

Questions ?

☎ Call 1-800-283-6266 9 a.m. to 5 p.m. EST Mon-Fri

Manufactured by:

Niagara Pharmaceuticals Inc.

60 Innovation Dr.

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PRINCIPAL DISPLAY PANEL - 236 mL Bottle Label

<p>HYDROSEP® POTABLE WATER ADDITIVE</p> <p>A preservative for potable water. Preserves from 5 - 20 US Gallons (15 - 76 Liters)</p> <p>FOR USE IN SELF-CONTAINED POTABLE WATER STATION</p> <p>Encon® SAFETY PRODUCTS</p> <p>Hydrosep® is specifically formulated to provide protection against bacteria, fungi, algae, staph and acanthamoeba growth for self-contained potable water stations.</p> <p>Contents: 8 fl. oz. (236.6 ml) HYDROSEP® is a registered trademark of Encon Safety Products, Inc. Houston, TX.</p> <p>MADE IN CANADA</p>	<p>Product Information</p>	
	<p>Ingredients Chlorhexidine gluconate 1% w/v Purified Water, Propylene Glycol</p>	<p>Purpose Preservative</p>
	<p>Use A preservative for use in potable water stations</p>	
	<p>Warnings For external use only. In case of contact with eye in undiluted form, flush with clean water</p>	
	<p>Do not use ■ in full strength</p>	
	<p>When using this product ■ do not change dilution or use with other chemicals ■ do not reuse</p>	
	<p>Stop use and ask a doctor if you have any of the following ■ changes in vision ■ eye pain ■ condition worsens or persists ■ continued redness or irritation of the eye</p>	
<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>		
<p>Directions ■ wear protective eyewear and gloves ■ clean potable water station and rinse with potable water ■ partially fill station with potable water ■ remove tamper evident seal and cap of bottle ■ add entire contents of the bottle to the potable water station container ■ fill the station to the manufacturer's required level ■ date and initial inspection tag ■ station should be cleaned and refilled every 120 days when using this product ■ in advance of emergency, add the concentrate to potable water to have a solution available</p>		
<p>Other information ■ lot number is printed on the bottle ■ store at 35° F to 95° F [2° C to 35° C] ■ for your protection, this bottle has an imprinted white seal with black printing "TAMPER EVIDENT SEAL" ■ do not use if this seal is missing or broken ■ use before expiration date marked on bottle</p>		
<p>Questions ? ☎ Call 1-800-283-6266 8 a.m. to 5 p.m. CST Mon-Fri</p>		

EYEWASH STATION ADDITIVE CONCENTRATE

chlorhexidine gluconate and propylene glycol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70290-120
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	145.6 kg in 2800 L
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	280 kg in 2800 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	2374.4 L in 2800 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70290-120-01	0.237 L in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	12/02/2020	
2	NDC:70290-120-05	0.946 L in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	12/02/2020	
3	NDC:70290-120-06	3.786 L in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	12/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part349	12/02/2020	

Labeler - Encon Safety Products, Inc. (008102410)

Registrant - Niagara Pharmaceuticals Inc. (205477792)

Establishment

Name	Address	ID/FEI	Business Operations
Niagara Pharmaceuticals Inc.		205477792	manufacture(70290-120)

Revised: 12/2020

Encon Safety Products, Inc.