

PUR-WASH- eyewash solution
Niagara Pharmaceuticals, Inc.

Niagara Pur-Wash

Active ingredient

Purified water 98.3%

Purpose

Eyewash

Warnings

For external use only

Do not use

- if you experience any open wounds in or near the eyes and obtain immediate medical treatment
- if solution changes color or becomes cloudy

When using this product

- to avoid contamination, do not touch tip of container to any surface
- do not reuse
- once opened, discard

Use

For cleansing the eye to help relieve irritation or burning by removing loose foreign material

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

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

Keep out of reach of children

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

Directions

- remove tamper evident seal and cap
- avoid contamination of rim and inside surfaces of the nozzle

- place nozzle to the affected area and tilt the bottle to pour liquid out through the nozzle
- open eyelids wide and rotate eyeball while controlling the rate of flow of solution by pressure on the bottle to ensure thorough bathing with the wash

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

Inactive ingredients

boric acid, sodium borate, sodium chloride

Questions?

☎ Call 973-227-1830 9 a.m. to 5 p.m. EST Mon-Fri

Dosage and Administration

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- avoid contamination of rim and inside surfaces of the nozzle
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Warnings

For external use only

Package Label.Principal Display Panel

NDC 65785-168-01

Pur-Wash™

**Purified Water, 98.3%
Ophthalmic Solution
Eyewash**

Single Use

Manufactured by:
Niagara Pharmaceuticals Inc.
60 Innovation Dr.
Flamborough ON L9H 7P3
Made in Canada

Sterile Solution (Terminal)

16 Fl Oz [473 mL]

Drug Facts

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PUR-WASH

eyewash solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65785-168
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	465 mL in 473 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65785-168-01	473 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	09/01/2015	

<p>NDC 65785-168-01</p> <p>Pur-Wash™</p> <p>Purified Water, 98.3% Ophthalmic Solution Eyewash</p> <p>Single Use</p> <p>Manufactured by: Niagara Pharmaceuticals Inc. 60 Innovation Dr. Flamborough ON L9H 7P3 Made in Canada</p> <p>Sterile Solution</p> <p>16 Fl Oz [473 mL]</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient Purified water 98.3%</td> <td style="text-align: right;">Purpose Eyewash</td> </tr> <tr> <td colspan="2">Use For cleansing the eye to help relieve irritation or burning by removing loose foreign material</td> </tr> <tr> <td colspan="2">Warnings For external use only</td> </tr> <tr> <td colspan="2">Do not use ■ if you experience any open wounds in or near the eyes and obtain immediate medical treatment ■ if solution changes color or becomes cloudy</td> </tr> <tr> <td colspan="2">When using this product ■ to avoid contamination, do not touch tip of container to any surface ■ do not reuse ■ once opened, discard</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if you have any of the following ■ continued redness or irritation of the eye ■ condition worsens or persists ■ eye pain ■ changes in vision</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions ■ remove tamper evident seal and cap ■ flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle</td> </tr> <tr> <td colspan="2">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</td> </tr> <tr> <td colspan="2">Inactive ingredients boric acid, sodium borate, sodium chloride</td> </tr> <tr> <td colspan="2">Questions ? ☎ Call 973-227-1830 9 a.m. to 5 p.m. EST Mon-Fri</td> </tr> </table>	Active ingredient Purified water 98.3%	Purpose Eyewash	Use For cleansing the eye to help relieve irritation or burning by removing loose foreign material		Warnings For external use only		Do not use ■ if you experience any open wounds in or near the eyes and obtain immediate medical treatment ■ if solution changes color or becomes cloudy		When using this product ■ to avoid contamination, do not touch tip of container to any surface ■ do not reuse ■ once opened, discard		Stop use and ask a doctor if you have any of the following ■ continued redness or irritation of the eye ■ condition worsens or persists ■ eye pain ■ changes in vision		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Directions ■ remove tamper evident seal and cap ■ flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle		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		Inactive ingredients boric acid, sodium borate, sodium chloride		Questions ? ☎ Call 973-227-1830 9 a.m. to 5 p.m. EST Mon-Fri	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022305	01/30/2015	

Labeler - Niagara Pharmaceuticals, Inc. (205477792)

Registrant - Niagara Pharmaceuticals, Inc. (205477792)

Establishment

Name	Address	ID/FEI	Business Operations
Niagara Pharmaceuticals, Inc.		205477792	manufacture(65785-168)