CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022305Orig1s000

<u>LABELING</u>

3.875"w x 1.5625"h - .125"R
Other Information
Inactive Ingredients
Questions?
1.42"w x 3.27"h
3.875"w x 1.5625"h - .125"R
Pur-Wash
Purified Water, 98.3%
Ophthalmic Solution
Eyewash
Single Use
1 Fl Oz [30 mL]
Drug Facts
Active Ingredient
Purpose
Purified water 98.3%
Eyewash
Use
Warnings
For external use only
Do not use
Stop use and ask a doctor if you experience
Keep out of reach of children.
Directions
DRUG FACTS CONTINUED
PEEL BACK

(b) (4)

5.375"w x 2.6875"h – .125"R

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

4 Fl Oz [118 mL]

Drug Facts

Active ingredient	Purpose
Purified water 98.3%	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 experience*
- 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 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 905 690-6277 9 a.m. to 5 p.m. EST Mon-Fri

(b) (4)

Reference ID: 3008437

Reference ID: 3009362

7"w x 3.1875"h - .125R

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

8 Fl Oz [236 mL]

Drug Facts

Active ingredient	*Purpose*
Purified water 98.3%	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*
- 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 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 905 690-6277 9 a.m. to 5 p.m. EST Mon-Fri

(b) (4)

8.875"w x 3.2813"h - .0312R

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

16 Fl Oz [473 mL]

Drug Facts

Active ingredient — ***Purpose***
Purified water 98.3% — 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
- eye pain
- condition worsens or persists
- 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
- replace with sterile eyecup provided
- avoid contamination of rim and inside surfaces of the eyecup
- place eyecup surface to the affected eye, pressing tightly to prevent the escape of the liquid and tilt the head backward
- 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 905 690-6277 9 a.m. to 5 p.m. EST Mon-Fri

(b) (4)

Reference ID: 3008437

7.25"w x 5.5"h - .0625R

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

16 Fl Oz [473 mL]

Drug Facts

Active ingredient	*Purpose*
Purified water 98.3%	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
- eye pain
- condition worsens or persists
- changes in vision

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

Directions 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 905 690-6277 9 a.m. to 5 p.m. EST Mon-Fri

(b) (4)

Reference ID: 3009362

10.625"w x 4.25"h - .125R

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

32 Fl Oz [946 mL]

Drug Facts

Active ingredient	Purpose
Purified water 98.3%	Eyewash

Use For cleaning 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 ■ replace with sterile eyecup provided ■ avoid contamination of rim and inside surfaces of the eyecup ■ place eyecup surface to the affected eye, pressing tightly to prevent the escape of the liquid and tilt the head backward ■ 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 905 630-8277 9 a.m. to 5 p.m. EST Mon-Fri

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/s/

JOEL SCHIFFENBAUER
09/01/2011