

FIRSTSTEP FIRSTFLUSH- eyewash solution
Encon Safety Products, Inc.

Encon Firststep Firstflush

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
- 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


Dosage and Administration

- remove tamper evident seal and cap
- flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle

Warnings

For external use only

Package Label.Principal Display Panel

<p>FIRSTSTEP® FIRSTFLUSH®</p> <p>Purified Water, 98.3% Ophthalmic Solution Eyewash</p> <p>NDC 70290-310-32 Single Use</p> <p>Manufactured for Encon Safety Products, Inc. 6825 W. Sam Houston Pkwy. N. Houston, TX 77041 1(800) 283-6266 • CustomerService@enconsafety.com www.enconsafety.com</p> <p>Sterile Solution 32 fl. oz. [946 mL]</p>  <p>3 47682 21526 2</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Purified water 98.3%</td> <td>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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 800-283-6266</td> </tr> </table>	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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ 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 800-283-6266	
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FIRSTSTEP FIRSTFLUSH

eyewash solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70290-310
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	465 mL in 473 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70290-310-32	946 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product	04/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022305	04/27/2020	

Labeler - Encon Safety Products, Inc. (008102410)

Registrant - Niagara Pharmaceuticals, Inc. (205477792)

Establishment

Name	Address	ID/FEI	Business Operations
Niagara Pharmaceuticals, Inc.		205477792	manufacture(70290-310)

Revised: 4/2020

Encon Safety Products, Inc.