

KOLLOURION EYESALVE EYEWASH- purified water 98.3% solution
Miracle Eye Pharmaceuticals

Kollourion Eyesalve Eyewash

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

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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

- flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle

Other information

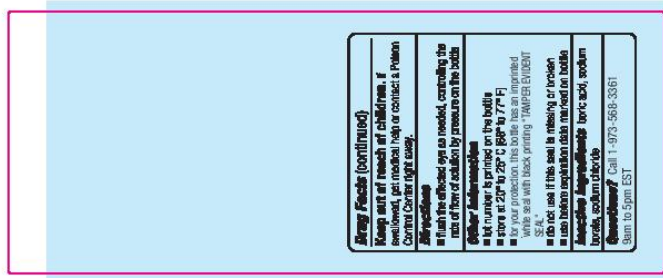
- lot number is printed on the bottle
- store at 20° to 25° C [68° to 77° F]
- for your protection, this bottle has an imprinted white seal with black printing "TAMPER EVIDENT SEAL"
- do not use if this seal is missing or broken

- use before expiration date marked on bottle

Inactive ingredients

boric acid, sodium borate, sodium chloride

Call 1-973-568-3361 9am to 5pm EST



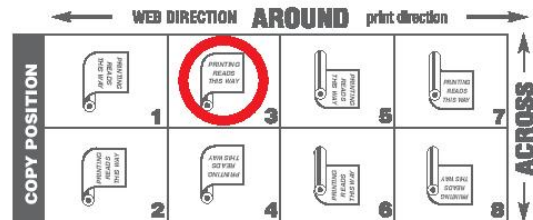
Please **READ PROOF CAREFULLY**. This proof is a **REPRESENTATION OF THE FINAL WORK**. We cannot be held responsible for errors approved in this proof. We will correct any errors without charge if they are noted on this proof. Any alterations from the original instructions will be charged to the customer. **BY SIGNING, YOU ACKNOWLEDGE HAVING THOROUGHLY REVIEWED THIS PROOF.**

Customer: Niagara Pharmaceuticals
 Product: Miracle Eye 1oz. Extended
 PO #: tbd WO #: tbd
 Finished Size: 1.575" x 3.937"
 Date: July 28, 2020
 Proof #: 10

Colours Used:



Barcode Check:
 Re-Proof:



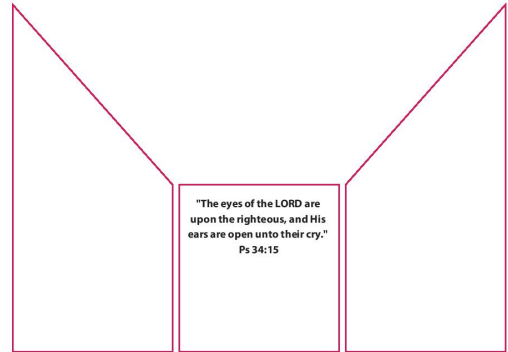
Approved: _____ Date: _____

OPTION 1

BOX OUTER



CUFF



5 - 6 pt



NDC XXXX-XXXX-XX
**Kollourion Eyesalve™
 Eyewash**
 Sterile - Isotonic - Buffered - Preservative Free
 Single use for cleansing the eye
 1 fl. oz. (30 mL)

 Purified Water Source includes: Ethicon "Holy" Water 

Manufactured for: Miracle Eye Pharmaceuticals®
 Chicago, IL 60640
 Opening the window to the gift of sight™
www.mea.vision Made in Canada
 © 2020 Johnson Living Trust

Drug Facts
Active Ingredient(s) Purified Water 98.3%
Other Ingredients Eyewash
Indications For cleansing the eye to help relieve irritation or burning by removing loose foreign material.
Directions For external use only.
Do not use if you experience any eye reactions to or use the eyes and obtain immediate medical treatment if a reaction can be seen or becomes blurry.
Warnings When using this product, do not touch tip of container to eye surface, do not touch tip of container to any surface, do not use if cap is damaged or cap is not sealed, discard if cap is cracked or cap is not sealed.
Side Effects See important information about this medicine at the end of this leaflet. You may report side effects to FDA at 1-800-FDA-1088 or continue medical use or irritation of the eye in condition worsens or persists or eye pain or changes in vision.
Other information See important information about this medicine at the end of this leaflet.

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Customer: Niagara Pharmaceuticals Product: Miracle Eye 1oz. Extended PO #: tbd WO #: tbd Finished Size: 1.575" x 3.937" Date: July 28, 2020 Proof #: 10	Colours Used:  Pantone Black  Release	Barcode Check: <input type="checkbox"/> Re-Proof: <input type="checkbox"/>
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← WEB DIRECTION AROUND print direction →

COPY POSITION	1	2	3	4	5	6	7	ACROSS
	8	9	10	11	12	13	14	

Approved: _____ Date: _____

KOLLOURION EYESALVE EYEWASH

purified water 98.3% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72924-001(NDC:65785-160)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	929 g in 946 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:72924-001-01	1 in 1 CARTON	12/01/2020	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	12/01/2020	

Labeler - Miracle Eye Pharmaceuticals (080055386)

Establishment

Name	Address	ID/FEI	Business Operations
Miracle Eye Pharmaceuticals		080055386	repack(72924-001)

Establishment

Name	Address	ID/FEI	Business Operations
Niagara Pharmaceuticals Inc		205477792	manufacture(72924-001)