

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

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**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**

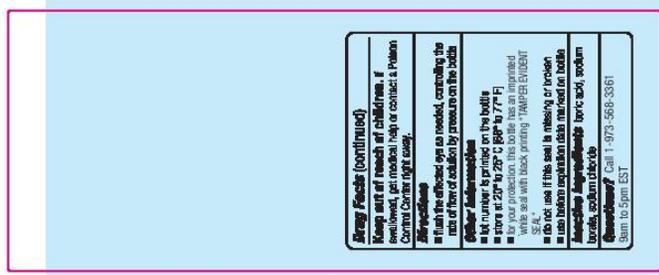
- lot number is printed on the bottle
- store at 20° to 25° C [68° to 77° F]
- for your protection, this bottle has an imprinted white seal with black printing "TAMPER EVIDENT SEAL"
- do not use if this seal is missing or broken

- use before expiration date marked on bottle

**Inactive ingredients**

boric acid, sodium borate, sodium chloride

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



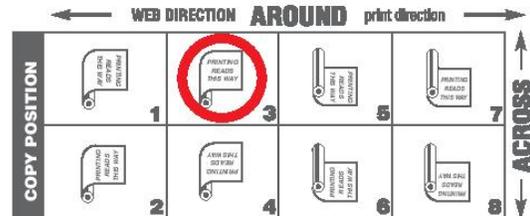
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Customer: Niagara Pharmaceuticals  
 Product: Miracle Eye 1oz. Extended  
 PO #: tbd WO #: tbd  
 Finished Size: 1.575" x 3.937"  
 Date: July 28, 2020  
 Proof #: 10

Colours Used:



Barcode Check:   
 Re-Proof:



Approved: \_\_\_\_\_ Date: \_\_\_\_\_



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](http://www.mea.vision) Made in Canada  
© 2020 Johnson Living Trust

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**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.

**Warnings**

- Do not use if you experience eye pain, redness, itchy or rose the eyes and obtain immediate medical treatment as it may cause eye color or increase clarity.
- When using this product, do not touch tip of container to eye surface.
- Do not reuse in eye opened, discard.

**Usage** Use and look in direction of effect(s) occur. You may report side effects to FDA at 1-800-FDA-1088 in continued redness or irritation of the eye in condition worsens or persists in eye pain or changes in vision.

**Drug Facts Continued Panel Back**

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 Process Black	 Release
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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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>WATER</b> (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	929 g in 946 mL

### Inactive Ingredients

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

### 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)