

ARTIFICIAL TEARS- carboxymethylcellulose sodium solution/ drops
Aru Pharma Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

QPACK ARTIFICIAL TEARS

Drug Facts

Active Ingredient

Carboxymethylcellulose Sodium 10 MG in 1 ml.

Purpose

Eye Lubricant

Uses

- for use as a protectant against further irritation or to relieve dryness of the eye
- for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun

Warnings

For external use only

- **Do not use this product if** solution changes color or becomes cloudy

Stop use and ask a doctor if you experience

- eye pain • changes in vision • continued redness or irritation of the eye or if the condition worsens or persists for more than 72 hours

When using this product

- to avoid contamination, do not touch tip of container to any surface • replace cap after using. Keep container tightly closed.
- remove contact lens before using

Keep out of the reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Instill 1 or 2 drops in the affected eye(s) as needed.

Other information

- Tamper Evident. Do not use this product if neckband is missing or broken.
- RETAIN THIS CARTON FOR FUTURE REFERENCE
- Store at 15°-30°C (59°-86°F)

Inactive Ingredients

Boric Acid, Potassium Chloride, Sodium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride, Sodium Chlorite, Sodium Hydroxide and Water for Injection

Compare to the active ingredient in Refresh Plus Eye drops

Lubricant Eye Drops

Refresh, Lubricate and Moisturizes

Distributed by.

ARU PHARMA INC.

MOUNT VERNON, NY 10552

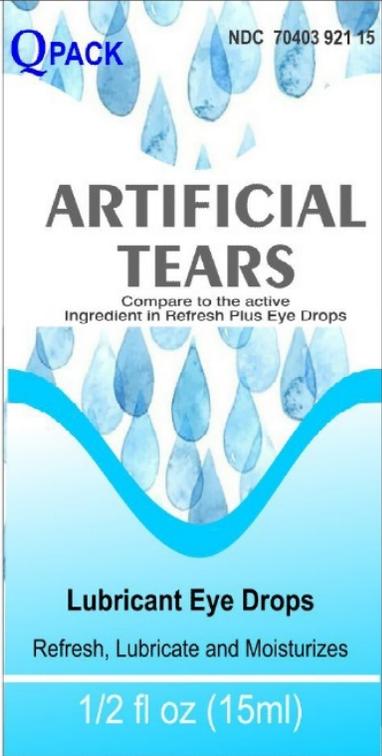
www.qpackrx.com

Packaging

INNER LABEL

<p>Drug Facts</p>	 <p>QPACK NDC 70403 921 15</p> <p>Compare to the active Ingredient in Refresh Plus Eye Drops</p> <p>ARTIFICIAL TEARS</p> <p>Lubricant Eye Drops</p> <p>Refresh, Lubricate and Moisturizes</p> <p>1/2 fl oz (15ml)</p>	<p>Mfg. Lic. No.: TN 00002176 7392192115</p>
<p>Active Ingredient Carboxymethylcellulose Sodium 10 MG in 1 ml. Purpose.....Eye Refresh</p>		<p>Lot No.:</p>
<p>Warnings: For external use only</p>		<p>Exp. Date:</p>
<p>Directions Instill 1 or 2 drops in the affected eye(s) as needed.</p>		
<p>For complete Drug Facts Refer to carton</p>	<p>Distributed by: ARU PHARMA INC. MOUNT VERNON, NY 10552 www.qpackrx.com</p>	

OUTER CARTON LABEL

			
<p>Drug Facts</p> <p>Active Ingredient Carboxymethylcellulose Sodium 10 MG in 1 ml. PurposeEye Lubricant</p> <p>Uses</p> <ul style="list-style-type: none"> for use as a protectant against further irritation or to relieve dryness of the eye for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun <p>Warnings For external use only</p> <ul style="list-style-type: none"> Do not use this product if solution changes color or becomes cloudy <p>Stop use and ask a doctor if you experience</p> <ul style="list-style-type: none"> eye pain changes in vision continued redness or irritation of the eye or if the condition worsens or persists for more than 72 hours <p>When using this product</p> <ul style="list-style-type: none"> to avoid contamination, do not touch tip of container to any surface replace cap after using. Keep container tightly closed. remove contact lens before using <p>Keep out of the reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Questions or comments? 1-844-500-2729 between 9 am and 4 pm EST, Monday- Friday. ▶</p>	<p>Drug Facts (continued)</p> <p>Directions Instill 1 or 2 drops in the affected eye(s) as needed.</p> <p>Other information</p> <ul style="list-style-type: none"> Tamper Evident. Do not use this product if neckband is missing or broken. RETAIN THIS CARTON FOR FUTURE REFERENCE Store at 15°-30°C (59°-86°F) <p>Inactive Ingredients Boric Acid Potassium Chloride Sodium Chloride Calcium Chloride Dihydrate. Magnesium Chloride Sodium Chlorite Sodium Hydroxide and Water for Injection</p>	 <p>QPACK NDC 70403 921 15</p> <p>Compare to the active Ingredient in Refresh Plus Eye Drops</p> <p>ARTIFICIAL TEARS</p> <p>Lubricant Eye Drops</p> <p>Refresh, Lubricate and Moisturizes</p> <p>1/2 fl oz (15ml)</p>	<p>QPACK ARTIFICIAL TEARS</p> <p>Mfg. Lic. No.: TN 00002176 7392192115</p> <p>Distributed by: ARU PHARMA INC. MOUNT VERNON, NY 10552 www.qpackrx.com</p> 
<p>Lot No.:</p> <p>Exp. Date:</p> 		<p>NDC 70403 921 15</p>	

ARTIFICIAL TEARS

carboxymethylcellulose sodium solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70403-921
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZ17B19X)	CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SODIUM CHLORITE (UNII: G538EBV4VF)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70403-921-15	1 in 1 CARTON	01/22/2018	03/31/2025
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/22/2018	03/31/2025

Labeler - Aru Pharma Inc. (079736192)

Revised: 5/2023

Aru Pharma Inc.