ARTIFICIAL TEARS- polyvinyl alcohol 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

Polyvinyl Alcohol 1.4%

Purpose

Eye Lubricant

Uses

- relieves dryness of the eye
- prevents further irritation

Warnings

Do not use

- if solution changes colour or becomes cloudy
- with contact lenses

When using this product

- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor

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

Keep out of reach of children

- if swallowed, get medical help or contact a poison control center right away.

Question or comments?

1-844-500-2729

between 9 am and 4 pm EST, Monday-Friday.

Directions

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

Other information

- store at 15°-25°C (59°-77°F)
- keep tightly closed

Inactive Ingredients

benzalkonium chloride, dibasic sodium phosphate hydrate, edetate disodium hydrate, monobasic sodium phosphate dihydrate, purified water, sodium chloride

Compare to the active Ingredient in Liquifilm Tears Eye Drops

Lubricant Eye Drops

Prevents Irritation and Relieves Dryness of the eye

Distributed by.

ARU PARMA INC.

MOUNT VERNON, NY 10552

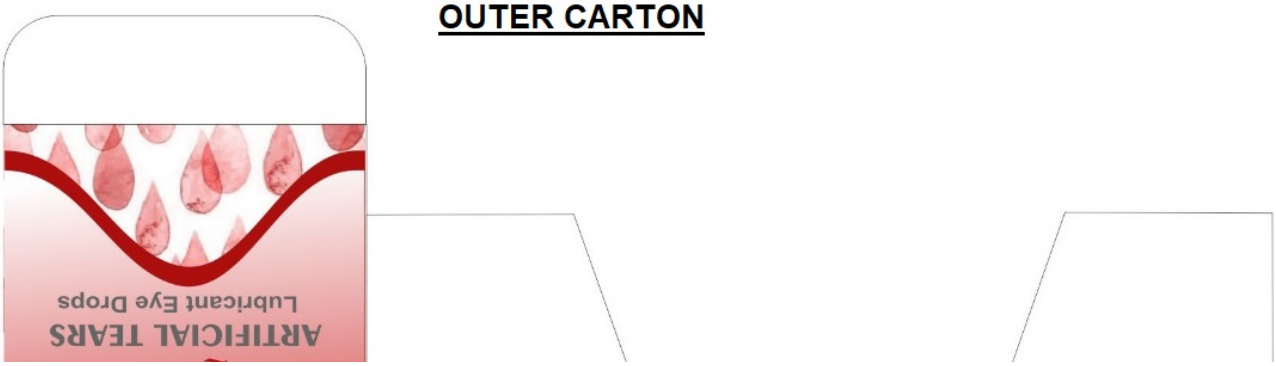
www.qpackrx.com

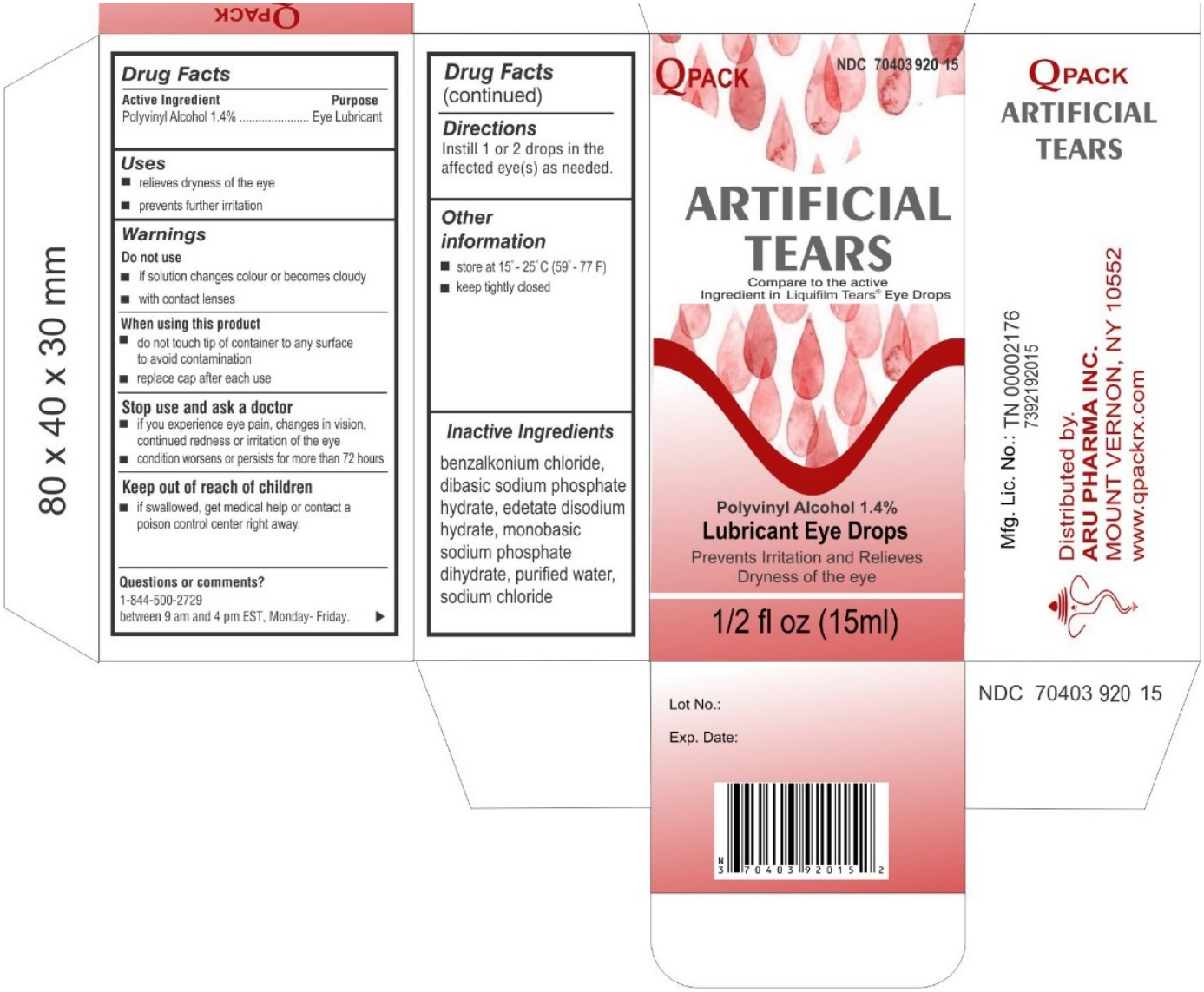
Packaging

70 x 24 mm

INNER LABEL

OUTER CARTON





ARTIFICIAL TEARS

polyvinyl alcohol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70403-920
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNSPECIFIED	14 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE (UNII: E1W4N241FO)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70403-920-15	1 in 1 CARTON	03/31/2020	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	03/31/2020	03/31/2025

Labeler - Aru Pharma Inc. (079736192)

Revised: 5/2023

Aru Pharma Inc.