

**THERATEARS LUBRICANT- carboxymethylcellulose sodium solution/ drops**  
**Advanced Vision Research (Subsidiary of Akorn, 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.*

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**Drug Facts**

**Active ingredient (In each unit dose)**

Sodium Carboxymethylcellulose 0.25%

**Purpose**

Eye lubricant

**Uses**

- As a lubricant to relieve dryness of the eye.
- As a protectant against further irritation of the eye.
- For temporary relief of burning, irritation, and discomfort including exposure to wind or sun.

**Warnings**

For external use only

- To avoid contamination do not touch tip of opened container to any surface. Do not reuse. Once opened discard. Use individual vials within 90 days of opening foil pouch.
- **This product contains no preservatives.** Any solution not used immediately after opening should be discarded. Re-use of this single-use product may lead to inflammation of the eye and/or discomfort, based on potential contamination during handling.

**Do not use**

- 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.
- 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 immediately.

**Directions**

- To open, **twist** tab completely off.
- Instill 1 or 2 drops in the affected eye(s) as needed.

**Other information**

- Use only if foil pouch is sealed and single-use container is intact.
- Do not touch unit-dose tip to eye.

**Inactive ingredients**

Borate buffers, calcium chloride, magnesium chloride, potassium chloride, purified water, sodium bicarbonate, sodium chloride and sodium phosphate

## Questions and comments?

1-800-579-8327

Principal Display Panel Text for Container Label:

PRESERVATIVE FREE

thera

tears®

THERAPY FOR YOUR EYES™

dry eye therapy

LUBRICANT

EYE DROPS

RESTORES EYES

NATURAL BALANCE™

4 Single-Use STERILE

Vials 0.08 FL OZ (2.4mL) TOTAL

**Seal Area**

**Seal Area**

**Drug Facts (continued)**

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

**Directions** ■ To open, twist tab completely off.  
■ Instill 1 or 2 drops in the affected eye(s) as needed.

**Other information** ■ Use only if foil pouch is sealed and single-use container is intact.  
■ Do not touch unit-dose tip to eye.

**Drug Facts (continued)**

**Inactive ingredients** Borate buffers, calcium chloride, magnesium chloride, potassium chloride, purified water, sodium bicarbonate, sodium chloride and sodium phosphate

**Questions or comments?** 1-800-579-8327

**MADE IN USA** [theratears.com](http://theratears.com)  
© 2014 Alcon Consumer Health, A Division of Alcon, Inc.  
Ann Arbor, MI 48105 T1-CA-F00

**Drug Facts**

**Active ingredient Purpose**  
Sodium carboxymethylcellulose 0.25%...eye lubricant

**Uses** ■ As a lubricant to relieve dryness of the eye. ■ As a protectant against further irritation of the eye. ■ For temporary relief of burning, irritation, and discomfort including exposure to wind or sun.

**Drug Facts (continued)**

**Warnings For external use only**

■ To avoid contamination do not touch tip of opened container to any surface. Do not reuse. Once opened discard. Use individual vials within 90 days of opening foil pouch.

**Do not use** 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, or if condition worsens or persists for more than 12 hours.

**RESTORES EYES NATURAL BALANCE™**

STERILE

4 Single-Use Vials 0.08 FL OZ (2.4mL) TOTAL

**Seal Area**

Principal Display Panel Text for Carton Label:

PRESERVATIVE

FREE

RECOMMENDED

DOCTOR

CREATED

thera

tears®

THERAPY FOR YOUR EYES®

dry eye therapy

LUBRICANT

EYE DROPS

IMMEDIATE

LONG LASTING

RELIEF

32 STERILE

Single-Use Vials\* 0.65 FL OZ (19.2mL) TOTAL



## THERATEARS LUBRICANT

carboxymethylcellulose sodium solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58790-000
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311) (carboxymethylcellulose - UNII:05JZI7B19X)	carboxymethylcellulose sodium, unspecified form	2.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength

<b>boric acid</b> (UNII: R57ZHV85D4)	
<b>sodium borate</b> (UNII: 91MBZ8H3QO)	
<b>calcium chloride</b> (UNII: M4I0D6VV5M)	
<b>magnesium chloride</b> (UNII: 02F3473H9O)	
<b>potassium chloride</b> (UNII: 660YQ98I10)	
<b>water</b> (UNII: 059QF0K00R)	
<b>sodium bicarbonate</b> (UNII: 8MDF5V39QO)	
<b>sodium chloride</b> (UNII: 451W47IQ8X)	
<b>sodium phosphate</b> (UNII: SE337SVY37)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58790-000-32	8 in 1 CARTON	01/01/1995	
1		4 in 1 POUCH		
1		19.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:58790-000-24	6 in 1 CARTON	01/01/1995	
2		4 in 1 POUCH		
2		19.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
3	NDC:58790-000-20	5 in 1 CARTON	01/01/1995	
3		4 in 1 POUCH		
3		19.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
4	NDC:58790-000-30	5 in 1 CARTON	12/07/2018	
4		6 in 1 POUCH		
4		0.6 mL in 1 APPLICATOR; 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	01/01/1995	

**Labeler** - Advanced Vision Research (Subsidiary of Akorn, Inc.) (969124536)