THERATEARS- carboxymethylcellulose sodium gel
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.

Drug Facts

Active ingredient (In each unit dose)

sodium carboxymethylcellulose 1%

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 or comments? 1-800-579-8327

Principal Display Panel Text for Container Label:

PRESERVATIVE FREE

thera

tears®

THERAPY FOR YOUR EYES®

Liquid Gel

nighttime

dry eye therapy

LUBRICANT EYE GEL

SOOTHING

OVERNIGHT

RELIEF

STERILE

4 Single-Use

Vials 0.08 FL OZ (2.4mL) TOTAL

Principal Display Panel Text for Carton Label:

PRESERVATIVE

FREE

RECOMMENDED

DOCTOR

CREATED

thera

tears®

THERAPY FOR YOUR EYES®

Liquid Gel

nighttime

dry eye therapy

LUBRICANT EYE GEL

SOOTHING

OVERNIGHT

RELIEF

28 STERILE

Single-Use Vials* 0.57 FL OZ (16.8mL) TOTAL

THERATEARS

carboxymethylcellulose sodium gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58790-002
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311) (carboxymethylcellulose - UNII:05JZI7B19X)	carboxymethylcellulose sodium, unspecified form	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
boric acid (UNII: R57ZHV85D4)	
sodium borate (UNII: 91MBZ8H3QO)	
calcium chloride (UNII: M4I0D6VV5M)	
magnesium chloride (UNII: 02F3473H9O)	
potassium chloride (UNII: 660YQ98I10)	
water (UNII: 059QF0KO0R)	
sodium bicarbonate (UNII: 8MDF5V39QO)	
sodium chloride (UNII: 451W47IQ8X)	
sodium phosphate (UNII: SE337SVY37)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58790-002-28	7 in 1 CARTON	12/01/2002	
1		0.6 mL in 1 POUCH; 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	12/01/2002	

THERATEARS

carboxymethylcellulose sodium gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58790-003
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
carboxymethylcellulose sodium, unspecified form (UNII: K679OBS311) (carboxymethylcellulose - UNII:05JZI7B19X)	carboxymethylcellulose sodium, unspecified form	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
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magnesium chloride (UNII: 02F3473H9O)	
potassium chloride (UNII: 660YQ98I10)	

water (UNII: 059QF0KO0R)	
sodium bicarbonate (UNII: 8MDF5V39QO)	
sodium chloride (UNII: 451W47IQ8X)	
sodium phosphate (UNII: SE337SVY37)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58790-003-30	6 in 1 CARTON	12/07/2018	
1		0.6 mL in 1 POUCH; 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	12/07/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Pharma Solutions, LLC		043911403	MANUFACTURE(58790-002, 58790-003) , LABEL(58790-002, 58790-003) , PACK(58790-002, 58790-003)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoire Unither		574139809	MANUFACTURE(58790-002, 58790-003) , LABEL(58790-002, 58790-003) , PACK(58790-002, 58790-003)

Revised: 12/2018 Advanced Vision Research (Subsidiary of Akorn, Inc.)