

**THERATEARS LUBRICANT- carboxymethylcellulose sodium solution/ drops
MEDTECH PRODUCTS 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.

TheraTears MD 58790-001

Drug Facts

Active ingredient

Sodium carboxy-
methylcellulose 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. Replace cap after using.

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

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

Other information

- Do not use if neck ring is broken or missing.
- Discard 45 days after opening.

Inactive ingredients

Borate buffers, calcium chloride, Dequest®, magnesium chloride, potassium chloride, sodium bicarbonate, sodium chloride, sodium perborate, sodium phosphate, and water for injection.

Questions or comments?

1-800-579-8327

Principal Display Panel Text for Carton Label:

VALUE SIZE

RECOMMENDED

DOCTOR

CREATED

thera

tears®

THERAPY FOR YOUR EYES®

dry eye therapy

LUBRICANT

EYE DROPS

IMMEDIATE

LONG LASTING

RELIEF

STERILE

Multi-Use Bottle*

1 FL OZ (30 mL)

Bottle image is actual size

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.

Warnings

For external use only.

- To avoid contamination do not touch tip of opened container to any surface. Replace cap tightly after each use.

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

Other information

- Use only if cap seal is intact at time of purchase.
- Discard 45 days after opening.

Inactive ingredients Borate buffers, calcium chloride, Dequest 2060S phosphate, magnesium chloride, potassium chloride, sodium bicarbonate, sodium chloride, sodium perborate, sodium phosphate and water.

Questions or comments? 1-800-579-8327

VALUE SIZE

RECOMMENDED DOCTOR CREATED

RESTORES EYES NATURAL BALANCE™

dry eye therapy

WITH

OSMO-CORRECTION®
HYPOTONIC & ELECTROLYTE BALANCED

Clinically Proven Formula

- Replicates healthy tears
- Preservative free in the eye

Part of the TheraTears® Dry Eye Therapy Line Formulated for Dry Eye Symptoms

Learn more at theratears.com

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A Prestige Consumer Healthcare company
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82062100 TTU5004101

STERILE Multi-Use Bottle

1 FL OZ (30 mL)

IMMEDIATE LONG LASTING RELIEF

Back

"I had seen hundreds of patients frustrated by dry eyes and I wanted to help them. That's why I developed TheraTears. I worked on this for 18 years and didn't give up."

Jeffrey P. Gilbard, MD
Ophthalmologist

108.74

THERATEARS LUBRICANT

carboxymethylcellulose sodium solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58790-001
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
boric acid (UNII: R57Z HV85D4)	
sodium perborate (UNII: Y52BK1W96C)	
calcium chloride (UNII: M4I0D6V5M)	
diethylenetriamine pentamethylene phosphonic acid (UNII: 0Q75589TM3)	
magnesium chloride (UNII: 02F3473H9O)	
potassium chloride (UNII: 660YQ98110)	
water (UNII: 059QF0K00R)	
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:58790-001-30	1 in 1 CARTON	07/01/1999	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:58790-001-15	1 in 1 CARTON	07/01/1999	
2		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:58790-001-31	2 in 1 CARTON	12/01/2020	
3		30 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	07/01/1999	

Labeler - MEDTECH PRODUCTS INC (114707784)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	analysis(58790-001) , label(58790-001) , manufacture(58790-001) , pack(58790-001)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn Operating Company LLC (dba Akorn)		117696790	label(58790-001) , pack(58790-001)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn Operating Company LLC (dba Akorn)		117696832	analysis(58790-001) , manufacture(58790-001) , sterilize(58790-001)

Revised: 3/2022

MEDTECH PRODUCTS INC