

**THERATEARS EXTRA- carboxymethylcellulose sodium, unspecified 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 Extra PF 58790-010

Drug Facts

Active ingredient

Sodium carboxymethylcellulose 0.25%

Purpose

Eye lubricant

Uses

- For use as a protectant against further irritation or to relieve dryness of the eye.
- For use as a lubricant to prevent further irritation or to relieve dryness of the eye.

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 right away.

Directions

- To open, **twist** tab completely off.
- Instill 1 or 2 drops of TheraTears® EXTRA® 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

Boric acid, calcium chloride, hydrochloric acid*, magnesium chloride, potassium chloride, sodium bicarbonate, sodium borate, sodium chloride, sodium hydroxide*, sodium phosphate, trehalose, and water for injection. *May contain these ingredients to adjust pH.

Questions or comments?

1-800-579-8327

Principal Display Panel Text for Carton Label:

PRESERVATIVE

FREE

RECOMMENDED

DOCTOR

CREATED

thera

tears®

THERAPY FOR YOUR EYES®

EXTRA®

dry eye therapy

LUBRICANT

EYE DROPS

EXTRA MOISTURIZING

✓ Rehydrates

✓ Protects

✓ Supports pH Level

30 STERILE

Single-Use Vials 0.60 FL OZ (18.0 mL) TOTAL

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Warnings
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 • **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.

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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
 Jeffrey P. Gilbard, MD
 Ophthalmologist

Part of the TheraTears® Dry Eye Therapy Line Formulated for Dry Eye Symptoms
 Learn more at theratears.com

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PRESERVATIVE FREE

RECOMMENDED DOCTOR CREATED

RESTORES EYES NATURAL BALANCE®

TheraTears® EXTRA®
 DRY EYE SYMPTOM RELIEF

EXTRA MOISTURIZING
 ✓ Rehydrates Dry Eyes
 ✓ Protects Against Further Irritation
 ✓ Supports Natural Tear pH Level
 ✓ Preservative free for sensitive eyes

EXTRA MOISTURIZING
 ✓ Rehydrates
 ✓ Protects
 ✓ Supports pH Level

30 STERILE Single-Use Vials
 0.60 FL OZ (18.0 mL) TOTAL

THERATEARS EXTRA

carboxymethylcellulose sodium, unspecified solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58790-010
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	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Boric Acid (UNII: R57ZHV85D4)	
calcium chloride (UNII: M4I0D6VV5M)	
hydrochloric acid (UNII: QTT17582CB)	
magnesium chloride (UNII: 02F3473H90)	
potassium chloride (UNII: 660YQ981I0)	
sodium bicarbonate (UNII: 8MDF5V39QO)	
sodium borate (UNII: 91MBZ8H3QO)	
sodium chloride (UNII: 451W47IQ8X)	
sodium hydroxide (UNII: 55X04QC32I)	
sodium phosphate (UNII: SE337SVY37)	
trehalose (UNII: B8WCK70T7I)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58790-010-30	6 in 1 CARTON	01/21/2021	
1		5 in 1 POUCH		
1		0.6 mL in 1 VIAL, SINGLE-USE; 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	01/21/2021	

Labeler - MEDTECH PRODUCTS INC (114707784)

Revised: 3/2022

MEDTECH PRODUCTS INC