

**THERATEARS EXTRA- carboxymethylcellulose sodium, unspecified form 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 MD 58790-007

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 risk of 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 right away.

Directions

Instill 1 or 2 drops of TheraTears® Extra® 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

Boric acid, calcium chloride, Dequest®, 2060S phosphonate, magnesium chloride, potassium chloride, sodium bicarbonate, sodium borate, sodium chloride, sodium perborate, sodium phosphate, trehalose, and water for injection.

Questions or comments?

1-800-579-8327

Principal Display Panel Text for Container Label:

thera

tears®

THERAPY FOR YOUR EYES®

EXTRA®

dry eye therapy

LUBRICANT

EYE DROPS

EXTRA MOISTURIZING

✓ Rehydrates

✓ Protects

✓ Supports pH Level

STERILE

Multi-Use

Bottle TWO 0.5 FL OZ (15 mL) BOTTLES

| | | | |
|---|---|---|--|
| Drug Facts <i>Bottle image is actual size</i> | <p>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."</p> <p><i>Jeffrey F. Glubard, MD</i> Jeffrey F. Glubard, MD Ophthalmologist</p> | VALUE TWIN PACK |  <p>RESTORES EYES NATURAL BALANCE*</p> |
| Active ingredient Sodium carboxymethylcellulose 0.25%... Purpose Eye lubricant | <p>ON THE GO</p> <p>AT HOME</p> |  | <p>EXTRA dry eye therapy</p> |
| Uses <ul style="list-style-type: none"> 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. | <p>Part of the TheraTears® Dry Eye Therapy Line Formulated for Dry Eye Symptoms</p> <p>Learn more at theratears.com</p> | <p>thera tears® THERAPY FOR YOUR EYES®</p> <p>EXTRA® dry eye therapy LUBRICANT EYE DROPS</p> | <p>— WITH — OSMO-CORRECTION® HYPOTONIC & ELECTROLYTE BALANCED</p> |
| Warnings For external use only. <ul style="list-style-type: none"> To avoid risk of contamination do not touch tip of opened container to any surface. Replace cap tightly after each use. | <p>Dist. by Medtech Products Inc. Tarrytown, NY 10591</p> <p>A Prestige Consumer Healthcare company.</p> <p>©2022 Trade dress is owned by Medtech Products Inc. All rights reserved.</p> <p>TTUS014101</p> |  | <ul style="list-style-type: none"> ✓ Rehydrates Dry Eyes ✓ Protects Against Further Irritation ✓ Supports Natural Tear pH Level |
| Do not use if solution changes color or becomes cloudy. | | <p>STERILE Multi-Use Bottle</p> |  |
| Stop use and ask a doctor if <ul style="list-style-type: none"> you experience eye pain, changes in vision, continued redness or irritation. condition worsens or persists for more than 72 hours. | | <p>TWO 0.5 FL OZ (15 mL) BOTTLES</p> | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | | | |
| Directions Instill 1 or 2 drops of TheraTears® EXTRA® in the affected eye(s) as needed. | | | |
| Other information <ul style="list-style-type: none"> Use only if cap seal is intact at time of purchase. Discard 45 days after opening. | | | |
| Inactive ingredients Boric acid, calcium chloride, Disquest® 2060S phosphonate, magnesium chloride, potassium chloride, sodium bicarbonate, sodium borate, sodium chloride, sodium perborate, sodium phosphate, trehalose, and water. | | | |
| Questions or comments? 1-800-579-8327 | | | |

Principal Display Panel Text for Carton Label:

RECOMMENDED

DOCTOR

CREATED

thera

tears®

THERAPY FOR YOUR EYES®

EXTRA®

dry eye therapy

LUBRICANT

EYE DROPS

EXTRA MOISTURIZING

✓ Rehydrates

✓ Protects

✓ Supports pH Level

STERILE

Multi-Use

Bottle 0.5 FL OZ (15 mL)

Drug Facts Bottle silhouette is actual size.

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

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Directions

Instill 1 or 2 drops of TheraTears® EXTRA® 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

Boric acid, calcium chloride, Daquest® 2060S phosphate, magnesium chloride, potassium chloride, sodium bicarbonate, sodium borate, sodium chloride, sodium perborate, sodium phosphate, trehalose, and water.

Questions or comments? 1-800-575-8327

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 at
96.84

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 TUS013101



thera tears
THERAPY FOR YOUR EYES®

EXTRA
dry eye therapy
LUBRICANT EYE DROPS

EXTRA MOISTURIZING

- ✓ Rehydrates
- ✓ Protects
- ✓ Supports pH Level

STERILE Multi-Use Bottle
0.5 FL OZ (15 mL)

RESTORES EYES NATURAL BALANCE*

EXTRA dry eye therapy

WITH OSMO-CORRECTION®
HYPOTONIC & ELECTROLYTE BALANCED

- ✓ Rehydrates Dry Eyes
- ✓ Protects Against Further Irritation
- ✓ Supports Natural Tear pH Level



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THERATEARS EXTRA

carboxymethylcellulose sodium, unspecified form solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58790-007 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---|----------------|
| Carboxymethylcellulose Sodium, Unspecified Form (UNII: K679OBS311) (Carboxymethylcellulose - UNII:05JZ17B19X) | Carboxymethylcellulose Sodium, Unspecified Form | 2.5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Boric Acid (UNII: R57ZHV85D4) | |
| calcium chloride (UNII: M4I0D6V5M) | |
| Diethylenetriamine Pentamethylene Phosphonic Acid (UNII: 0Q75589TM3) | |
| potassium chloride (UNII: 660YQ98I10) | |
| sodium bicarbonate (UNII: 8MDF5V39QO) | |
| sodium borate (UNII: 91MBZ8H3QO) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| magnesium chloride (UNII: 02F3473H9O) | |
| sodium perborate (UNII: Y52BK1W96C) | |

sodium phosphate (UNII: SE337SVY37)

trehalose (UNII: B8WCK70T7I)

water (UNII: 059QF0KO0R)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58790-007-15 | 1 in 1 CARTON | 04/16/2018 | |
| 1 | | 15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |
| 2 | NDC:58790-007-16 | 2 in 1 CARTON | 12/01/2020 | |
| 2 | | 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 | 04/16/2018 | |

Labeler - MEDTECH PRODUCTS INC (114707784)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|---|
| Akorn AG | | 482198285 | analysis(58790-007) , label(58790-007) , manufacture(58790-007) , pack(58790-007) |

Revised: 3/2022

MEDTECH PRODUCTS INC