

THERATEARS- carboxymethylcellulose sodium gel
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 Liquid Night PF 58790-003

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 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

30 STERILE

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

<p>Drug Facts</p> <p>Active ingredient (in each unit dose) Purpose Sodium carboxymethylcellulose 1% Eye lubricant</p> <p>Uses</p> <ul style="list-style-type: none"> 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. <p>Warnings</p> <p>For external use only.</p> <ul style="list-style-type: none"> To avoid contamination do not touch tip of opened container to any surface. Do not reuse. Once opened discard. Use individual vials within 30 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. <p>Do not use if solution changes color or becomes cloudy.</p> <p>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.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Directions</p> <ul style="list-style-type: none"> To open, twist tabs completely off. Insert 1 or 2 drops in the affected eye(s) as needed. <p>Other information</p> <ul style="list-style-type: none"> Use only if foil pouch is sealed and single-use container is intact. Do not touch unit-dose tip to eye. <p>Inactive ingredients Borate buffers, calcium chloride, magnesium chloride, potassium chloride, sodium bicarbonate, sodium chloride, sodium phosphate and water for injection.</p> <p>Questions or comments? 1-800-575-8327</p>	<p>Nighttime is the time when your eyes naturally rest and recover. But I have seen hundreds of frustrated dry-eye patients who told me their eyes still felt dry and irritated in the morning. That is why I developed TheraTears®. Try TheraTears® at bedtime and you will feel the difference in the morning.</p> <p><i>Jeffrey P. Glibard, MD</i> Jeffrey P. Glibard, MD Ophthalmologist</p> <p>Part of the TheraTears® Dry Eye Therapy Line Formulated for Dry Eye Symptoms</p> <p>Learn more at theratears.com</p> <p>theratears.com MADE IN FRANCE Dtd. by Melick Products Inc., Tarrytown, NY 10591 A Pledge Company Healthcare company ©2022 Melick Products Inc. All rights reserved. TR20201101</p> <p><small>*Product may vary slightly from illustration.</small></p>	<p>PRESERVATIVE FREE</p> <p>RECOMMENDED DOCTOR CREATED</p> <p>theratears THERAPY FOR YOUR EYES®</p> <p>Liquid Gel nighttime dry eye therapy LUBRICANT EYE GEL</p> <p>SOOTHING OVERNIGHT RELIEF</p> <p>30 STERILE Single-Use Vials* 0.60 FL OZ (18.0 mL) TOTAL</p>	<p>RESTORES EYES NATURAL BALANCE*</p> <p>Liquid Gel nighttime dry eye therapy</p> <p>WITH OSMO-CORRECTION® HYPOTONIC & ELECTROLYTE BALANCED</p> <p>Clinically Proven Formula Unique formula replicates healthy tears Preservative free for sensitive eyes</p>
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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

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

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

Drug Facts

Active ingredient Purpose
Sodium carboxymethylcellulose 1%.....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
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Drug Facts (continued)

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. ▼

MADE IN USA theratears.com
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Ann Arbor, MI 48105 TTE-CA-01

Questions or comments? 1-800-579-8327

Drug Facts (continued)

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

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

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:05JZ17B19X)	carboxymethylcellulose sodium, unspecified form	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
boric acid (UNII: R57Z HV85D4)	

sodium borate (UNII: 91MBZ8H3QO)
calcium chloride (UNII: M4IOD6VV5M)
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	

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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		5 in 1 POUCH		
1		0.6 mL in 1 VIAL; 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 - MEDTECH PRODUCTS INC (114707784)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoire Unither		574139809	label(58790-002, 58790-003) , manufacture(58790-002, 58790-003) , pack(58790-002, 58790-003)

Revised: 3/2022

MEDTECH PRODUCTS INC