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 PF 58790-000

THERATEARS LUBRICANT- carboxymethylcellulose sodium solution/ drops
Medtech Products Inc., a Prestige Consumer Healthcare company

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Drug Facts

Active ingredient (In each unit dose)

Sodium Carboxymethylcellulose 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. 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 ptential 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 and comments?

1-800-579-8327

Principal Display Panel

PRESERVATIVE FREE

thera

tears®

THERAPY FOR YOUR EYES TM

dry eye therapy

LUBRICANT

EYE DROPS

IMMEDIATE

LONG LASTING

RELIEF

30 STERILE Single-Use Vials

0.60 FL OZ (18.0mL) TOTAL

THERATEARS LUBRICANT

carboxymethylcellulose sodium solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58790-000
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	2.5 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**
	NDC:58790			

1	NDC:58790-000-32	8 in 1 CARTON	01/01/1995	
1		4 in 1 POUCH		
1		19.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:58790-000-24	6 in 1 CARTON	01/01/1995	
2		4 in 1 POUCH		
2		19.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
3	NDC:58790-000-20	5 in 1 CARTON	01/01/1995	
3		4 in 1 POUCH		
3		19.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
4	NDC:58790-000-30	6 in 1 CARTON	12/07/2018	
4		5 in 1 POUCH		
4		0.6 mL in 1 VIAL; Type 0: Not a Combination Product		
5	NDC:58790-000-00	6 in 1 CARTON	12/07/2018	
5		5 in 1 POUCH		
5		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	01/01/1995	

Labeler - MEDTECH PRODUCTS INC (114707784)

Revised: 3/2022 MEDTECH PRODUCTS INC