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)

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: R57ZHV85D4)	
sodium perborate (UNII: Y52BK1W96C)	
calcium chloride (UNII: M4I0D6VV5M)	
diethylenetriamine pentamethylene phosphonic acid (UNII: 0Q75589TM3)	
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:58790-001-30	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