

ARTIFICIAL TEARS- glycerin, hypromellose, polyethylene glycol 400 liquid
American Sales Company

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.

CareOne Artificial Tears

Active Ingredient

Glycerin 0.2%

Hypromellose 0.2%

Polyethylene Glycol 400 1%

Purpose

Lubricant

Lubricant

Lubricant

Uses

- for use as a protectant against further irritation or to relieve dryness of the eye
- for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun

Warnings

Do not use this product 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 of the eye or if the condition worsens or persists for more than 72 hours

When using this product

- to avoid contamination, do not touch tip of container to any surface
- replace cap after using. Keep container tightly closed.
- remove contact lens before using

Keep out of reach of children.

If accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Instill 1 or 2 drops in the affected eye(s) as needed.

Other information

- Do not use if the tamper-resistant bottle cap is broken or opened.
- **RETAIN THIS CARTON FOR FUTURE REFERENCE**
- store between 15° to 30°C (59°F to 86°F)

Inactive ingredients

aminoacetic acid, ascorbic acid, benzalkonium chloride, boric acid, dextrose, disodium phosphate, magnesium chloride, potassium chloride, purified water, sodium borate, sodium chloride, sodium citrate, sodium lactate

Package principal display panel

Care One Tears



ARTIFICIAL TEARS

glycerin, hypromellose, polyethylene glycol 400 liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-865
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 -	POLYETHYLENE	10 mg

UNII:B697894SGQ)	GLYCOL 400	in 1 mL
HYPROMELLOSES (UNII: 3NXW29V3WO) (HYPROMELLOSES - UNII:3NXW29V3WO)	HYPROMELLOSES	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
DEXTROSE (UNII: IY9XDZ35W2)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
GLYCINE (UNII: TE7660XO1C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-865-05	1 in 1 BOX	09/10/2010	
1		15 mL in 1 BOTTLE; 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	09/06/2010	

Labeler - American Sales Company (809183973)

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