ARTIFICIAL TEARS- glycerin solution/ drops
Geri-Care Pharmaceuticals, Corp

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.

GC Artificial Tears 181

Active ingredients

Glycerin 0.2%

Hypromellose 0.2%

Polyethylene glycol 400 1%

Purpose

Lubricant

Uses

- for protection against further irritation
- for temporary relief of burning and irritation due to dryness of the eye

Warnings

For external use only

Do not use this product if solution changes color or becomes cloudy

When using this product

- to avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- remove contact lenses before using

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- instill 1 or 2 drops in the affected eye(s) as needed
- children under 6 years of age: ask a doctor

Other information

- store at 15°-30°C (59°-86°F)

Inactive ingredients

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, sodium phosphate monobasic

Questions or comments?

1-800-540-3765

package label

ARTIFICIAL TEARS

glycerin solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57896-181
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.002 mg in 1 mg
HYPROMELLOSES (UNII: 3NXW29V3WO) (HYPROMELLOSES - UNII:3NXW29V3WO)	HYPROMELLOSES	0.002 mg in 1 mg
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	0.01 mg in 1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DEXTROSE (UNII: IY9XDZ35W2)	
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57896-181-05	1 in 1 CARTON	06/01/2018	
1		15 mg 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	06/01/2018	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - Geri-Care Pharmaceuticals, Corp (611196254)

Revised: 12/2018 Geri-Care Pharmaceuticals, Corp