ARTIFICAL TEARS- glycerin and propylene glycol solution/ drops Rite Aid Corporation

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.

Drug Facts

Active ingredients

Glycerin (0.3%)

Propylene glycol (1.0%)

Purpose

Lubricant

Lubricant

Uses

- temporary relief of burning and irritation due to dryness of the eye
- prevents further irritation

Warnings

Do not use

if solution changes color or becomes cloudy

When using this product

- do not touch tip of container to any surface to avoid contamination
- remove contact lenses before using
- replace cap after use

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye
- 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 right away.

Directions

• instill 1 or 2 drops in the affected eye(s) as needed

Other information

- store at 15°-25°C (59°-77°F)
- keep tightly closed
- use before expiration date marked on the carton and bottle
- serious side effects associated with use of the product may be reported to the phone number provided below

Inactive ingredients

benzalkonium chloride (0.01%), boric acid, edetate disodium, potassium chloride, purified water, sodium borate, sodium chloride. Hydrochloric acid and/or sodium hydroxide may be used to adjust pH.

Questions?

Call: 1-866-767-8975

U.S. Patent No. 5,800,807

DISTRIBUTED BY: RITE AID

30 HUNTER LANE, CAMP HILL, PA 17011

MADE IN USA

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ITEM 398549

3123703

Package/Label Principal Display Panel



RITE

AID®

PHARMACY

eye care

artificial

tears

lubricant eye drops

DRY EYE FORMULA

fast relief from

age-related dry eyes replenishes tears refreshes eyes Sterile 1 FL OZ (30 mL)

ARTIFICAL TEARS

glycerin and propylene glycol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-9854
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.3 g in 100 mL	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	1 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
BORIC ACID (UNII: R57ZHV85D4)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)		
WATER (UNII: 059QF0KO0R)		
SODIUM BORATE (UNII: 91MBZ8H3QO)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
HYDRO CHLORIC ACID (UNII: QTT17582CB)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		

]	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-9854-	1 in 1 CARTON	09/01/2010	
1		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	09/01/2010		

Labeler - Rite Aid Corporation (014578892)

Registrant - Baush & Lomb Incorporated (196603781)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bausch & Lomb Incorporated		114406598	MANUFACTURE(11822-9854)	

Revised: 12/2018 Rite Aid Corporation