BIOLLE GEL TEARS- carboxymethylcellulose sodium, unspecified form solution/ drops
SAGE Ethnographic Research, dba Biollé

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.

Biollé Gel Tears®

Drug Facts

Active ingredient

Carboxymethylcellulose sodium 1%

Purpose

Eye lubricant

Inactive Ingredients

Boric Acid, calcium chloride; magnesium chloride, potassium chloride; purified water, sodium borate; and sodium chloride. May contain sodium hydroxide and/or hydrochloric acid to adjust pH.

Uses

- For temporary relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind or sun.
- May be used as a protectant against further irritation.

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

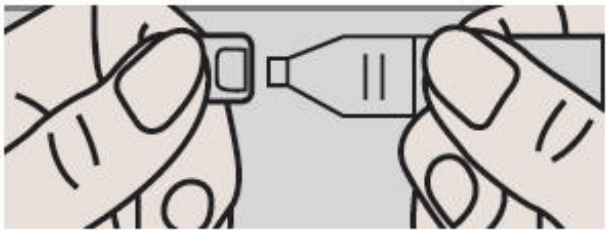
Other Information

- Use before expiration date marked on container.
- Store at 59-86 F (15-30C).
- Retain this carton for future reference.

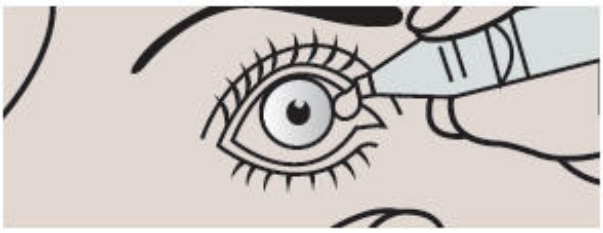
Warnings

- **For external use only.**
- **To avoid contamination, do not touch tip of container to any surface. Replace cap after using.**
- **If solution changes color or becomes cloudy, do not use.**

Directions



To open, twist and pull tab to remove.



Drop 1 to 2 drops in the affected eye as needed and discard the container.

Distributed by:
Biollé Inc.
PO Box 1386
New York, NY 10185

PRINCIPAL DISPLAY PANEL - 32 Vial Carton

Preservative-Free

Biollé
Gel Tears®

Rejuvenation in every drop

Severe dry eye relief

32 Single-use containers
0.02 fl oz (0.6mL) each sterile

BIOLLE GEL TEARS

carboxymethylcellulose sodium, unspecified form solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69994-002
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	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Calcium Chloride (UNII: M4I0D6VV5M)	
Magnesium Chloride (UNII: 02F3473H9O)	
Potassium Chloride (UNII: 660YQ98I10)	
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Lactate (UNII: TU7HW0W0QT)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69994-002-32	32 in 1 CARTON	06/01/2015	
1		0.6 mL in 1 VIAL, SINGLE-USE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:69994-002-72	72 in 1 CARTON	06/01/2015	
2		0.6 mL in 1 VIAL, SINGLE-USE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:69994-002-10	102 in 1 CARTON	06/01/2015	
3		0.6 mL in 1 VIAL, SINGLE-USE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:69994-002-02	2 in 1 CARTON	06/01/2015	
4		0.6 mL in 1 VIAL, SINGLE-USE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:69994-002-52	52 in 1 CARTON	06/01/2015	
5		0.6 mL in 1 VIAL, SINGLE-USE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
6	NDC:69994-002-04	4 in 1 CARTON	06/01/2015	
6		0.6 mL in 1 VIAL, SINGLE-USE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part349	06/01/2015	

Labeler - SAGE Ethnographic Research, dba Biollé (079824445)

Registrant - Biollé (000000000)