

**MAJOR LUBRICATING EYE DROPS- carboxymethylcellulose sodium solution/ drops
Harvard Drug Group L L C**

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.

Major Lubricating Eye Drops 30ct and 50ct

Active ingredient

Carboxymethylcellulose sodium 0.5%

Purpose

Lubricant

Uses

- for the temporary relief of burning, irritation, and discomfort due to dryness of the eyes or exposure to wind or sun
- may be used as a protectant against further irritation

Warnings

For external use only

Do not use this product if

- solution changes color or becomes cloudy

When using this product

- do not reuse
- once opened, discard
- to avoid contamination, do not touch tip of container to any surface
- do not touch unit-dose tip to eye

Stop use and ask a doctor if

- you experience eye pain
- changes in vision occur
- redness or irritation of the eye continues
- redness or irritation of the eye worsens or persists for more than 72 hours

Keep out of the reach of children.

If accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- to open, twist and pull tab to remove
- instill 1 or 2 drops in the affected eye(s) as needed and discard container
- if used for post-operative (e.g., LASIK) dryness and discomfort, follow your eye doctor's instructions

Other information

- store at 15°-25°C (59°-77°)
- use only if single use container is intact
- use before expiration date marked on container
- **RETAIN THIS CARTON FOR FUTURE REFERENCE**

Inactive ingredients

calcium chloride, **hydrochloric acid, magnesium chloride, potassium chloride, purified water, sodium chloride, **sodium hydroxide, sodium lactate. **May contain these ingredients to adjust pH.

Questions or comments?

Call (800) 616-2471

Major Lubricating Eye Drops 30ct

MAJOR®
Lubricating Eye Drops
Carboxymethylcellulose Sodium 0.5%
Lubricant

MAJOR®
Lubricating Eye Drops
Carboxymethylcellulose Sodium 0.5%
Lubricant
Immediate, long-lasting relief for dry, irritated eyes
Preservative Free
Sterile
30 Single Use Containers
0.01 FL OZ (0.4 mL) Each

Drug Facts
Active Ingredient Carboxymethylcellulose sodium 0.5% **Purpose** Lubricant
Uses
• for the temporary relief of burning, irritation, and discomfort due to dryness of the eyes or exposure to wind or sun
• may be used as a protectant against further irritation
Warnings
For external use only
Do not use this product if:
• irritation changes color or becomes cloudy
When using this product
• do not reuse
• once opened, discard
• do not touch tip of applicator to any surface
• do not touch unit-dose tip to eye
Stop use and ask a doctor if
• you experience eye pain
• changes in vision occur
• redness or irritation of the eye worsens or persists for more than 72 hours
Keep out of the reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.
Directions • to open, twist and pull tab to remove
• instill 1 or 2 drops in the affected eye(s) as needed and discard container
• if used for post-operative eye, (LASIK) dryness and discomfort, follow your eye doctor's instructions
Other Information • store at 15°-25°C (59°-77°F)
• use only if single use container is intact • use before expiration date marked on container
• **RETAIN THIS CARTON FOR FUTURE REFERENCE**
Inactive ingredients calcium chloride, **hydrochloric acid, magnesium chloride, potassium chloride, purified water, sodium chloride, **sodium hydroxide, sodium lactate
**May contain these ingredients to adjust pH.
Questions or comments?
Call (800) 616-2471

How to use:
To open, TWIST AND PULL TAB TO REMOVE.
Instill 1 or 2 drops in the affected eye(s) as needed and discard container.

*This product is not manufactured or distributed by Allergan, distributor of Refresh Plus®.

Rev. 05/20 M-93 Re-order No. 7010223
3 09046 84846 2
CSDLP0030MR1

NDC 0904-0849-46
Compare to the active ingredient in Refresh Plus®

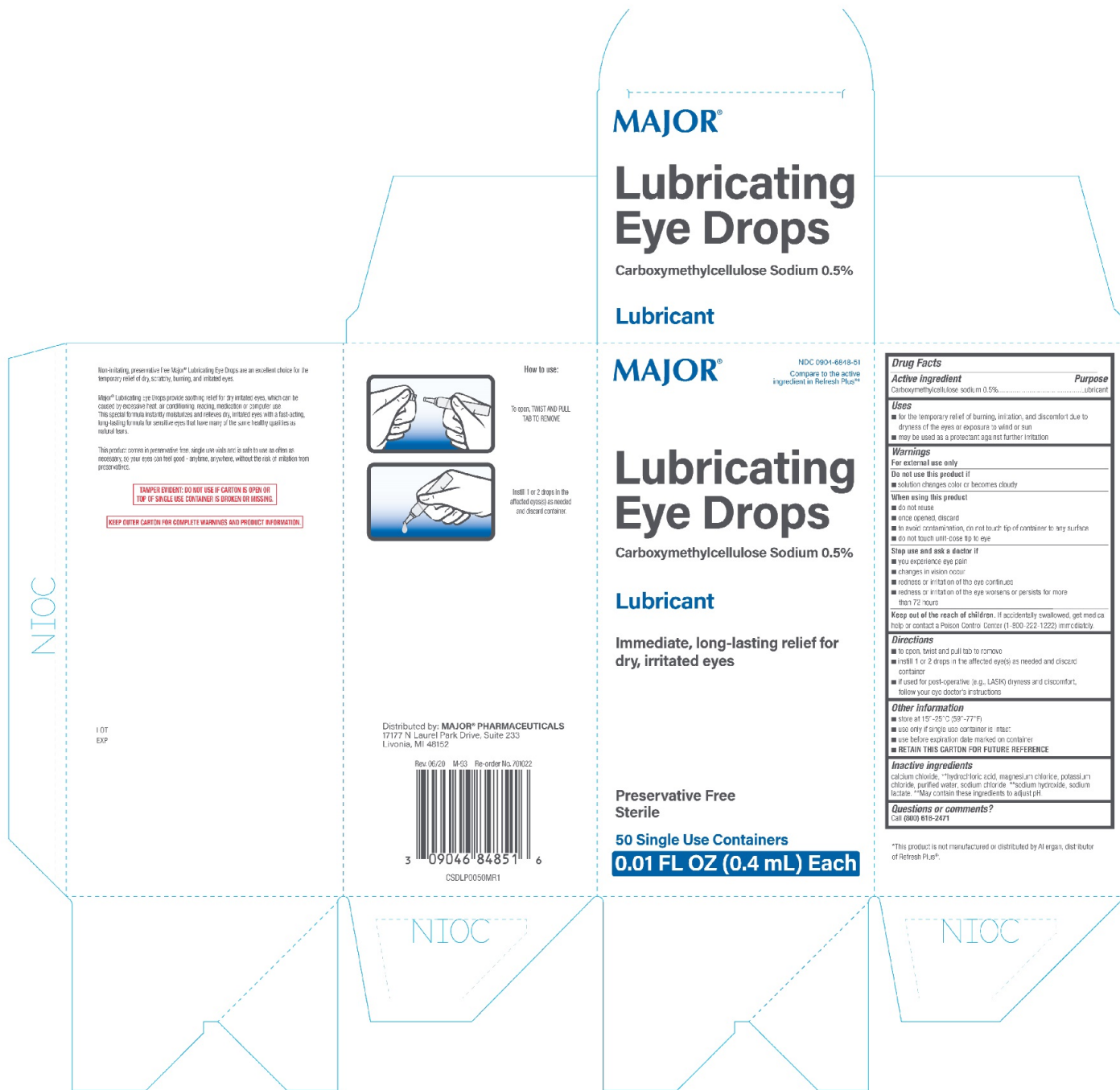
Non-irritating, preservative free Major® Lubricating Eye Drops are an excellent choice for the temporary relief of dry, itchy, burning, and irritated eyes.
Major® Lubricating Eye Drops provide soothing relief for dry irritated eyes, which can be caused by excessive heat, air conditioning, reading, medication or computer use. This special formula instantly moisturizes and relieves dry irritated eyes with a fast-acting, long-lasting formula for sensitive eyes that have many of the same healthy qualities as natural tears.
This product comes in preservative free, single use vials and is safe to use as often as necessary, as your eyes can feel good - anytime, anywhere, without the risk of irritation from preservatives.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR TOP OF SINGLE USE CONTAINER IS BROKEN OR MISSING.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

LOT
EXP

Distributed by: **MAJOR® PHARMACEUTICALS**
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152

Major Lubricating Eye Drops 50ct



MAJOR LUBRICATING EYE DROPS

carboxymethylcellulose sodium solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6848
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZI7B19X)	CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6848-51	50 in 1 BOX	06/23/2020	
1		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:0904-6848-46	30 in 1 BOX	06/23/2020	
2		0.4 mL in 1 VIAL, SINGLE-USE; 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	06/23/2020	

Labeler - Harvard Drug Group L L C (191427277)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	pack(0904-6848)

Establishment

Name	Address	ID/FEI	Business Operations
Unimed		689852052	manufacture(0904-6848) , label(0904-6848) , pack(0904-6848)