CARBOXYMETHYLCELLULOSE SODIUM- carboxymethylcellulose sodium solution
PROMED EXPORTS PRIVATE LIMITED

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.

ACTIVE INGREDIENT

Carboxymethylcellulose sodium (CMC) 0.5% ..... Eye lubricant

USES

- For the 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.

WARNINGS

- **For external use only.**
- **To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.**
- **Do not touch unit-dose tip to eye.**
- **Do not use 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.

KEEP OUT OF REACH OF CHILDREN

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

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

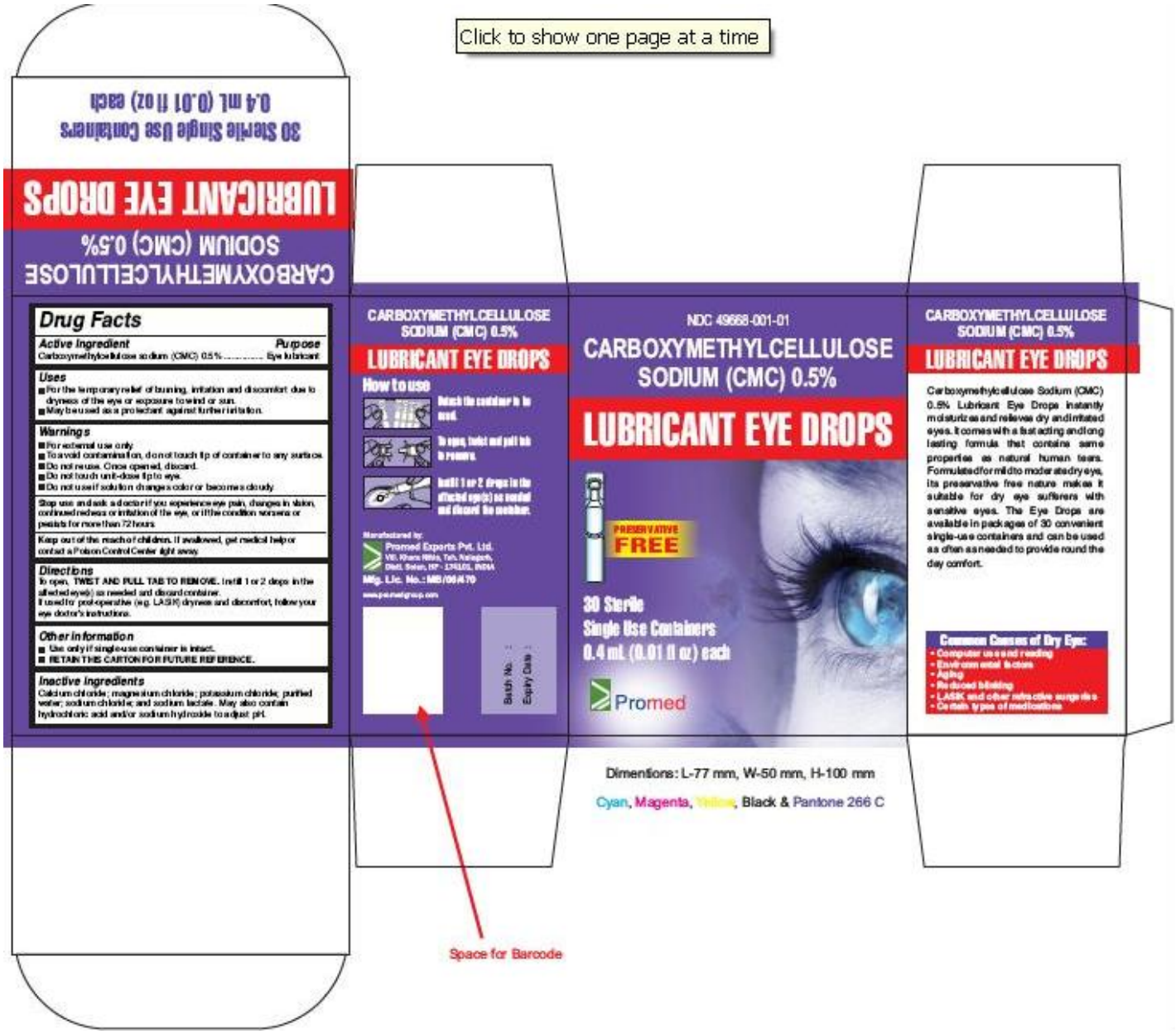
- **Use only if single-use container is intact.**
- **RETAIN THIS CARTON FOR FUTURE REFERENCE.**

INACTIVE INGREDIENTS

Calcium chloride; magnesium chloride; potassium chloride; purified water; sodium chloride; and sodium lactate. May also contain hydrochloric acid and/or sodium hydroxide to adjust pH.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 30 Sterile Single Use Containers

CARBOXYMETHYLCELLULOSE SODIUM (CMC) 0.5%
LUBRICANT EYE DROPS



CARBOXYMETHYLCELLULOSE SODIUM

carboxymethylcellulose sodium solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49668-001
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZI7B19X)	CARBOXYMETHYLCELLULOSE SODIUM	5 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:49668-001-01	30 in 1 CONTAINER		
1		0.4 mL in 1 VIAL, SINGLE-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part349	10/01/2009	

Labeler - PROMED EXPORTS PRIVATE LIMITED (650538325)

Establishment

Name	Address	ID/FEI	Business Operations
PROMED EXPORTS PRIVATE LIMITED		650538325	manufacture

Revised: 8/2009 PROMED EXPORTS PRIVATE LIMITED