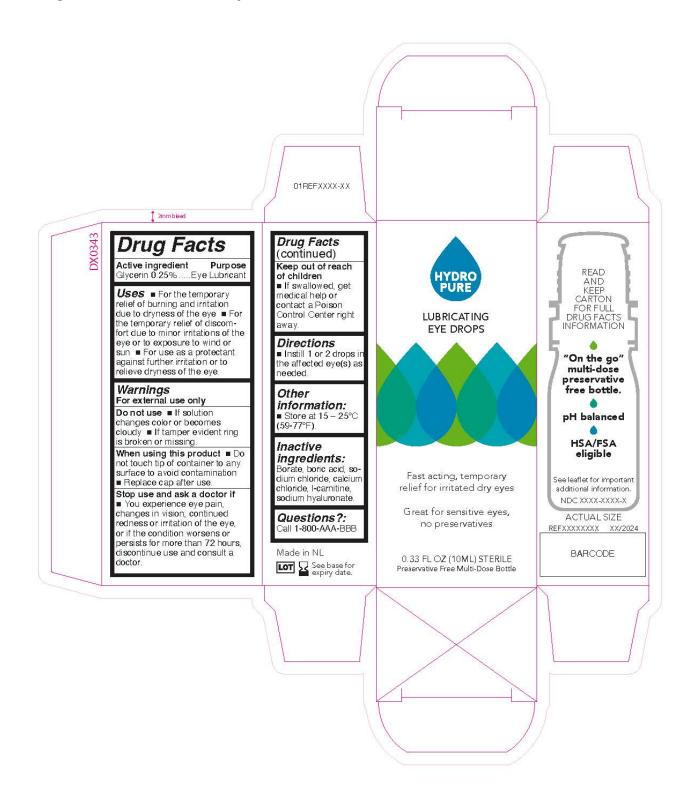
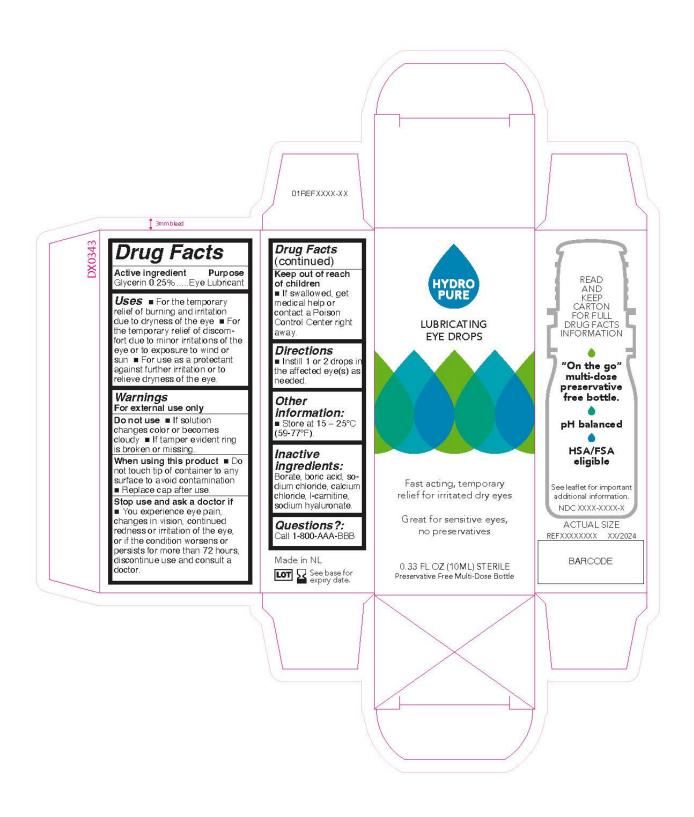
# 085 LUBRICATING EYE DROPS- lubricating eye drops solution/ drops OTE North America

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Warnings for External use only.

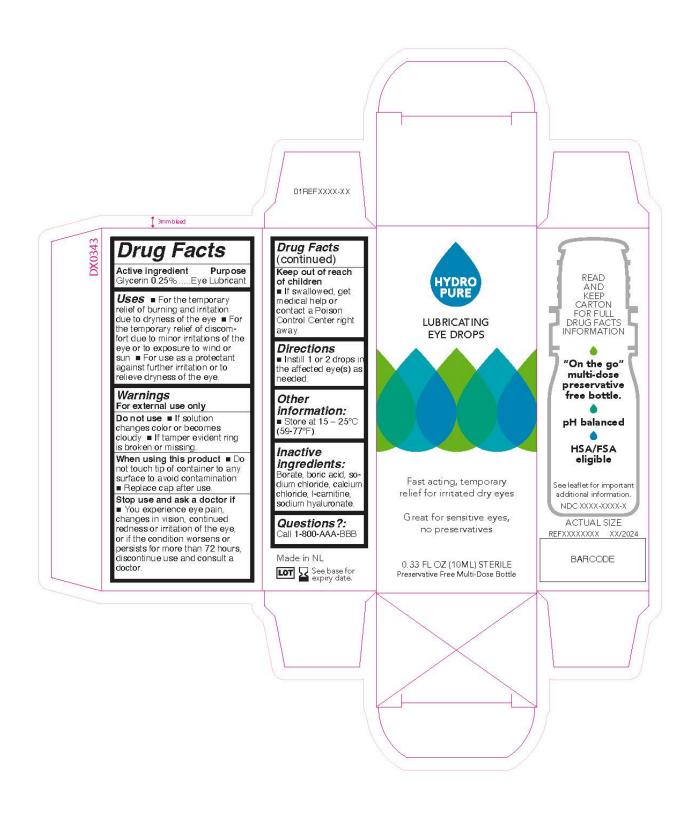


Inactive ingredients: borate, boric acid, sodium chloride, calcium chloride, l-carnitine, sodium hyaluronate

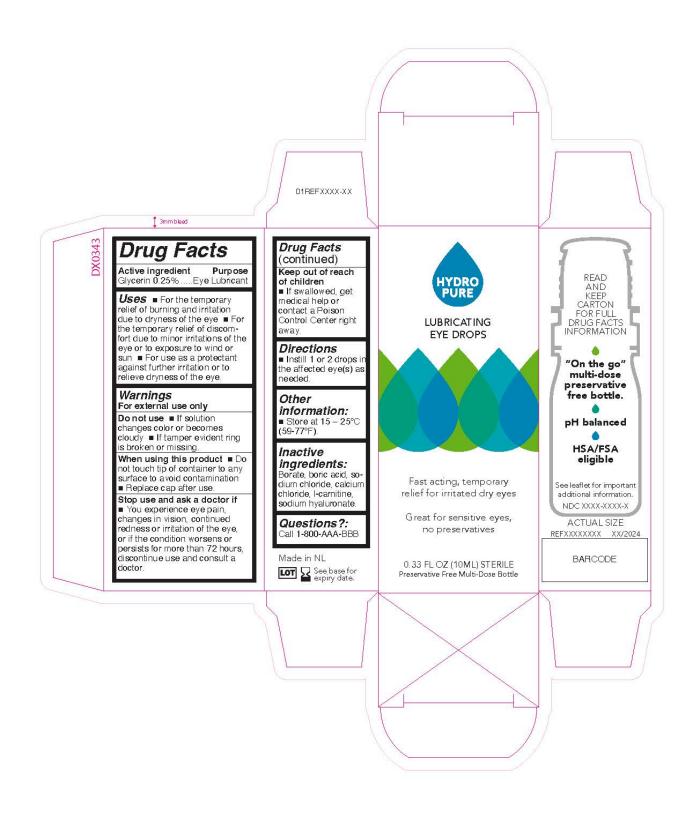


#### Uses

\*For the temporary relief of burning and irritation due to dryness of the eye \* For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun \* For use as a protectant against further irritation or to temporarily relieve dryness of the eye



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



I am not sure what is meant by purpose. There are the uses which is this section:

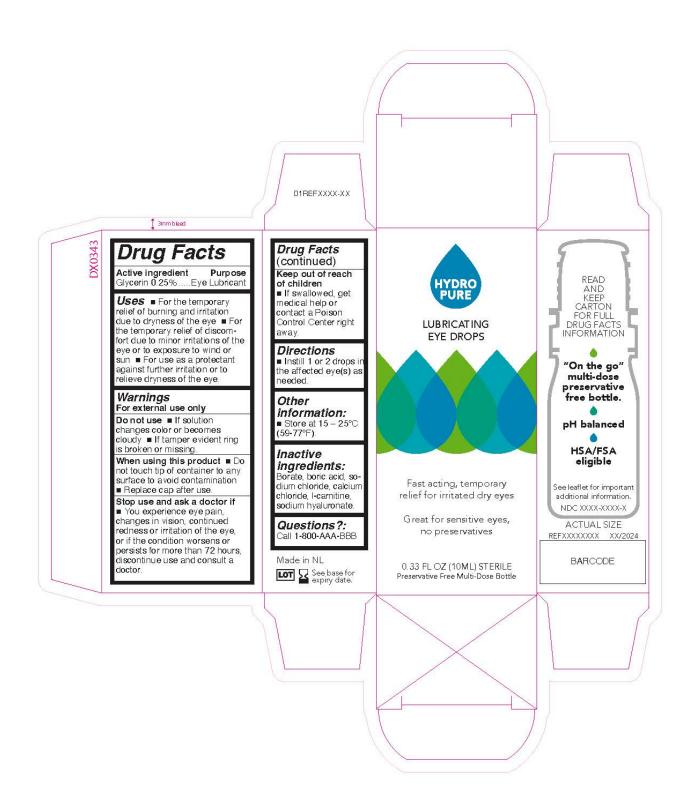
#### Uses

\*For the temporary relief of burning and irritation due to dryness of the eye \* For the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun \* For use as a protectant against further irritation or to temporarily relieve dryness of the eye

Then in the active ingredients section it describes the purpose like this:

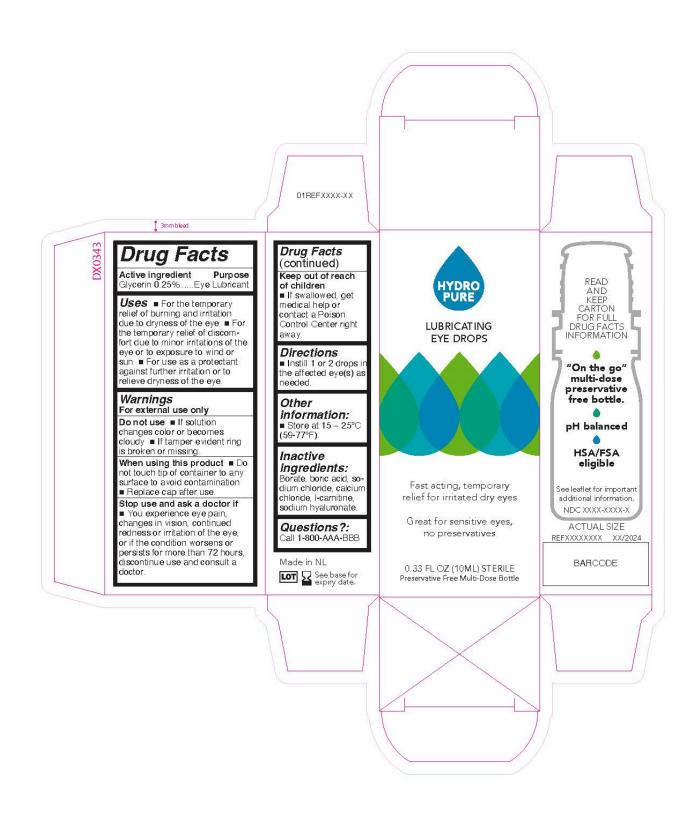
Active ingredient Purpose

Glycerin 0.25%..... Eye Lubricant



Active ingredient Purpose

Glycerin 0.25%..... Eye Lubricant



HydroPure box and label Page 1.jpg HydroPure box and label Page 2.jpg

01REFXXXX-XX 1 3mm bleed Drug Facts Drug Facts (continued) Active ingredient Glycerin 0.25% .... Purp ose Keep out of reach READ AND ...Eve Lubricant of children ■ If swallowed, get KEEP CARTON FOR FULL DRUG FACTS INFORMATION **Uses** ■ For the temporary medical help or relief of burning and irritation contact a Poison due to dryness of the eye ■ For Control Center right LUBRICATING the temporary relief of discomaway. EYE DROPS fort due to minor irritations of the eye or to exposure to wind or Directions sun ■ For use as a protectant ■ Instill 1 or 2 drops in "On the go" against further irritation or to the affected eye(s) as multi-dose relieve dryness of the eye. needed preservative Warnings free bottle. Other For external use only information: Do not use If solution ■ Store at 15 – 25°C (59-77°F). pH balanced changes color or becomes cloudy ■ If tamper evident ring is broken or missing. HSA/FSA Inactive When using this product ■ Do eligible ingredients: not touch tip of container to any Borate, boric acid, so-dium chloride, calcium surface to avoid contamination Fast acting, temporary See leaflet for important ■ Replace cap after use. chloride, I-carnitine, relief for irritated dry eyes additional information. Stop use and ask a doctor if sodium hyaluronate. NDC XXXX-XXXX-X You experience eye pain, changes in vision, continued Great for sensitive eyes, Questions?: ACTUAL SIZE redness or irritation of the eye, no preservatives Call 1-800-AAA-BBB REFXXXXXXXX XX/2024 or if the condition worsens or persists for more than 72 hours, Made in NL BARCODE discontinue use and consult a 0.33 FL OZ (10ML) STERILE doctor. See base for expiry date. Preservative Free Multi-Dose Bottle

DX0343

SEE CARTON AND LEAFLET FOR WARNINGS AND COMPLETE INFORMATION

TAMPER EVIDENT: Do not use if the pull strip on cap is broken or

missing.

DIRECTIONS:

Instill 1 or 2 drops in the affected eye(s) as needed.



Preservative Free Multi-Dose

0.33 FL OZ (10 ML) STERILE Active ingredient: Glycerin 0.25%

Manufactured in NL Distributed by: OTÉ North America LLC 265 E Merrick Rd, Ste 208 Valley Stream, NY 11580 Ph: +1 (516)620-2857

01REFXXXXXXXXX XX/2024





See base for expiry date.

### 085 LUBRICATING EYE DROPS

lubricating eye drops solution/ drops

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:84227-851

**Route of Administration** OPHTHALMIC

### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)

GLYCERIN

2.5 mg in 1 mL

### **Inactive Ingredients**

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LEVOCARNITINE (UNII: 0G389FZZ9M)	
BORATE ION (UNII: 440AE30D22)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	

### **Packaging**

i dekaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:84227- 851-10	1 in 1 CARTON	05/15/2024		
1	10 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 Drug	M018	05/15/2024	

## Labeler - OTE North America (963905034)

Revised: 5/2024 OTE North America