HYDROPURE LUBRICATING EYE DROPS- glycerin solution/ drops OTE North America

Hydropure Lubricating Eye Drops

Active ingredient

Glycerin 0.25%

Purpose

Eye Lubricant

Uses

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

Warnings for External use only.

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

Do not use

Do not use \blacksquare If solution changes color or becomes cloudy \blacksquare If tamper evident ring is broken or missing.

When using this product

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Do not touch tip of container to any surface to avoid contamination

■ Replace cap after use.

Stop use and ask a doctor if

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■ 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, discontinue use and consult a doctor.

Directions

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

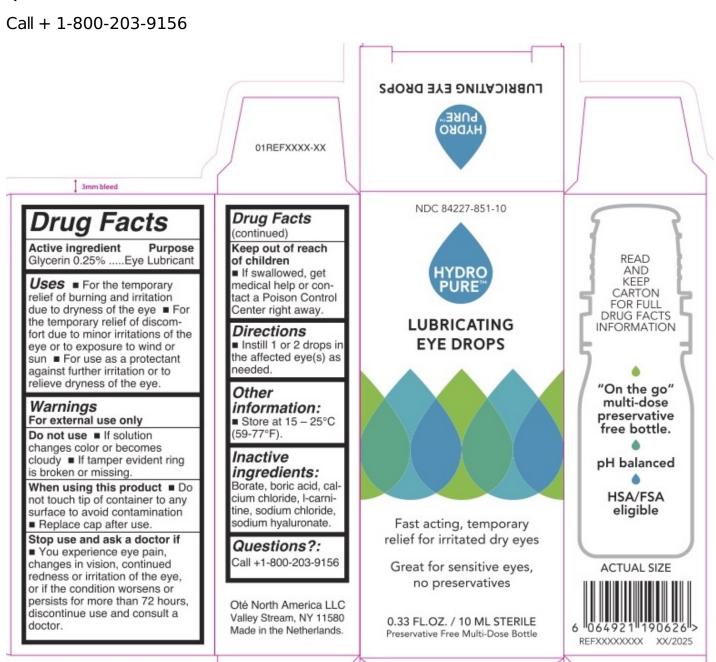
Inactive ingredients: borate, boric acid, sodium chloride, calcium chloride, l-carnitine, sodium hyaluronate

Other information

■ Store at 15 - 25 C (59-77 F).

Questions?

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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.



Multi-Dose

0.33 FL.OZ. / 10 ML

STERILE

Active ingredient: Glycerin 0.25%. Inactive ingredients: Borate, boric acid, calcium chloride, I-carnitine, sodium chloride, sodium hyaluronate.

Distributed by Ote North America LLC Valley Stream, NY 11580 Ph:1-800-203-9156 Manufactured in the Netherlands.

HYDROPURE LUBRICATING EYE DROPS

glycerin 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 GLYCERIN (UNII: PDC6A3C00X) (GLYCERIN - UNII:PDC6A3C00X) 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)					

ı	Packaging						
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
]	NDC:84227- 851-10	1 in 1 CARTON	05/15/2024				
]	L	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)

Establishment						
Name	Address	ID/FEI	Business Operations			
Ote Pharma Sol B.V.		418961173	manufacture(84227-851)			

Revised: 2/2025 OTE North America