REVITAL EYES- polyethylene glycol 400 and propylene glycol solution/ drops
Lunovus, LLC

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.

Revital eyes

Drug Facts

Active Ingredients	*Purpose*
Polyethylene Glycol 400 0.4%	Lubricant
Propylene Glycol 0.3%	Lubricant

Uses

For the temporary relief of burning and irritation due to dryness of the eye

Warnings

For external use only.

Do not use
- if solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

When using this product
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor if
- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists or lasts more than 72 hours

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

Directions
- Shake well before using.
- Instill 1 or 2 drops in the affected eye(s) as needed.

Other information
- Store at room temperature.

Inactive ingredients

Aminomethylpropanol, boric acid, hypromellose, magnesium chloride, potassium chloride, purified water, sodium chloride, sorbitol. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions or comments?

1-800-980-6551

Distributed by
Lunovus, LLC
729 1st Ave N,
Birmingham AL 35203

PRINCIPAL DISPLAY PANEL - 15 ml Bottle Carton

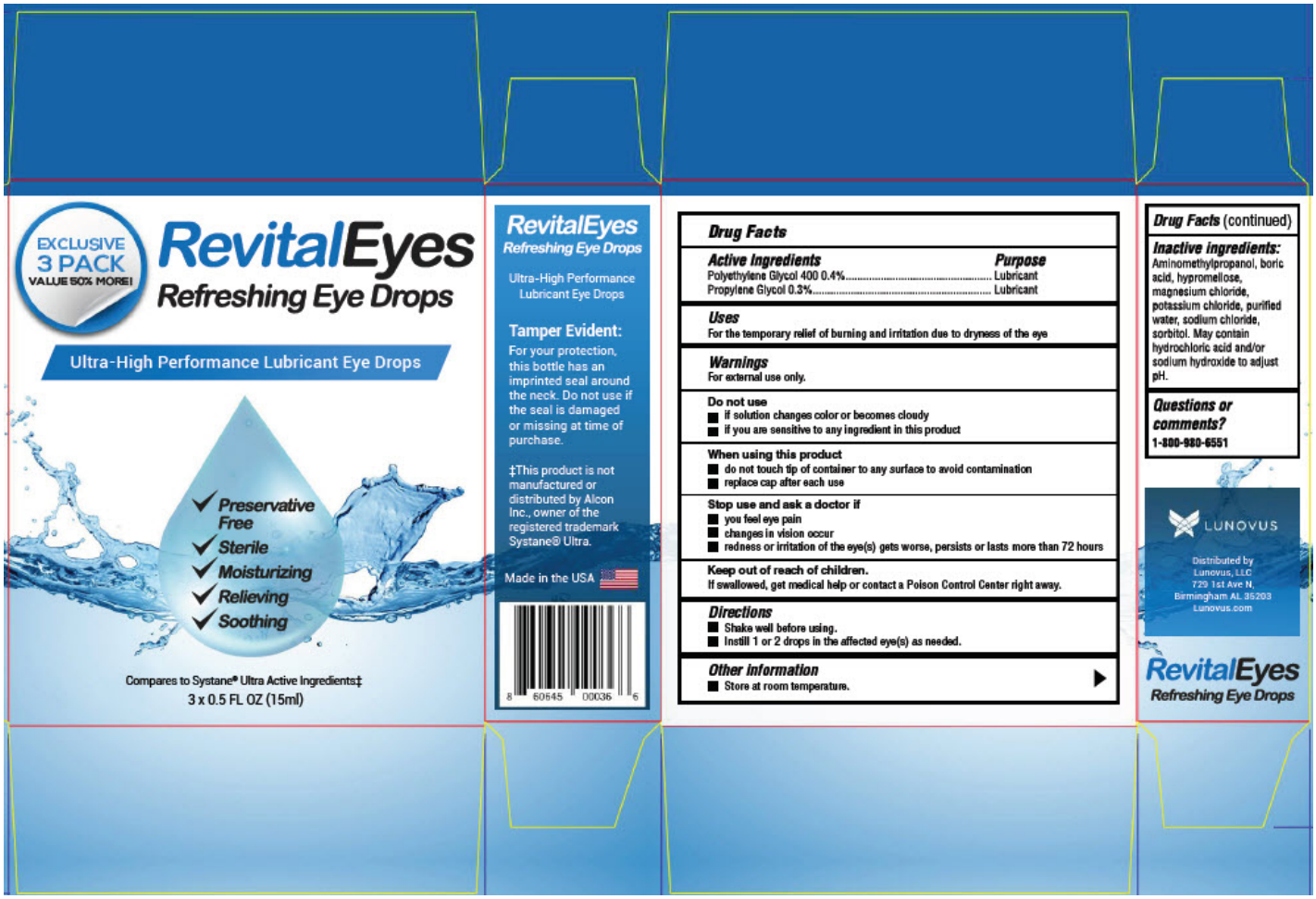
EXCLUSIVE
3 PACK
VALUE 50% MORE!

RevitalEyes
Refreshing Eye Drops

Ultra-High Performance Lubricant Eye Drops

- Preservative Free
- Sterile
- Moisturizing
- Relieving
- Soothing

Compares to Systane® Ultra Active Ingredients‡
3 x 0.5 FL OZ (15ml)



REVITAL EYES

polyethylene glycol 400 and propylene glycol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73197-001
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol 400 - UNII:B697894SGQ)	Polyethylene Glycol 400	4 mg in 1 mL
Propylene Glycol (UNII: 6DC9Q167V3) (Propylene Glycol - UNII:6DC9Q167V3)	Propylene Glycol	3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Aminomethylpropanol (UNII: LU49E6626Q)	
Boric Acid (UNII: R57ZHV85D4)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Chloride (UNII: 02F3473H9O)	

Potassium Chloride (UNII: 660YQ98I10)	
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sorbitol (UNII: 506T60A25R)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73197-001-01	3 in 1 CARTON	01/01/2020	
1		15 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 FINAL	part349	01/01/2020	

Labeler - Lunovus, LLC (166987656)

Establishment

Name	Address	ID/FEI	Business Operations
Excite Pharma Services - Tonganoxie KS		069731710	MANUFACTURE(73197-001) , LABEL(73197-001) , PACK(73197-001)

Establishment

Name	Address	ID/FEI	Business Operations
Excite Pharma Services -- Lee's Summit, MO		961636367	ANALYSIS(73197-001)

Revised: 8/2019 Lunovus, LLC