

**SOUNDBODY EYE LUBRICANT- polyethylene glycol, propylene glycol liquid
Kareway Product, Inc.**

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.

Soundbody Lubricant Eye Drops Ultra

Active ingredients

Polyethylene Glycol 400 0.4%

Propylene Glycol 0.3%

Purpose

Lubricant

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 this product 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

benzalkonium chloride, boric acid, hydrochloric acid, hydroxyethyl cellulose, potassium chloride, purified water, sodium chloride, sodium hydroxide

Soundbody Lubricant Eye Drops Ultra



SOUNDBODY EYE LUBRICANT

polyethylene glycol, propylene glycol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0649
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0649-5	1 in 1 BOX	05/30/2018	
1		15 mL in 1 BOTTLE; 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	05/30/2018	

Labeler - Kareway Product, Inc. (121840057)