SOUNDBODY ADVANCED RELIEF- dextran 70, polyethylene glycol 400, povidone, tetrahydrozoline hcl 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 Advanced Relief Eye Drops

Active Ingredient

Dextran 70 0.1%

Polyethylene Glycol 400 1%

Povidone 1%

Tetrahydrozoline HCl 0.5%

Purpose

Lubricant

Lubricant

Lubricant

Redness reliever

Use

- for the relief of redness of the eye due to minor eye irritations
- for use as a protectant against further irritation or to relieve dryness of the eye

Warnings

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- overuse may cause more eye redness
- remove contact lenses before using
- do not use if this solution changes color or become cloudy
- 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 lasts
- condition worsens or lasts more than 72 hours

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- Put 1 to 2 drops in the affected eye(s) up to 4 times daily
- children under 6 years of age: ask a doctor

Other information

- store between 15° to 25°C (59°F to 77°F)

Inactive ingredients

boric acid, sodium borate, edetate disodium, benzalkonium chloride, sodium chloride, dilite hydrochloric acid, sterile purified water

package label

Soundbody Advance relief Eye Drops

SOUNDBODY ADVANCED RELIEF

dextran 70, polyethylene glycol 400, povidone, tetrahydrozoline hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0652
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL
DEXTRAN 70 (UNII: 7SA290YK68) (DEXTRAN 70 - UNII:7SA290YK68)	DEXTRAN 70	1 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	10 mg in 1 mL
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0652-5	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)

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