REFRESH OPTIVE SINGLE VIAL- carboxymethylcellulose sodium, and glycerin solution/ drops
United Exchange Corp.

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.

NBE Refresh Optive Single Eye Drops 0.4 ml 13548ZZ (2018)

Active ingredients Purpose

Carboxymethylcellulose sodium 0.5%.....Eye Lubricant

Glycerin 0.9%.....Eye Lubricant

Uses

- for the temporary relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind or sun
- may be used as a protectant against further irritaiton

Warnings

- for external use only
- to avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.
- Do not touch tip unit-dose to eye
- If solution changes color, do not use.

Stop use and ask a doctor if 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

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

Directions

To open, TWIST AND PULL TAB TO REMOVE. Instill 1 or 2 drops in the affected eye(s) as needed and discard container.

If used for post-operative (e.g. LASIK) dryness and discomfort, follow your eye doctor's instructions

Other information

- use only if single-use container is intact
- use before expiration date marked on the container
- store at 59°-86°F (15°-30°C)

Inactive ingredients

boric acid, calcium chloride, levocarnitine, magnesium chloride, polyethylene glycol 400, potassium chloride, purified water, sodium borate, trisodium citrate dihydrate

Made in South Korea

REFRESH OPTIVE SINGLE VIAL

carboxymethylcellulose sodium, and glycerin solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-548
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZI7B19X)	CARBOXYMETHYLCELLULOSE SODIUM	5 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BORIC ACID (UNII: R57ZHV85D4)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
LEVOCARNITINE (UNII: 0G389FZZ9M)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-548-04	0.4 mL in 1 VIAL; Type 0: Not a Combination Product	01/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/02/2017	

Labeler - United Exchange Corp. (840130579)

Revised: 1/2018 United Exchange Corp.