REFRESH OPTIVE GEL DROPS- carboxymethylcellulose sodium and glycerin solution/ drops Allergan, 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.

Drug Facts

Active ingredients

Carboxymethylcellulose sodium 1%

Glycerin 0.9%

Purpose

Eye lubricant

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 irritation.

Warnings

- For external use only.
- To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- 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

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

Other information

- Use only if imprinted tape seals on top and bottom flaps are intact and clearly legible.
- Use before expiration date marked on container.
- Discard 90 days after opening.
- Store at 59°-86°F (15°-30°C).
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

Inactive ingredients

Boric acid; calcium chloride dihydrate; erythritol; levocarnitine; magnesium chloride hexahydrate; potassium chloride; purified water; PURITE (stabilized oxychloro complex); sodium borate [®]

decahydrate; sodium citrate dihydrate.

Questions or comments?

1.800.678.1605

refreshbrand.com

Refresh Optive $^{\mathbb{R}}$

GEL DROPS

Lubricant Eye Gel

EXTENDED THERAPY

Quick, soothing coverage delivers moisture day or night

0.33 fl oz (10 mL) Sterile



REFRESH OPTIVE GEL DROPS

carboxymethylcellulose sodium and glycerin solution/ drops

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0023-5459 Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
carboxymethylcellulose sodium (UNII: K679OBS311) (carboxymethylcellulose - UNII:05JZI7B19X)	carbo xymethylcellulo se so dium	10 mg in 1 mL	
glycerin (UNII: PDC6A3C0OX) (glycerin - UNII:PDC6A3C0OX)	glycerin	9 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
sodium chlorite (UNII: G538EBV4VF)	
boric acid (UNII: R57ZHV85D4)	
sodium borate (UNII: 91MBZ8H3QO)	
trisodium citrate dihydrate (UNII: B22547B95K)	
potassium chloride (UNII: 660 YQ 98 I10)	
calcium chloride (UNII: M4I0 D6 VV5M)	
magnesium chloride (UNII: 02F3473H9O)	
erythritol (UNII: RA96B954X6)	
levocarnitine (UNII: 0G389FZZ9M)	
water (UNII: 059QF0KO0R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0023-5459- 10	1 in 1 CARTON	09/30/2015		
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product			
2	NDC:0023-5459- 02	1 in 1 CARTON	09/30/2015		
2		2 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	09/30/2015		

Labeler - Allergan, INC (144796497)

Establishment				
Name	Address	ID/FEI	Business Operations	
Allergan Sales, LLC		362898611	MANUFACTURE(0023-5459)	

Revised: 9/2016 Allergan, INC