

REFRESH OPTIVE MEGA-3- carboxymethylcellulose sodium, glycerin and polysorbate 80 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.

REFRESH OPTIVE Mega-3 (Preservative-free)
Drug Facts

Active ingredients

Carboxymethylcellulose sodium 0.5%
Glycerin 1%
Polysorbate 80 0.5%

Purpose

Eye lubricant
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. Do not reuse. Once opened, discard.**
- **Do not touch unit-dose tip 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.

Other information

- Use only if single-use container is intact.
- Use before expiration date marked on container.
- Store at 59°-77°F (15°-25°C).
- Store vials in pouch until use.
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

Inactive ingredients

Boric acid; butylated hydroxyl toluene; carbomer copolymer type A; castor oil; erythritol; flaxseed oil; levocarnitine; polyoxyl 40 stearate; purified water; and trehalose. May contain hydrochloric acid and/or sodium hydroxide (to adjust pH).

Questions or comments?

1.800.678.1605

refreshbrand.com

v1.0DFL5773

PRINCIPAL DISPLAY PANEL

Preservative-free

Refresh

Optive®

MEGA-3

Lubricant Eye Drops

ENHANCED WITH FLAXSEED OIL

Prevents tear evaporation and restores all three layers of the tear film damaged by Dry Eye.

30 Single-Use Containers

0.01 fl oz (0.4 mL) each Sterile



PRINCIPAL DISPLAY PANEL

VALUE SIZE 60 Vials

PRESERVATIVE-FREE

Refresh

OPTIVE

MEGA-3®

Lubricant Eye Drops

For Eye Dryness

with **HydroCell™**

Moisture-rich Relief

Protects Tears from Evaporating

60 Vials 0.01 fl oz (0.4 mL) each Sterile



0362501

REFRESH OPTIVE MEGA-3

carboxymethylcellulose sodium, glycerin and polysorbate 80 solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0023-5773
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) (CARBOXYMETHYLCELLULOSE - UNII:05JZ17B19X)	CARBOXYMETHYLCELLULOSE SODIUM	5 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	10 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H) (POLYSORBATE 80 - UNII:6OZP39ZG8H)	POLYSORBATE 80	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CASTOR OIL (UNII: D5340Y2I9G)	
ERYTHRITOL (UNII: RA96B954X6)	
LINSEED OIL (UNII: 84XB4DV00W)	
LEVOCARNITINE (UNII: 0G389FZZ9M)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
WATER (UNII: 059QF0KO0R)	
TREHALOSE (UNII: B8WCK70T7I)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
May contain	HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0023-5773-05	5 in 1 BOX	05/30/2017	
1		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:0023-5773-30	30 in 1 BOX	05/30/2017	
2		0.4 mL in 1 VIAL, SINGLE-USE; 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	05/30/2017	

REFRESH OPTIVE MEGA-3

carboxymethylcellulose sodium, glycerin and polysorbate 80 solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0023-7151
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	10 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H) (POLYSORBATE 80 - UNII:6OZP39ZG8H)	POLYSORBATE 80	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CASTOR OIL (UNII: D5340Y2I9G)	
ERYTHRITOL (UNII: RA96B954X6)	
LINSEED OIL (UNII: 84XB4DV00W)	
LEVOCARNITINE (UNII: 0G389FZZ9M)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
WATER (UNII: 059QF0KO0R)	
TREHALOSE (UNII: B8WCK70T7I)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
May contain	HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0023-7151-60	60 in 1 BOX	06/15/2021	
1		0.4 mL in 1 VIAL, SINGLE-USE; 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	06/15/2021	

Labeler - Allergan, Inc. (144796497)