RETAINE MGD- mineral oil emulsion OCuSOFT, 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

Light Mineral Oil (0.5)	Emollient
Mineral Oil (0.5%)	Emollient

Uses

For use as a protectant against further irritation or to relieve dryness of the eye.

Warnings

For use in the eyes only.

Do not use

• if this product changes color.

When using this product

- do not touch tip of container to any surface to avoid contamination.
- do not reuse once opened.

Stop use and ask a doctor if

- you feel eye pain or changes in vision, continued redness or irritation of the eye.
- the condition worsens or persists for more than 72 hours.

KEEP OUT OF THE REACH OF CHILDREN

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

Directions

- Shake well before using.
- Instill 1 or 2 drops in the affected eye(s) as needed and discard container.

Other Information

- Use only if printed tamper seals on top and bottom flaps are intact.
- Drops appear as a milky white solution.
- Store between 15 °-30 °C (59 °-86 °F).

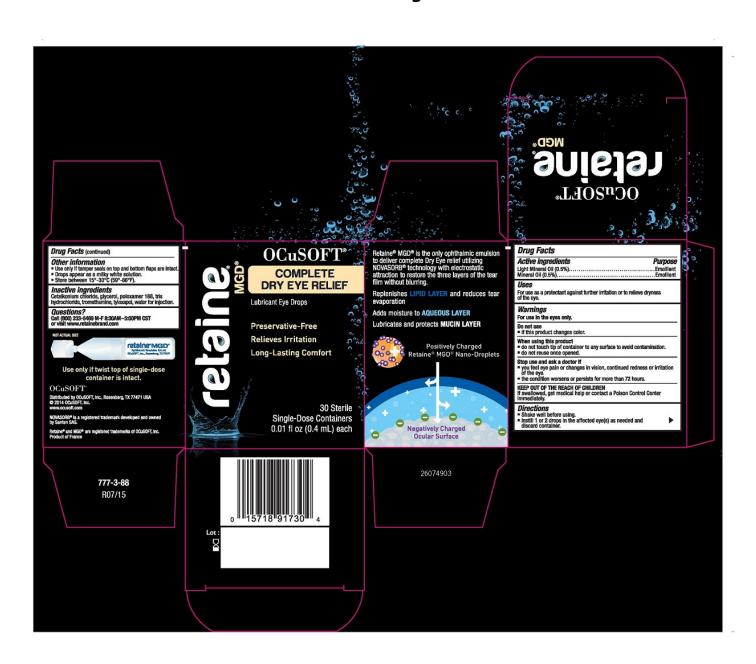
Inactive ingredients

Cetalkonium chloride, glycerol, poloxamer 188, tris hydrochloride, tromethamine, tyloxapol, water for injection.

Questions?

Call (800)233-5469 M-F 8:30AM-5:00PM CST or visit www.retainebrand.com Emollient

PRINCIPAL DISPLAY PANEL - 30 sterile Single-Dose Containers Carton



RETAINE MGD

mineral oil emulsion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54799-917

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIGHT MINERAL OIL (UNII: N6K5787QVP) (LIGHT MINERAL OIL - UNII: N6K5787QVP)	LIGHT MINERAL OIL	2 mg in 0.4 mL	
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	2 mg in 0.4 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CETALKONIUM CHLORIDE (UNII: 85474O1N9D)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLOXAMER 188 (UNII: LQA7B6G8JG)			
TROMETHAMINE HYDROCHLORIDE (UNII: 383V75M34E)			
TROMETHAMINE (UNII: 023C2WHX2V)			
TYLOXAPOL (UNII: Y27PUL9H56)			
WATER (UNII: 059QF0KO0R)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:54799- 917-30	30 in 1 CONTAINER	01/05/2012		
1	0.4 mL in 1 VIAL, SINGLE-DOSE; 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	01/05/2012	

Labeler - OCuSOFT, Inc. (174939207)

Registrant - OCuSOFT, Inc. (174939207)

Establishment			
Name	Address	ID/FEI	Business Operations
Excelvision		274234566	pack(54799-917), manufacture(54799-917)

Establishment				
Name	Address	ID/FEI	Business Operations	
Servipac		571772875	pack(54799-917)	

Revised: 1/2023 OCuSOFT, Inc.