

RETAINÉ 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}

OCuSOFT[®]

COMPLETE DRY EYE RELIEF

Lubricant Eye Drops

Preservative-Free
Relieves Irritation
Long-Lasting Comfort

30 Sterile Single-Dose Containers
0.01 fl oz (0.4 mL) each

Retaine[®] MGD[®] is the only ophthalmic emulsion to deliver complete Dry Eye relief utilizing NOVASORB[®] technology with electrostatic attraction to restore the three layers of the tear film without blurring.

Replenishes **LIPID LAYER** and reduces tear evaporation

Adds moisture to **AQUEOUS LAYER**

Lubricates and protects **MUCIN LAYER**

Positively Charged Retaine[®] MGD[®] Nano-Droplets

Negatively Charged Ocular Surface

Drug Facts (continued)

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NOT ACTUAL SIZE

Use only if twist top of single-dose container is intact.

OCuSOFT[®]
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www.ocusoft.com

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Retaine[®] and MGD[®] are registered trademarks of OCuSOFT, Inc. Product of France.

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Lot :

RETAINÉ 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: 8547401N9D)				
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
1	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)