OPTIMEL MANUKA DRY EYE DROPS- glycerin solution/ drops Melcare Biomedical Pty Ltd

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.

Optimel Manuka+ Dry Eye Drops

Drug Facts

Active ingredients

Glycerin 0.2%

Purpose

Lubricant

Uses

- for the temporary relief of burning and irritation due to dryness of the eye.
- for use as a protectant against further irritation or to relieve dryness of the eye.

Warnings

For external use only

Do not use

- if you have a history of hypersensitivity or sensitive to honey or benzoate preservatives without seeking medical advice.
- if solution changes color or becomes cloudy.
- if packaging is damaged.
- serious conditions should be managed under the supervision of a doctor.

When using this product

- Before first use: check tamper ring is attached to cap base remove cap and discard ring.
- to avoid contamination, do not touch tip of container to any surface.
- replace cap after using.
- remove contact lenses before using.
- wait at least 10 minutes before contact lens insertion.
- Initial stinging and redness on drop application is to be expected.

Stop use and ask a doctor if

- You experience eye pain change in vision, continued redness or irritation of the eye.
- Condition worsens

Keep out of reach of children.

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

Directions

- Wash hands.
- Instill 1 drop to the inner corner of the affected of the affected eye up to 3 times daily.
- Children under 16 years of age ask a doctor.

Other information

- Single patient use only.
- Discard 2 months after opening.
- Store below 25°C (77°F).

Inactive ingredients

Honey (Leptospermum spp.), Sodium benzoate, Sodium chloride, Water.

Questions?

Web: www.melcare.com Email: info@melcare.com Phone: 8557082611

PRINCIPAL DISPLAY PANEL





DRUG FACTS

Active ingredient Glycerin 0.2%...... Purpose Lubricant

USES

- for the temporary relief of irritation due to dryness of the eye.
- for use as a protectant against further irritation or to relieve dryness of the eye.

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DRUG FACTS (continued) WARNINGS

Stop use and ask a doctor if:

 You experience eye pain, change in vision, continued redness or irritation of the eye.

CAP END

Condition worsens
 Keep out of reach of children.
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DIRECTIONS

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OPTI MEL



MANUKA © DRY EYE DROPS

- Eye discomfort
- 🤣 Eye lid irritation

STERILE R

0.34oz (10mL)

OPTIMEL

Optimel® Manuka+ Dry Eye Drops also contains a proprietary pharmaceutical grade *Leptospermum* spp. honey (165mg/g) as an excipient. For use as an adjunct therapy in addition to good eyelid hygiene. Natural by Design Clinical by Nature

MADE IN AUSTRALIA

Melcare Biomedical Pty Ltd Mt Cotton 4165, Australia

Distributed by Optimel USA LLC 1603 Capitol Ave., Suite 310 A168 Wyoming 82001, USA

DROP IN BARCODE 85%

V12.06.2019



OPTIMEL MANUKA DRY EYE DROPS

glycerin solution/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73024-399

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)

GLYCERIN (UNII: PDC6A3C0OX) GLYCERIN 2 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
HONEY (UNII: Y9H1V576FH)				
WATER (UNII: 059QF0KO0R)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

Packaging	ackaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:73024- 399-10	1 in 1 CARTON	07/19/2019			
1	10 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	07/19/2019			

Labeler - Melcare Biomedical Pty Ltd (743166886)

Revised: 4/2023 Melcare Biomedical Pty Ltd