

OPTASE- glycerin spray
Scope Health Inc

Optase Dry Eye Spray 17 ml (part of 3 step process)

- Condition worsens or lasts more than 72 hours.

Keep out of reach of children. If swallowed get medical help or contact a poison control center right away.

Purpose
Eye lubricant

Warning

- For external use only.
- To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- If solution changes color or becomes cloudy, do not use.

Stop use and ask doctor if

- You feel eye pain.
- Changes in vision occur.
- Redness or irritation of the eye lasts.
- Condition worsens or lasts more than 72 hours.

Uses

- For use as a lubricant to prevent further irritation or to relieve dryness of the eye.
- May be used as a protectant against further irritation.

Warning

Directions

Spray 1-2 times the equivalent of 1 to 2 drops in affected eye.

Other Information

- Use only if tamper seal on top and bottom of box is intact.

Inactive ingredients Citric Acid Monohydrate, Polyoxyethylenesorbitan Monooleate, Potassium Chloride, Purified Water, Sea Buckthorn Seed Oil, Sodium Chloride, Sodium Hyaluronate, Sorbitan Monooleate, Tromethamine.

OPTASE®

Dry Eye Spray

What this is and what it is intended for

OPTASE® Dry Eye Spray relieves dryness and irritation of the eyes, the eyelids, and the skin around the eyes.

Always apply the spray on closed eyelids. OPTASE® Dry Eye Spray contains Glycerin. Glycerin is a humectant (moistening effect) that comes from plant sources. Glycerin reduces the damaging effects of high osmolarity on the ocular surface. On blinking, the oil slowly spreads over the tear film, strengthening the lipid layer to protect the eyes from drying out. Glycerin and other natural compounds protect both the surface of the eye and the skin against cell damage, and assist healing. Thanks to its special design, the bottle can be used in any position. OPTASE® Dry Eye Spray is a product with no alcohol, no preservatives, and no ingredients of animal origin.

Instructions for use

Take off the protection cap. Before the first application, test the spraying mechanism a few times on your arm or in the air. Notice that there is a small step in the nozzle; to apply the spray, press the nozzle fully down. Next, hold the bottle approximately 6–10 inches (15–25 cm) from the eyes. Close both eyes and then apply 1–2 sprays on the eyelids.

Once you are ready, put the protection cap back on the nozzle head. You may use the spray several times a day and during contact lens wear. If you are using other personal care products in the eye area, let them settle for at least 10 minutes before applying the spray, or use the other product not earlier than 10 minutes after applying the spray. If you are using eye make-up, you may wish to apply the spray from a longer distance to avoid spreading, depending on the type of make-up. Use within three (3) months from opening the bottle and by the expiry date indicated in the stamp on the bottle.

Precautions and warnings

- For external use only.
- To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- Do not use if you are sensitive to any of the ingredients.
- Do not use if the bottle is damaged.
- To avoid contamination, do not touch the eye or skin with the tip of the nozzle.
- Do not touch the tip of the nozzle with fingers.
- If the spray is applied on an open eye, you may temporarily experience mild discomfort.
- Leave at least 10 minutes between applications of the spray and an ophthalmic medication.
- Keep out of reach and sight of children.
- Store at 41–77°F; protect from direct sunshine and heat. Do not use the product in the event it has frozen or it has been stored in hot conditions for a long time.
- Discard the empty bottle appropriately. Due to intentional overfill, a small volume of the solution will remain in the bottle.
- Stop use and ask doctor if you feel pain, changes in vision occur, redness or irritation of the eye lasts or if condition worsens or lasts more than 72 hours.
- If solution changes color or becomes cloudy, do not use.

Composition: Active ingredient: Glycerin. Glycerin in hypotonic solution reduces the damaging effects of high osmolarity on the ocular surface. Inactive ingredients: Citric Acid Monohydrate, Polyoxyethylenesorbitan Monooleate, Potassium Chloride, Purified Water, Sea Buckthorn Seed Oil, Sodium Chloride, Sodium Hyaluronate, Sorbitan Monooleate, Tromethamine.

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OPTASE

glycerin spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72972-001
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

WATER (UNII: 059QF0KO0R)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TROMETHAMINE (UNII: 023C2WHX2V)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72972-001-01	1 in 1 BOX	04/22/2019	
1		17 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	04/22/2019	

Labeler - Scope Health Inc (116778693)

Registrant - Regulatory Matters Consulting (080711165)

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Scope Health Inc