

OPTASE- glycerin spray

Scope Health 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.

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

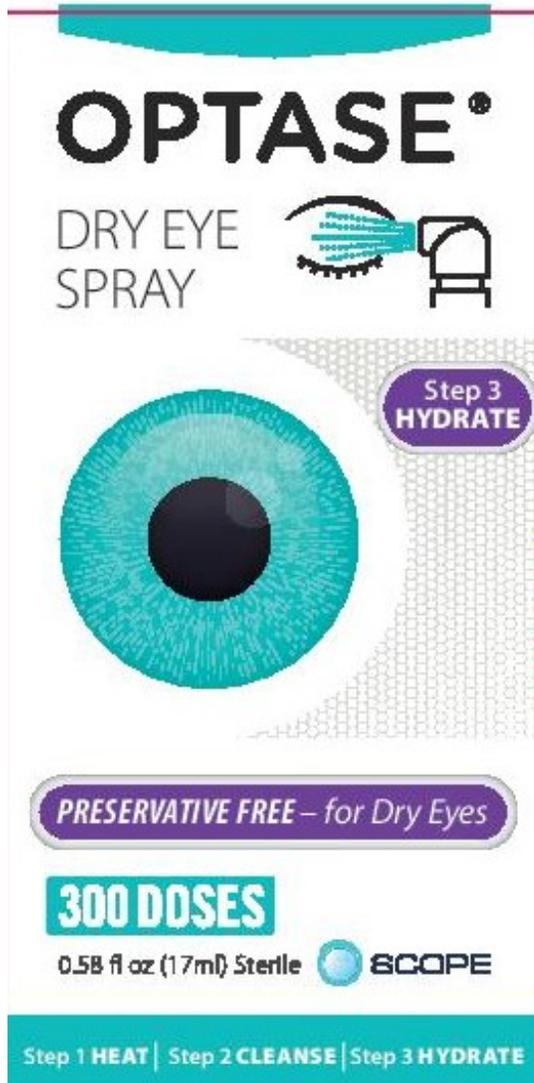
Directions

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

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
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

TROMETHAMINE (UNII: 023C2WHX2V)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

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 final	part349	04/22/2019	

Labeler - Scope Health Inc (116778693)

Registrant - Regulatory Matters Consulting (080711165)

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Scope Health Inc