OASIS TEARS PRESERVATIVE-FREE LUBRICANT EYE- glycerin solution/ drops OASIS Medical, 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.

Oasis TEARS® Preservative-Free Lubricant Eye Drops Drug Facts

Active Ingredients

Glycerin (0.22%)

Purpose

Lubricant Eye Drops

Uses

- for the temporary relief of burning and irritation due to dryness of the eye.
- for the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun.
- for use as a protectant against further irritation or to relieve dryness of the eye.
- for use as a lubricant to prevent further irritation or to relieve dryness of the eye.

Warnings

For external use only

Do not use

- if solution changes color or becomes cloudy.
- if you are sensitive to any ingredient in this product.

When using this product

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

Stop use and ask a doctor if

• you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the conditions worsens or persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

instill 1 or 2 drops in the affected eye(s) as needed.

Questions, or to report an adverse event call

(800) 631-7180 or (909) 305-5400 or log onto www.oasistears.com

Other Information

- protect from light and freezing
- store at or below 77°F (25°C) and above 32°F (0°C).

Inactive Ingredients

Sodium chloride, sodium hyaluronate, sodium phosphate dibasic, sodium phosphate monobasic, water.

PRINCIPAL DISPLAY PANEL - 0.3 mL Pouch Carton

N 42126-6100-1

Oasis TEARS®

PRESERVATIVE - FREE

LUBRICANT EYE DROPS

VISCOADAPTIVE RELIEF FOR DRY EYES

30

STERILE (0.3 mL/0.01 FL. OZ.) SINGLE USE CONTAINERS



OASIS TEARS PRESERVATIVE-FREE LUBRICANT EYE

glycerin solution/ drops

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42126-6100	
Route of Administration	OPHTHALMIC			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	.22 g in 100 mL		

Inactive Ingredients		
	Ingredient Name	Strength

Hyaluronate Sodium (UNII: YSE9PPT4TH)	0.15 g in 100 mL
Sodium chloride (UNII: 451W47IQ8X)	
Sodium phosphate, monobasic, unspecified form (UNII: 3980JIH2SW)	
Sodium phosphate, dibasic, unspecified form (UNII: GR686LBA74)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42126- 6100-1	3 in 1 CARTON	11/01/2017	
1		10 in 1 POUCH		
1		0.3 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:42126- 6100-2	5 in 1 POUCH	11/01/2017	
2		0.3 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category					
OTC monograph final	part349	11/01/2007			

Labeler - OASIS Medical, Inc. (194121018)

Establishment				
Name	Address	ID/FEI	Business Operations	
LABORATOIRE UNITHER COUTANCES		574139809	MANUFACTURE(42126-6100)	

Establishment				
Name	Address	ID/FEI	Business Operations	
UNITHER MANUFACTURING LLC		079176615	MANUFACTURE(42126-6100)	

Revised: 4/2021 OASIS Medical, Inc.