VISCO SHIELD LUBRICANT- hypromellose 2208 (15000 mpa.s) 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.

VISCO SHIELD® Ophthalmic Lubricant Drops

Drug Facts

Active Ingredients

Hypromellose (1.7%)

Purpose

Ophthalmic lubricant

Uses

- For the temporary relief of burning and irritation due to 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
- To avoid contamination do not touch tip of container or applicator 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 condition worsens or persists for more than 72 hours, discontinue use and consult a doctor
- If solution changes color or becomes cloudy, do not use

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

Directions

- Remove cap from syringe and screw on applicator tip
- Instill 1 or 2 drops in the affected eve(s) as needed.

Questions, or comments

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

Other information

- Do not sue if pouch is damage or has been previously opened
- Protect from freezing
- Store at or below 77°F/25°C

Inactive Ingredients

Calcium chloride dihydrate, hydrochloric acid 1 , magnesium chloride hexahydrate, potassium chloride, purified water, sodium acetate trihydrate, sodium chloride, sodium citrate dihydrate, and sodium hydroxide 1

1 May contain one or more of these ingredients for pH adjustment

PRINCIPAL DISPLAY PANEL - 2 ml Syringe Carton

VISCO SHIELD® Topical Drops

Ophthalmic Lubricant Drops

- Sterile
- Preservative-free
- Single use, disposable container

CONTAINS: 6 Pouches, each Pouch containing 1 Single Use Syringe, 0.07 fl oz (2 ml) 1 Single Use Applicator Tip

OASIS®

OASIS® Medical, Glendora CA 91741 USA© 2014 OASIS Medical P940 3/2014

Certain manufacturing operations have been performed by other firms

TOP FRONT PANEL



Ophthalmic Lubricant Drops

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- Preservative-free
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3 46160 JEUUU 1 - 1010 (OASIS® Medical, Glendora CA 91741 USA © 2014 OASIS Medical P940 3/2014 Certain manufacturing operations have been performed by other firms **Drug Facts** Active Ingredients
Hypromellose (1.7%) ... Purpose Ophthalmic Lubricant Indications ■ For the temporary relief of burning and irritation due to dryness of the eve.

 For use as a lubricant to prevent further initation or to relieve dryness of the eye. Warnings ■ For external use only. ■ To avoid contamination do not touch tip of container or applicator to any surface. Do not reuse. Once opened, discard. Stop use and ask a doctor if If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor. If solution changes color or becomes cloudy, do not use. Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away. Directions Remove cap from syringe and screw on applicator tip.
 Instill 1 or 2 drops in the affected eye(s) as needed. Other Information Do not use if pouch is damaged or has been previously opened. ■ Protect from freezing Store at or below 25°C (77°F) Inactive Ingredients Calcium chloride dihydrate, hydrochloric acid", magnesium chloride hexahydrate, potassium chloride, purified water, sodium acetate trihydrate, sodium chloride, sodium citrate dihydrate, and sodium hydroxide*
*May contain one or more of these ingredients for pH adjustment Questions or Comments? (800) 631-7180 or (909) 305-5400 or log onto www. Oasis Medical.com

VISCO SHIELD LUBRICANT

hypromellose 2208 (15000 mpa.s) solution/drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42126-5200
Route of Administration	OPHTHALMIC		

l	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
	HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2) (HYPROMELLOSE 2208 (15000 MPA.S) - UNII: Z78RG6M2N2)	HYPROMELLOSE 2208 (15000 MPA.S)	17 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM CHLO RIDE (UNII: M4I0 D6 VV5M)			
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)			
HYDRO CHLO RIC ACID (UNII: QTT17582CB)			
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)			
SODIUM ACETATE (UNII: 4550K0SC9B)			
SO DIUM CHLO RIDE (UNII: 451W47IQ8 X)			
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
WATER (UNII: 059QF0KO0R)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:42126-5200-	6 in 1 CARTON	06/16/2014	
1	1 in 1 POUCH		
1	2 mL in 1 SYRINGE, PLASTIC; 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	06/16/2014	

Labeler - OASIS Medical, Inc. (194121018)

Establishment			
Name	Address	ID/FEI	Business Operations
OASIS Medical, Inc.		194121018	MANUFACTURE(42126-5200)

Revised: 2/2018 OASIS Medical, Inc.