IVIZIA LUBRICANT EYE FOR SEVERE NIGHT DRY EYES- povidone solution, gel forming / drops Similasan Corporation

iVizia Lubricant Eye Gel for Severe Night Dry Eyes

Active Ingredient

Povidone 0.5%

Purpose

Eye lubricant

Uses

(one or more of these)

- 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 and 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 (in the eye)
- Wait at least 15 minutes between using two different eye products. Use this gel last.
- **Do not use** if you are allergic to any of the ingredients.
- If solution changes color or becomes cloudy, do not use.
- **Do not use** if the pouch or vial is damaged.
- To avoid contamination, do not touch the tip of container to any surface. Do not reuse. Once opened, discard.
- Store below 86°F. Expiration date refers to the product in intact packaging, stored correctly.
- 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.

Keep out of reach of children.

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

When using this product

- Rare possibility of mild eye irritation and ocular redness. In such cases, contact lens wearers should remove their contact lenses.
- You might experience bothersome symptoms such as a burning sensation, stinging sensation, foreign body sensation in the eye and blurred vision for a short time.

Directions:

Gel is particularly suited for severe dry eye or nighttime use.

- Wash hands well before use.
- Take one single-use vial off the strip. Turn upside down, tap the vial and twist off the top.
- Instill 1 or 2 drops in the affected eye(s) as needed.
- If you wear contact lenses: you must remove them before using iVIZIA gel. After use wait at least 30 minutes before putting your lenses back in.

Inactive Ingredients

Carbomer, Purified water, Sodium hyaluronate, Sodium hydroxide, Sorbitol, Trehalose

Questions?

1-800-240-9780 or info@ivizia.com.

Principle Display Panel

iVizia Lubricant Eye Gel For Severe/Night Dry Eyes 0.014 OZ (0.4g) each

30 sterile single-use vials



IVIZIA LUBRICANT EYE FOR SEVERE NIGHT DRY EYES

povidone solution, gel forming / drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59262-701

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E) (POVIDONE, UNSPECIFIED - UNII: FZ 989GH94E)	POVIDONE, UNS PECIFIED	2.5 mg in 0.5 g

Inactive Ingredients				
Ingredient Name	Strength			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
WATER (UNII: 059QF0KO0R)				
HYALURONATE SODIUM (UNII: YSE9PPT4TH)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
SORBITOL (UNII: 506T60A25R)				
TREHALOSE (UNII: B8WCK70T7I)				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:59262- 701-12	30 in 1 CARTON	10/14/2021		
1	0.4 g in 1 VIAL, SINGLE-USE; 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	10/14/2021		

Labeler - Similasan Corporation (111566530)

Registrant - Laboratoire Unither (574139809)

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