IVIZIA DRY EYE- povidone solution/ drops Laboratoires Thea

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.

iVizia Dry Eye Drops 5ml Sample

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 10 minutes between using two different eye products
- **Do not use** if you are allergic to any of the ingredients.
- If solution changes color or becomes cloudy, do not use.
- To avoid contamination, do not touch the tip of container to any surface. Replace cap after using.
- Use up to 90 days after opening. Store below 77°F. Do not use after the expiration date on the carton. 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.
- After first use, if exposed to low atmospheric pressure, the bottle can leak.

If pregnant, trying to get pregnant or breast feeding,

ask a health professional before use.

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:

- Wash hands well before use.
- Instill 1 or 2 drops in the affected eye(s) as needed. Can be used when wearing contact lenses.
- *To limit blurriness when using contact lenses: remove contacts, apply drops, then insert contacts.

Inactive Ingredients

Hydrochloric acid, purified water, sodium chloride, sodium hyaluronate, trehalose, tromethamine

Questions?

1-800-240-9780 or getinfo@similasanusa.com.

Principle Display Panel

iVizia Sterile Lubricant Eye Drops For Dry Eyes 0.16 FL OZ (5ml)



IVIZIA DRY EYE

povidone solution/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82095-700

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

1	,			
	Ingredient Name	Basis of Strength	Strength	
	POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	25 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
HYDROCHLORIC ACID (UNII: QTT17582CB)			
WATER (UNII: 059QF0KO0R)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
HYALURONATE SODIUM (UNII: YSE9PPT4TH)			
TREHALOSE (UNII: B8WCK70T7I)			
TROMETHAMINE (UNII: 023C2WHX2V)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82095- 700-13	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	09/30/2021	

Marketing In			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	09/30/2021	

Labeler - Laboratoires Thea (576949457)

Registrant - Similasan Corporation (111566530)

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