IVIZIA DRY EYE- povidone solution/ drops Thea Pharma Inc.

iVIZIA Eye Drops

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)

Do not use if:

- you are allergic to any of the ingredients.
- solution changes color or becomes cloudy.
- To avoid contamination, do not touch the tip of container to any surface. Replace cap after using.
- 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:

Wash hands well before use.

Twist cap counterclockwise to break tamper evident seal.

Press firmly on bottle sides. Dispensing drops is slower due to preservative-free filter. Dispense 1-2 drops in the affected eye as needed.

Safe with contacts. *To limit blurriness when using contact lenses: remove contacts, apply drops, then insert contacts.

Other Information

- 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.
- After first use, if exposed to low atmospheric pressure, the bottle can drip.

Inactive Ingredients

Purified water, sodium chloride, sodium hyaluronate, trehalose, tromethamine. May contain hydrochloric acid to adjust pH.

Questions?

1-833-838-4028 or info@ivizia.com

Principle Display Panel

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



E10020C5USA/1223

Drug Facts (continued)

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.
 Twist cap counterclockwise to break tamper evident seal.
- Press firmly on bottle sides. Dispensing drops is slower due to preservative-free filter.
- Dispense 1-2 drops in the affected eye as needed.
- Safe with contacts. *To limit blurriness when using contact lenses: remove contacts, apply drops, then insert contacts.

 Wait at least 10 minutes between
- using two different eye products.

Other Information

- 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.
- After first use, if exposed to low atmospheric pressure, the bottle can

Inactive ingredients

urified water, sodium chloride, sodium nyaluronate, trehalose, tromethamine. May ontain hydrochloric acid to adjust pH.

Questions?

-833-838-4028 or info@ivizia.com

5_{ml}



Sterile Lubricant Eye Drops FOR DRY EYES

up to 8 HOURS of relief

Instant & Long-Lasting Preservative-Free Safe With Contacts'

0.16 FL OZ (5ml)

84% of users reported iVIZIA works better than their previous eye drops'.

- From the makers of the #1 doctor prescribed dry eye brand in Europe.
- Scientifically formulated to relieve dryness and discomfort.
- iVIZIA lubricant eye drops are a unique, preservative-free formulation including povidone 0.5% (active), trehalose (inactive) and hyaluronic acid (inactive).

ABAK® Filter System

- No need for
- preservatives Press firmly on bottle to dispense



Our preservative-free bottle is patented in US territory (US7971755, US9174777, US10857067 and US11116694)

Do not use if the tamper evident seal is broken or bottle is damaged. Don't use a tool to open the bottle.



Based on a dry eye patient study; data on file (or see website for details).

Drug Facts

Active Ingredients .. 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)

- you are allergic to any of the ingredients.
- solution changes color or
- becomes cloudy. To avoid contamination, do not touch the tip of container to any surface.
- Replace cap after using.

 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 remov their contact lenses.

iVIZIA is a trademark of Thea Pharma Inc. Made in Italy.

Distributed by: Thea Pharma Inc. , Waltham, MA 02451 1-833-838-4028 NDC 82584-700-05





IVIZIA DRY EYE

povidone solution/ drops

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:82584-700 **Route of Administration OPHTHALMIC**

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	25 mg in 5 mL		

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

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:82584- 700-05	1 in 1 CARTON	12/01/2024		
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product			
2	NDC:82584- 700-11	1 in 1 CARTON	12/01/2024		
2		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product			
3	NDC:82584- 700-13	1 in 1 CARTON	12/01/2024		
3		5 mL in 1 BOTTLE, DROPPER; 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	12/01/2024			

Labeler - Thea Pharma Inc. (117787029)

Revised: 8/2024 Thea Pharma Inc.