

## **NATURAL CARE - poloxamer 407 liquid**

**K&J.C Co., Ltd**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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### **Drug Facts**

Active Ingredient: Poloxamer 407

Instructions for use (IFU)

Cleans, Rinses, Disinfects, Stores and Removes Protein Daily.

All Steps In One Bottle.

Directions: To clean, disinfect and remove protein daily, complete these simple steps:

#### **STEP 1:**

Place 3 drops of Dream Eye on each side of contact lens and rub for 20 seconds. No necessary. separate daily cleaner

#### **STEP 2:**

Remove surface debris by rinsing thoroughly with Dream Eye

#### **STEP 3:**

Place cleaned contact lens in the lens case and fill with fresh Dream Eye MPS. Soak at least four(4) hours.

**CONTENTS:** Dream Eye is a sterile, isotonic, buffered solution that contains poloxamer, sodium borate, sodium chloride; preserved with Polyhexamethylenebiguanide.

**ACTIONS:** Cleans, loosens and removes accumulations of film, deposits and debris from soft contact lenses. Destroys harmful micro-organisms on the surface of the lens. Rinse, stores and rewets lenses before insertion. For dissolving of Enzymatic Contact Lens Cleaner tablets for removal of protein deposits.

**INDICATIONS(Uses):** Dream Eye is indicated for use in daily cleaning, dissolving of Enzymatic Contact Lens Cleaner tablets, rinsing and storage of daily and extended wear soft contact lenses and chemical (not heat) disinfection, as recommended by your eye care professional.

**CONTRAINDICATIONS (Reasons not to use):** If you are allergic to any ingredient in Dream Eye, do not use this product.

**WARNING: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case.

- To avoid contamination, do not touch tip of container to any surface. Replace cap after using.

- Not intended for use directly in the eye.

- Not for use with heat(thermal) disinfection.

**PRECAUTIONS:**

- Never re-use this solution.

- Keep the bottle tightly closed when not in use.

- Store at room temperature.

- Use before the expiration date marked on the bottle and carton.

- Keep out of the reach of children

**ADVERSE REACTIONS (Problems and what to do):**

The following problems may occur: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), or dry eyes.

If you notice any of the above:

- **IMMEDIATELY REMOVE YOUR LENSES.**

- If the discomfort or problem stops, then look closely at the lens.

- If the lens is in any way damaged, **DO NOT** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.

- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops

and the lens appears undamaged, thoroughly clean, rinse, and disinfect the lens, then reinsert it.

□ If the problem continues, IMMEDIATELY remove the lens and consult your eye care practitioner.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

#### GOOD LENS CARE PRACTICES:

□ Always wash and rinse your hands before you handle your lenses.

□ Clean, rinse and disinfect your lenses each time you remove them. □ Always handle the same lens, the right or left, first in order to avoid mix-ups.

□ After use, always empty and rinse lens case with fresh rinsing solution and allow to air dry.

#### DIRECTIONS:

□ After removing the lens, place it in the palm of your hand, and place three drops of Daily Cleaner on each lens surface. or Soak at least four(4) hours in Dream Eye.

□ Rub the lens for 20 seconds either in the palm of your hand using the forefinger of the other hand, or between the thumb and forefinger. Be sure to clean each side of the lens.

□ Rinse the lens thoroughly by holding the lens in a steady stream of saline solution for approximately 10 seconds.

□ Disinfect using the procedure which your practitioner has recommended.

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Inactive ingredient: Sodium Chloride, Sodium Borate, Boric Acid, HYPROMELLOSE, EDETATE DISODIUM, Water

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**RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your

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and care of your lenses and lens care products, including the lens case.

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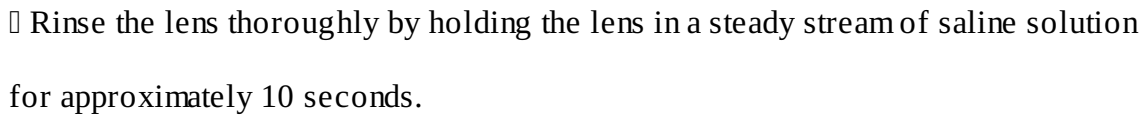
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Active Ingredient: POLOXAMER 407



## NATURAL CARE

poloxamer 407 liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52345-2001
Route of Administration	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLOXAMER 407 (UNII: TUF2IVW3M2) (POLOXAMER 407 - UNII:TUF2IVW3M2)	POLOXAMER 407	0.1 mL in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
BORIC ACID (UNII: R57ZHV85D4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52345-2001-1	150 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/05/2010	

**Labeler** - K&J.C Co., Ltd (690257639)

**Registrant** - K&J.C Co., Ltd (690257639)

### Establishment

Name	Address	ID/FEI	Business Operations
K&J.C Co., Ltd		690257639	manufacture