

LUTESOL HOMEOPATHIC MEDICINE STERILE EYE DROPS- calendula officinalis solution/drops

Yokina Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

LuteSol Homeopathic Medicine Sterile Eye Drops

DRUG FACTS

Active Ingredients

Calendula Officinalis (Marigold containing Lutein), HPUS 3x, 6x, 12x

"HPUS" indicates the active ingredients of this product are officially monographed in the Homeopathic Pharmacopoeia of the United States

Purpose

Corneal health

Uses*

According to homeopathic indications these ingredients provide temporary relief from symptoms such as Dryness, redness and promote corneal health, after a serious causes have been ruled out by physician.

*These statements are based on traditional homeopathic practice. They have not been reviewed by Food and Drug Administration

Warnings

For external use only.

- This product is intended to complement, not replace standard medical treatment • Suitable for adults and children ages 12 and over. • Initial worsening of symptoms may occur • If pregnant or breast-feeding, ask a health professional before use • Contact lens wearers: Consult a physician before use
- Replace cap after every use • Expiration date only refers to the unopened bottle. • The use of this container to more than one person may spread infection

Do not use if : • Solution changes color or becomes cloudy • You feel eye pain or changes in vision, continued redness, or the irritation of the eye • The condition get worse • redness or irritation of the eye(s) get worse, persists or last longer than 72 hours.

- Keep out of reach of children • In case of accidental ingestion, get medical help or contact a poison control center right away

Direction:

- Shake well before using
- Instill 1-3 drops in the affected eye(s). Use several times per day as needed.
- Homeopathic remedies may not be effective for everyone.

- Individual results may vary.

Other information:

- There are known contraindications
- Active ingredients are micro-diluted in accordance with Homeopathic Pharmacopoeia of the United States and are therefore non-toxic with no known side effects.
- Store at room temperature
- Do not touch tip of container to any surface to avoid contamination
- Keep bottle tightly closed

Inactive ingredient:

Polyethylene Glycol, Propylene glycol, Benzalkonium chloride, Boric acid, Calcium chloride, Hydrochloric acid, Hypromellose, Magnesium chloride, Potassium chloride, Purified water, Sodium chloride, Sodium hydroxide, Zinc chloride

Supports:

Corneal Health

Healthy Vision

Dry Eyes

Made In USA

U.S. Distributor:

Yokina Inc.

Rancho cucamonga,

CA 91730

Packaging

NDC# 72709-821-78


LuteSolTM
 Homeopathic Medicine
 Sterile Eye Drops


LuteSolTM
 Homeopathic Medicine
 Sterile Eye Drops

Supports:
 Corneal Health
 Healthy Vision
 Dry Eyes



Supports:
 Corneal Health
 Healthy Vision
 Dry Eyes

Made In USA Net weight: 0.5 fl-oz. (15 ml)

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(continued)

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U.S. Distributor:
 Yokina, Inc.
 Rancho cucamonga, CA 91730



LUTESOL HOMEOPATHIC MEDICINE STERILE EYE DROPS

calendula officinalis solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72709-821
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	3 [hp_X] in 15 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ZINC CHLORIDE (UNII: 86Q357L16B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72709-821-78	1 in 1 BOX	11/28/2018	
1		15 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
unapproved homeopathic		11/28/2018	

Labeler - Yokina Inc. (075411878)

Revised: 12/2018

Yokina Inc.