

FRESHKOTE®
LUBRICANT EYE DROPS
STERILE OPHTHALMIC SOLUTION

DESCRIPTION:

Each mL of FreshKote® Ophthalmic Solution contains: Polyvinyl pyrrolidone 2.0%, Polyvinyl alcohol (87% hydrolyzed) 0.9%, Polyvinyl alcohol (99% hydrolyzed) 1.8%. Also contains Amisol® CLEAR. Other ingredients: Sodium chloride, Potassium chloride, Boric acid, Purified water and as preservatives Disodium edetate dihydrate, Polixetonium.

INDICATIONS:

FreshKote® sterile ophthalmic solution is a lubricant indicated for the treatment of moderate to severe dry eye.

CONTRAINDICATIONS:

FreshKote® is contraindicated in patients with known severe hypersensitivity to any of the ingredients in the formulation.

WARNINGS:

- To avoid contamination, do not touch 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.
- Do not use if solution changes color or becomes cloudy.
- Keep this and all medications out of the reach of children. In case of accidental ingestion, seek professional assistance or call a Poison Control Center immediately.
- Tamper Evident: For your protection, this bottle has an imprinted seal around the neck. Do Not Use if seal is damaged or missing at time of purchase.

Pregnancy:

There are no adequate and well-controlled studies in pregnant women. FreshKote® should be used during pregnancy only if the potential benefit justifies the potential risk.

ADVERSE REACTIONS:

To report SUSPECTED ADVERSE REACTIONS, contact FOCUS Laboratories, Inc. at (501) 753-6006 8am-5pm Monday-Friday CST.

DOSAGE and ADMINISTRATION:

Instill 1 or 2 drop(s) in the affected eye 3 or 4 times daily.

HOW SUPPLIED:

FreshKote® is packaged in 15 mL (NDC# 15821-101-15) and 1 mL (NDC# 15821-101-01) bottles; with a control dropper.

Storage:

Store at room temperature 15°-30°C (59°-86°F).
See box or dropper bottle for Lot Number and Expiration Date.

Rx Only

Protected by U.S. Patent Numbers: 7,758,883.

Manufactured for:
FOCUS Laboratories, Inc.
North Little Rock, AR 72113

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