

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.

DOSAGE and ADMINISTRATION:

Instill 1 or 2 drop(s) in the affected eye(s) as needed.

HOW SUPPLIED:

FreshKote® is packaged in 15 mL (NDC# 15821-101-15) and 3.5 mL (NDC# 15821-101-35) bottles; with a control dropper.

Storage:

Store at controlled 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:
5,300,296 & 5,380,303 & 4,883,658 & 4,744,980.
Additional U.S. Patent Pending.

Manufactured for:

FOCUS Laboratories, Inc.
North Little Rock, AR 72113
Rev. 10/05
MG #22080

FRESHKOTE®
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