

INTENDED USE

Nuvail™ is indicated for managing signs and symptoms of nail dystrophy, i.e., nail splitting and nail fragility, for intact or damaged nails. Nuvail coats and adheres to the nail surface preventing direct abrasion and friction on the nail surface while also providing protection against the effects of moisture.

PRODUCT DESCRIPTION

The product is a biocompatible, polymeric solution which forms a uniform film when applied to the nail. The product is dispersed in a noncytotoxic solution which dries rapidly, adhering to the contours of the nail to form a flexible, waterproof barrier. The film will wear off naturally and must be re-applied as directed to be effective. The film is colorless, transparent and possesses good moisture vapor permeability.

INGREDIENTS

16% Poly (urea-urethane) in organic solvents.

CONTRAINDICATIONS

Do not apply directly to deep, open, or profusely bleeding wounds.

WARNINGS AND PRECAUTIONS

The product is flammable in liquid form; avoid using near open flames and sources of ignition. Use in well-ventilated area. **Keep out of reach of children**.

Store at room temperature away from heat. Do not allow product to come into contact with floors, counter tops, furniture or other finished surfaces - will stain.

May temporarily sting upon application. Persons sensitized to isocyanate should not use this product. Should redness or other signs of irritation appear, discontinue use and consult your healthcare provider.

Use of other products, ointments, creams or lotions before application of this product may prevent the film from forming correctly and reduce effectiveness.

DIRECTIONS FOR USE

- Application is recommended once a day before bedtime
- Remove bottle cap, dip applicator into product and wipe off excess on lip of bottle
- Apply in even strokes to affected nail plate [in entirety], proximal and lateral folds, and the distal tip
- Allow the product to dry completely before applying pads or clothing
- · Replace cap on bottle when not in use
- Clean affected nails with nail polish remover once a week

HOW SUPPLIED

Nuvail Nail Solution is supplied in a: 15 ml non-sterile bottle with applicator NDC 68712-044-01.

STORAGE AND SHELF LIFE

For best results the product should be stored at room temperature (15° to 30°C, 59° to 86°F).

Avoid storage in excessive heat and humidity. Refer to the bottle label for expiration date.

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