

**NUVAIL- lauric acid liquid**  
**EPI Health, Inc**

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**Nuvail™**  
**(poly-ureaurethane, 16%)**

NAIL SOLUTION

Rx Only

**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 non-cytotoxic 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 with applicator 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 71403-044-01.

## **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.

Manufactured for:  
EPI Health, LLC  
Charleston, SC 29403  
Toll Free: 1-800-499-4468

**www.nuvail-rx.com**

N. Code : HR/DEVICE/MFG/MD/2018/000004  
Made in India

December 2018

This product may be covered by one or more of the US Patent Nos. 7,008,997/8,771,725/9,259,436.  
NUV-PI-0617

Version - 1

## **PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton**

71403-044-01

Rx Only

**Nuvail™**

**(poly-ureaurethane, 16%)**

**NAIL SOLUTION**

For Topical Use Only  
Not For Ophthalmic Use

**EPIHEALTH**

*Advancing Dermatology*

**15 mL**



## NUVAIL

bandage, liquid liquid

### Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRC:71403-044
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAURIC ACID (UNII: 1160N9NU9U) (LAURIC ACID - UNII:1160N9NU9U)	LAURIC ACID	2.4 mg in 15 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71403-044-01	15 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
PREMARKET NOTIFICATION	K120059	05/01/2017	

**Labeler** - EPI Health, Inc (080638894)

Revised: 1/2019

EPI Health, Inc