NUVAIL- bandage, liquid
Innocutis Holdings LLC

Nuvail

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 daybefore 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 suppled in a: 15 ML non-sterile bottle with applicator 68712-044-01

Manufactured for: Inncoutis Holdings LLC, Charleston SC 29401

1-800-499-4468 www.Innocutis.com

Storage

For best results the product should be stored at room temperature (15º to 30ºC, 59º to 86ºF). Avoid storage in excessive heat and humidity.
Refer to the bottle label for expiration date.

Carton

NUVAIL

bandage, liquid

Product Information			
Product Type	PRESCRIPTION MEDICAL DEVICE	**Item Code (Source)**	NHRIC:68712-044

Inactive Ingredients

Ingredient Name	Strength
ACETONE (UNII: 1364PS73AF)	
METHYL ETHYL KETONE (UNII: 6PT9KLV9IO)	
ETHYLENE GLYCOL (UNII: FC72KVT52F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
1,2-ETHANEDITHIOL (UNII: 92T634FLAR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:68712-044-01	15 mL in 1 BOTTLE, GLASS; NCPDP billing unit = ML		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K120059	04/01/2004	

Labeler - Innocutis Holdings LLC (451549861)

Revised: 2/2013 Innocutis Holdings LLC