

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 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 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 (15° to 30°C, 59° to 86°F). Avoid storage in excessive heat and humidity.
 Refer to the bottle label for expiration date.

Carton

<p>Ingredients: 16% Poly (urea-urethane) in organic solvents.</p> <p>Contraindications: Do not apply directly to deep, open, or profusely bleeding wounds.</p> <p>⚠ WARNING: 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.</p> <p>For topical use only. Not for ophthalmic use.</p>	<p>NDC 68712-044-01</p> <p>Rx Only</p> <p>Nuvail™ (poly-ureaurethane, 16%) NAIL SOLUTION</p> <p>For Topical Use Only Not For Ophthalmic Use</p> <p>Net Wt 15 mL</p> <p> INNOCUTIS <small>accelerating dermatology</small></p>	<p>Storage: 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.</p> <p>Manufactured for: Innocutis Holdings, LLC Charleston, SC 29401 Toll Free: 1-800-499-4468 www.Innocutis.com</p> <p>US Patent No. 7,008,997; others pending</p> <p> INNOCUTIS FOUNDATION <small>Increasing the well-being of humankind</small> www.InnocutisCare.org</p>	<p>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.</p> <p>Dosage of Use:</p> <ul style="list-style-type: none"> • 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 <p>See insert for additional instructions. Use only as directed by a physician.</p>
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NUVAIL

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Product Information

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