MEDESSENCE PLUS HOMEOPATHIC NAIL - thuja occidentalis, antimonium crudum solution Deep Cover Systems LLC

Deep Cover Systems LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Inactive Ingredients:

Polysorbate 20, Melaleuca Artenrifolia (Tea Trea) Leaf Oil, Caprylic Acid, Citrus Grandis (Grapefruit) Seed Extract, Alpha-Arbutin, Capric Acid, Arctostaphylos Uva Ursi Leaf Extract, Pinus Pinaster Bark Extract, Citrus Limonum Seed Oil, Peppermint Oil, Sugar Cane Extract, Lauric Acid, Undecylenoyl Phenylalnine, Salicylic Acid, Ethyl Nicotinate, Citric Acid

Purpose:

Anti-fungal, anti-microbial

Brittle and out of shape nails

Inflamed nail matrix

nails discolored and deformed

white spots; in grown nails

pain and throbbing

swelling; disinfectant

Equal Volumes of each ingredient: 10C, 20C, 30C potency

Distributed By Deep Cover Systems LLC

8851 Boardroom Circle Ft Myers FL 33919

1-866-685-6245

www.deepcoversystem.com

For External Use Only

Avoid contact with eyes. If contact occurs flush with water.

Intended for adult use only. Do not use on children under 2 years of age unless directed by a doctor If irritation occurs or if there is no improvement within 4 weeks, discontinue use and see your health care provider

For Directions, uses and other information:

See the package insert

Deep Cover Directions for Use:

1. Remove old nail polish or other product from your finger and toe nails.

- 2. Gently brush the Medessence PLUS Homeopathic Nail Solution over nails, nail tips and surrounding cuticles.
- 3. Wait 2 minutes to allow the Medessence PLUS Homeopathic Nail Solution to work its way into your nails, nail beds and cuticles.
- 4. Using a dry cotton ball or tissue, completely remove Medessence PLUS Homeopathic Nail Solution from your nails and the surrounding area.
- 5. Next using the Primer PLUS Cover up, brush 1-2 coats onto your nails. Once this is dry you can brush on two coats of any fashionable Deep Cover nail color.

<u>For Men or Women</u> you can leave the Primer PLUS Cover up on for 5-7 days for a great healthy look and repeat regimen above (steps 1-5).

<u>For Women</u> After 5-7 days repeat regimen above (steps 1-5).

What do I need to get started?

- 1. Medessence PLUS Homeopathic Nail Solution
- 2. Dry cotton ball or tissue.
- 3. The Primer PLUS Cover-up.
- 4. Fashionable Deep Cover nail color of your choice.

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DRUG FACTS:

Active ingredients (Purpose):

Thuja Occidentalia (Anti-fungal; Anti-microbial), Antimonium Crudum (Brittle & out-of-shape nails), Dioscorea Villosa (Inflamed nail matrix) Graphites (Nalls discolored & deformed), Silices (White spots; in-grown nails), Borax (Pain & throbbing), Cinnamonum (Swelling; distrisctant) Equal volumes of each ingredient 10C, 20C, 30C potency. Inactive Ingredients: Polysorbate 20, Melaleuca Artemifolia (Tea Tree) Leaf Oil, Caprylic Acid, Citrus Grandis (Grapefruit) Seed Extract, Alpha-Arbutin, Capric Acid, Arctostaphylos Uva Ursi Leaf Extract, Pinus Pinaster Bank Extract, Citrus Limonum Seed Oil, Peppermint Oil, Sugar Cane Extract, Leuric Acid, Undecylencyl Phenylainine, Salicylic Acid, Ethyl Nicotinate, Citric Acid. Ethyl Acetate, Butyl Acetate, Nitrocallulose, Propyl Acetate, Tosylamide/Formaldahyde Resin, isopropyl Alcohol, Trimethyl Pentanyl Disobutyrate, Triphenyl Phosphate, Ethyl Tosylamide, Camphor, Stearalkonium Bentonite, Diacetone Alcohol, Stearalkonium Hectorite, Benzophenone-1, Dimethicone. May Contain: Mice, Bismuth Oxychioride, Titanium Dicodde, Red Iron Oxide, Black Iron Oxide, Ferric Ammonium Ferrocyanide, FD&C Yellow #5 Aluminium Lake, D&C Red #6 Barium Lake, D&C Red #7 Calcium Lake, D&C Red #30, D&C Red #34 Caldium Lake, Aluminium Powder, Polyethylene Terephthalete, Guenine, Calcium Sodium Borcellicate (&) Tranium Dioxide. Warnings:

- FOR EXTERNAL USE ONLY.
- Avoid contact with eyes. If contact occurs flush with water, Adult Use Only.

Ser Complete Wernings Directions Lines

& other Information: See the Package Insert.
Distributed by Deep Cover Nells Systems, LLC.
8851 Boardroom Circle, Ft. Myers, FL 33919
1-888-885-6245
www.deepcoversystem.com

WHAT DO I NEED TO GET STARTED?

- Medessence PLUS™ Homeopathic Nail Solution.
- Dry cotton ball or tissue.
- 3. The Primer PLUS™ Cover-up.
- Fashionable Deep Cover™ nail color of your choice.

DEEP COVER™ DIRECTIONS FOR USE:

- 1. Remove old nail polish or other product from your finger and toe nails.
- Gently brush the Medessence PLUS[™] Homeopathic Nail Solution over nails, nail tips and surrounding cuticles.
- 3. Wait 2 minutes to allow the **Medessence PLUS[™] Homeopathic Nail Solution** to work its way into your nails, nail beds and cuticles.
- Using a dry cotton ball or tissue, completely remove the Medessence PLUS™
 Homeopathic Nail Solution from your nails and the surrounding area.
- 5. Next using the **Primer PLUS[™] Cover-up**, brush 1-2 coats onto your nails. Once this is dry you can brush on two coats of any fashionable **Deep Cover[™]** nail color!

<u>For Men or Women</u> you can leave the **Primer PLUS™ Cover-up** on for 5-7 days for a great healthy look and repeat regimen above (steps 1-5).

For Women After 5-7 days repeat regimen above (steps 1-5).

Uses: For the relief of common nail fungus symptoms such as brittle & out of shape nails, fungus under the nails, discolored & deformed nails, inflammed nail matrix. Based on homeopathic use as described in the Materia Medica.

*If you have severe cracked, discolored, damaged nails, <u>Men or Women</u>: **Deep Cover**TM recommends for the first 14 days (or 2 weeks) to apply the **Medessence PLUS**TM **Homeopathic Nail Solution** once in the morning and once in the evening. Remember after applying the **Medessence PLUS**TM **Homeopathic Nail Solution**, leave on for 2 minutes, and remove completely. You can re-apply again later that evening. After 14 days, you can then feel confident to apply **Primer PLUS**TM **Cover-up** and any fashionable **Deep Cover**TM nail color as described above in our Directions For Use.

Warnings:

- FOR EXTERNAL USE ONLY
- Avoid contact with eyes. If contact occurs flush with water.
- Adult use only. Do not use on children under 2 years of age unless directed by a doctor.
- If irritation occurs or if there is no improvement within 4 weeks, discontinue use \$ see your health care provider."

Other Information: Store at room temperature.

MEDESSENCE PLUS HOMEOPATHIC NAIL

thuja occidentalis, antimonium crudum solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50125-001 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
THUJA O CCIDENTALIS TWIG (UNII: 1NT28 V9397) (THUJA OCCIDENTALIS TWIG - UNII:1NT28 V9397)	THUJA OCCIDENTALIS TWIG	10 [hp_X] in 10 mL	
ANTIMO NY TRISULFIDE (UNII: F79059A38U) (ANTIMO NY - UNII:9IT35J3UV3)	ANTIMO NY TRISULFIDE	10 [hp_X] in 10 mL	
DIOSCOREA VILLOSA EXTRACT (UNII: IWY3IWX2G8) (DIOSCOREA VILLOSA EXTRACT - UNII:IWY3IWX2G8)	DIOSCOREA VILLOSA EXTRACT	10 [hp_X] in 10 mL	
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	10 [hp_X] in 10 mL	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) (SILICON DIO XIDE - UNII: ETJ7Z6 XBU4)	SILICON DIOXIDE	10 [hp_X] in 10 mL	

SODIUM BORATE (UNII: 91MBZ8H3QO) (BORIC ACID - UNII:R57ZHV85D4)	SODIUM BORATE	10 [hp_X] in 10 mL
CINNAMON (UNII: 5S29HWU6QB) (CINNAMON - UNII:5S29HWU6QB)	CINNAMON	10 [hp_X] in 10 mL

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50125-001-10	10 mL in 1 PACKET		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/01/2009	

Labeler - Deep Cover Systems LLC (011636505)

Registrant - Deep Cover Systems LLC (011636505)

Establishment				
Name	Address	ID/FEI	Business Operations	
Deep Cover Systems LLC		011636505	relabel	

Establishment			
Name	Address	ID/FEI	Business Operations
Gar Laboratories		074933615	manufacture

Revised: 1/2010 Deep Cover Systems LLC