REMEDY NAILS- undecylenic acid lotion Adwill Labs Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

ACTIVE INGREDIENT:

Undecylenic Acid USP 10%

PURPOSE:

Anti-Fungal

USES:

Treats cuticle and skin fungal infections.

- Heals and moisturizes cuticles and skin.
- Athlete's foot treatment.
- Relieves itching, burning and cracking.

WARNINGS: FOR EXTERNAL USE ONLY.

Keep out of reach of children.

- Consult your doctor if you are pregnant before using this product.
- It is not known whether this drug passes into breast milk.
- Consult your doctor before breast feeding.
- If swallowed, call Poison Control Center immediately.

STOP USE AND ASK A DOCTOR IF:

Irritation occurs.

No improvement within 2 weeks.

DIRECTIONS:

Wash and dry affected area.

- Apply a thin layer over affected area twice daily or as directed by a doctor.
- Apply enough medication to cover the affected area and surrounding skin.
- Wash hands after use.
- For maximum results, use twice daily or as instructed.
- Discontinuing use of this medication may allow recurrence of infection.
- If condition persists, consult your doctor.

CAUTION:

Do not accept if safety seal is broken or missing.

- Store at room temperature 60-85F.
- Keep in tight, light resistant container.

ALLERGIC REACTIONS:

Contact doctor if unusual reactions to this medicine occur.

• This product does not contain FD&C Yellow #5 or FD&C Yellow #6.

INACTIVE INGREDIENTS:

Mineral Oil, Isopropyl Myristate, Lavandula Angustifolia (Lavender) Oil, Linalool, Carthamus Tinctorius (Safflower) Seed Oil, Limonene, Aleurites Moluccana (Kukui) Seed Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Oil, Algae Extract.

Principal Display Panel - 15 mL Bottle Label

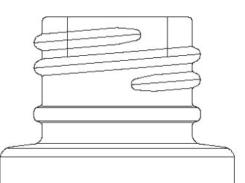
Dr.'s REMEDY®

Therapeutic Cuticle Oil

Lavender Safflower Tea Tree Oil Algae Extract

Nourishing Anti-Fungal Treatment

15_mL



Dr.'s REMEDY® Therapeutic Cuticle Oil

Lavender Safflower Tea Tree Oil Algae Extract

Nourishing Anti-Fungal Treatment

15 mL

Formulated By Doctors
FDA Approved
Anti-Fungal Medicine
Visible Results • Proven Effective

Active Ingredient: Undecylenic Acid USP 10%

For external use only.

Dist. by: AdWill Labs, Inc. Huntington, NY 11743 www.remedynails.com MADE IN U.S.A.

REMEDY NAILS

undecylenic acid lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72222-224

Route of Administration TOPICAL

Active Ingredient/Active Moiety

-		
Ingredient Name	Basis of Strength	Strength
LINDECVIENIC ACID (LINII), KADOCKIAMI) (LINDECVIENIC ACID		0F m a

UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)

UNDECYLENIC ACID

85 mg
in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ingredient Name	Strength

MINERAL OIL (UNII: T5L8T28FGP)

ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)

SAFFLOWER OIL (UNII: 65UEH262IS)	
TEA TREE OIL (UNII: VIF565UC2G)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72222- 224-10	1 in 1 CARTON	06/01/2018	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	06/01/2018	

Labeler - Adwill Labs Inc (081136982)

Establishment			
Name	Address	ID/FEI	Business Operations
PhytogenX, Inc.		624386772	manufacture(72222-224)

Revised: 5/2023 Adwill Labs Inc