

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

15mL



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
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	85 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

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

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