

FUNGINIX ANTI-FUNGAL TREATMENT- undecylenic acid ointment
The Sisquoc Healthcare Corporation

Sisquoc HC (as PLD) - FUNGINIX ANTI-FUNGAL TREATMENT (71229-102)

ACTIVE INGREDIENT

UNDECYLENIC ACID 10%

PURPOSE

ANTIFUNGAL

USES

- ANTI-FUNGAL TREATMENT

WARNINGS

FOR EXTERNAL USE ONLY.

DO NOT USE ON CHILDREN UNDER 2 YEARS OF AGE UNLESS DIRECTED BY A DOCTOR.

WHEN USING THIS PRODUCT AVOID CONTACT WITH THE EYES. IF CONTACT OCCURS, RINSE THE EYES VERY THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF IRRITATION OCCURS OR THERE IS NO IMPROVEMENT WITHIN 4 WEEKS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- For the cure of most ringworm (tinea corporis) and athlete's foot (tinea pedis). For relief of itching, scaling, cracking, burning, redness, soreness, irritation and discomforts which may accompany these conditions.
- Clean the affected area with soap and warm water and dry thoroughly. Apply a thin layer of FUNGINIX over the affected area twice daily (morning and night), or as directed by a physician. Allow 3-5 minutes for the solution to penetrate the skin and absorb fully into the surrounding tissue.
- FUNGINIX should be applied to cuticles, around nail edges and under nail tips where reachable with the applicator brush. This product is not intended to, nor will it, penetrate hard nail surfaces.
- For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes and change shoes and socks at least once daily. For athlete's foot and ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor.
- Intended for use by normally healthy adults only. Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor.

INACTIVE INGREDIENTS

Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Oleth-10 Phosphate, Triethanolamine, Polysorbate 20, Acrylates Copolymer, Glycerin, Propylene Glycol, Uva Ursi (Bearberry) Extract, Beta-Glucan, Propolis Extract, Aloe Barbadensis Juice, Tocopheryl Acetate (Vitamin E), Camphor, Menthol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Lavandula Angustifolia (Lavender) Oil, Jasminum Officinale (Jasmine Oil), Eugenia Caryophyllus (Clove) Flower Oil, Theobroma Cacao (Cocoa) Seed Butter, Rosa Canina (Rose Hip) Flower Oil, Cetyl Hydroxyethylcellulose, Ethylhexylglycerin, Phenoxyethanol

Store between 20°C to 25°C (68° to 77°F)



Drug Facts

Active Ingredient	Purpose
Undecylenic acid 10% w/w.....	Antifungal

Uses: For the cure of most tinea corporis (ringworm) and tinea pedis (athlete's foot)

For relief of ■discomforts which may accompany these conditions
 ■itching ■burning ■cracking ■redness ■irritation ■scaling ■sores-ness

Warnings

For external use only

If pregnant or breastfeeding consult a healthcare professional before use

Do not use on children under 2 years of age unless directed by a doctor

When using this product avoid contact with the eyes

Use only as directed by a doctor on persons with highly sensitive skin

Stop use and consult a doctor if

- there is no improvement within 4 weeks
- irritation occurs

Keep out of reach of children. If accidental ingestion occurs, get medical help or contact a Poison Control Center right away

Directions ■Use only as directed. ■Clean the affected area with soap and warm water and dry thoroughly. ■Apply a thin layer over the affected area twice daily (morning and night), or as directed by a physician. ■For athlete's foot, pay special attention to spaces between toes; wear well fitting, ventilated shoes and change shoes and socks at least once daily. ■For athlete's foot and ringworm, use daily for 4 weeks. If condition persists longer, consult a doctor. ■Intended for use by normally healthy adults only. ■Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor. ■This product is not effective on the scalp or nails.

Other Information ■Keep tightly closed when not in use.

■Store at room temperature 15°-30°C (59°-86° F)

■Protect from freezing. If freezing occurs warm to room temp

Inactive Ingredients: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Arctostaphylos Uva Ursi Leaf Extract, Avena Sativa (Oat) Kernel Extract, C13-14 Isoparaffin, Camphor, Cetyl Hydroxyethylcellulose, DI Water, Ethylhexylglycerin, Eugenia Caryophyllus (Clove) Flower Oil, Glycerin, Jasminum Officinale (Jasmine) Oil, Laureth-7, Lavandula Angustifolia (Lavender) Oil, Magnesium Asorbil Phosphate, Melaleuca Alternifolia (Tea Tree) Leaf Oil Menthol, Oleth-10, Phenoxyethanol, Polyacrylamide, Propylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Rosa Canina Fruit Oil, Sodium Hydroxide, Theobroma Cacao (Cocoa) Seed Butter, Tocopherol Acetate

Questions?.....800-589-8913

FUNGINIX ANTI-FUNGAL TREATMENT

undecylenic acid ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71229-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALMOND OIL (UNII: 66YXD4DKO9)	
OLETH-10 PHOSPHATE (UNII: Q95361F4VS)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARCTOSTAPHYLOS UVA-URSI WHOLE (UNII: 37SXO36KR7)	
OAT (UNII: Z6J799EAJK)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	
MENTHOL (UNII: L7T10EIP3A)	
TEA TREE OIL (UNII: VIF565UC2G)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
JASMINUM OFFICINALE WHOLE (UNII: X3314B4SYD)	
CLOVE OIL (UNII: 578389D6D0)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ROSA CANINA FLOWER OIL (UNII: DUY7M48I1T)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71229-102-11	30 mL in 1 TUBE; Type 0: Not a Combination Product	03/25/2019	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M005	03/25/2019	

Labeler - The Sisquoc Healthcare Corporation (021517142)

Revised: 4/2025

The Sisquoc Healthcare Corporation