

UNDESINE - undecylenic acid, zinc undecylenate ointment
Indiana Botanic Gardens

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.

Undesine

Active Ingredient

Undecylenic acid 5%

Zinc undecylenate 20%

Purpose

topical antifungal

topical antifungal

Uses:

- cures athlete's foot (dermatophytosis)
- clears up ringworm (tinea corporis)
- cures jock itch (tinea cruris)

Warnings: For external use only.

Avoid contact with the eyes.

Do not use:

- on children under 2 years of age
- for diaper rash
- on scalp or nails

Stop using and ask a doctor if

- irritation occurs
- if 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:

- clean the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor
- supervise children in the use of this product
- For athlete's foot: pay special attention to spaces between the toes, wear well fitting, ventilated shoes, and change shoes and socks at least once daily
- use for 4 weeks. (for athlete's foot and ringworm)
- for jock itch: use daily for 2 weeks

Other information:

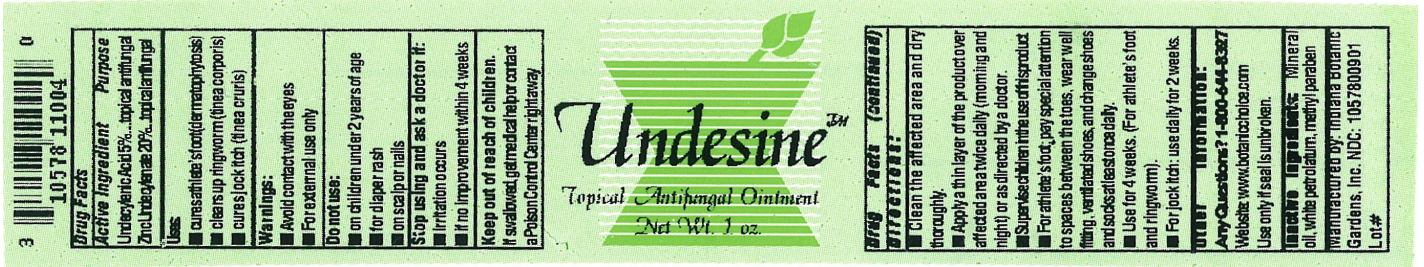
To reorder call: 1-800-644-8327
 website: www.botanicchoice.com

Use only of seal is unbroken

Manufactured by: Indiana Botanic Gardens, Inc.

NDC# 1057800901

Inactive ingredients: light mineral oil, white petrolatum, methylparaben



| UNDESINE | | | |
|--|-------------------|--------------------|---------------|
| undecylenic acid, zinc undecylenate ointment | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10578-009 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N) | UNDECYLENIC ACID | 5 g in 100 g | |
| ZINC UNDECYLENATE (UNII: 388VZ25DUR) (ZINC UNDECYLENATE - UNII:388VZ25DUR) | ZINC UNDECYLENATE | 20 g in 100 g | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | | |
| Product Characteristics | | | |
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:10578-009-01 | 29 g in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C | 01/01/1995 | |

Labeler - Indiana Botanic Gardens (005421771)

Registrant - Indiana Botanic Gardens (005421771)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| Indiana Botanic Gardens | | 005421771 | label, manufacture |

Revised: 12/2010

Indiana Botanic Gardens