SANAFITIL- undecylenic acid liquid
ZURICH MEDICAL LABS, LLC

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.

Sanafitil® Solución

Drug Facts

Active Ingredients

Undecylenic Acid 10%

Purpose

Antifungal

Uses

- Cures most athlete's foot, jock itch & ringworm
- Relieves itching, burning, cracking, and discomfort which accompany these conditions

Warning

- For external use only.
- Not for diaper rash
- When using this product avoid contact with eyes and mucous membrane.
- Do not use on children under 2 years of age except under the advice and supervision of a doctor.

Stop use and ask a doctor if:

- Irritation occurs
- There is no improvement within 4 weeks of treatment for athlete's foot and ringworm and 2 weeks of treatment for jock itch discontinue use and consult a doctor.

KEEP OUT OF REACH OF CHILDREN.

In case of accidental ingestion seek professional assistance or contact a poison control center right away.

Directions

- Clean affected area and dry thoroughly.
- Apply a thin layer over affected area twice daily (morning & night) or as directed by a doctor.
- For athlete's foot pay special attention to the space between the toes. Wear well fitting, ventilated shoes and change shoes & socks at least once a day.
- For athlete's foot and ringworm, use daily for 4 weeks
- For jock itch use daily for 2 weeks.
- Supervise Children in use of this product.
- Product not effective in the scalp or nails.

Other Information

Store at 59° - 86° F

Other ingredients

isopropyl alcohol, purified water, benzocaine, salicylic acid, benzoic acid, methyl salicylate, boric acid, methyl paraben, mentol, propyl paraben, FD&C red #22.

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

SANAFITIL®

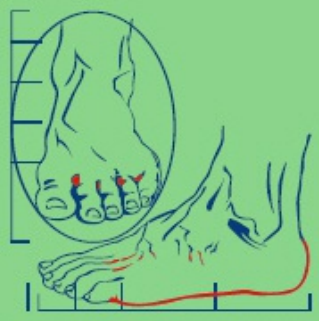
ANTIFUNGAL
SOLUTION

• Relieves itching, burning, cracking, and discomfort

1 OZ (30mL)

SANAFITIL®

SOLUCIÓN ANTIHONGOS



ANTIFUNGAL SOLUTION

- Alivia la picazón, ardor, grietas, descamación
- Relieves itching, burning, cracking, and discomfort

1 OZ (30mL)

SOLUCIÓN ANTIHONGOS

ANTIFUNGAL SOLUTION

zürich medical labs
502 NE 190th St. • Miami, FL 33179

85499400517

Lot

Lot

Exp

SOLUCIÓN ANTIHONGOS

SANAFITIL®

SANAFITIL®

Datos del Medicamento

Ingredientes Activos	Categoría
Acido Undecilénico 10 %.....	Antihongos

Usos:
- Para el tratamiento de la mayoría de los casos de pie de atleta, tiña inguinal y tiña corporis
- Alivia la comezón, ardor, descamación y molestias que acompañan estas condiciones

Advertencia:
- **Para uso externo solamente**
- Cuando use este producto evite el contacto con ojos y mucosas
- No utilizar en niños menores de 2 años de edad, excepto bajo la recomendacion y la supervisión de un médico.
- No para dermatitis del pañal

Pare el uso y consulte a un médico si
- Ocurre irritación
- No ocurre mejoría en 4 semanas de tratamiento para el pie de atleta y la tiña corporis y 2 semanas de tratamiento para la tiña inguinal.

MANTENER FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión accidental, busque asistencia profesional o contacte un centro de control de envenenamientos de inmediato.

Instrucciones:
- Limpie la zona afectada y seque bien

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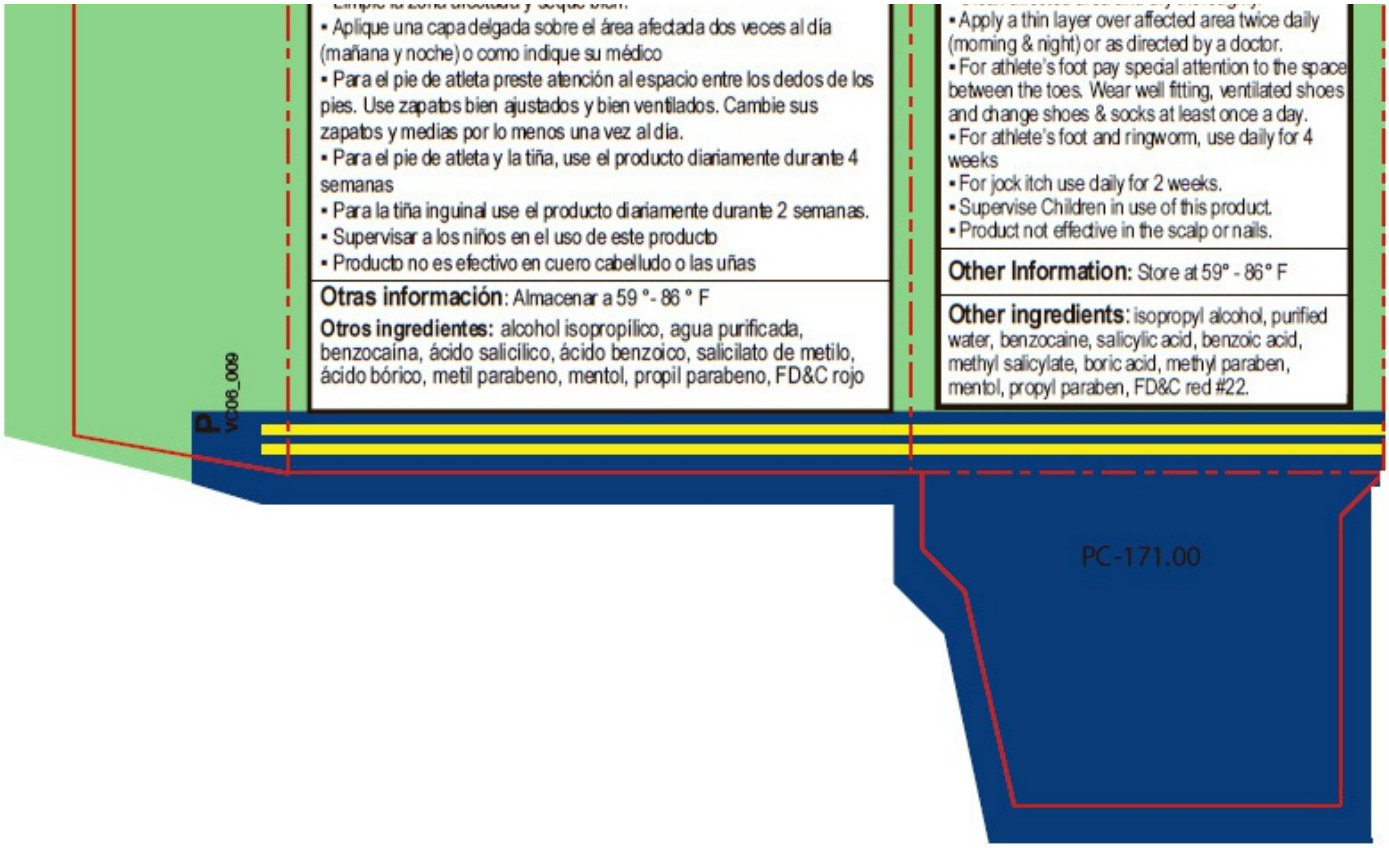

SANAFITIL

undecylenic acid liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61357-146
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Undecylenic Acid (UNII: K3D86KJ24N) (Undecylenic Acid - UNII:K3D86KJ24N)	Undecylenic Acid	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZOCAINE (UNII: U3RSY48JW5)	
HEXYL SALICYLATE (UNII: 8F78EY72YL)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BORIC ACID (UNII: R57ZHV85D4)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MENTHOL (UNII: L7T10EIP3A)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61357-146-01	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333C	08/24/1966	

Labeler - ZURICH MEDICAL LABS, LLC (071904097)

Establishment

Name	Address	ID/FEI	Business Operations
ZURICH MEDICAL LABS, LLC		071904097	MANUFACTURE(61357-146)

Revised: 3/2014 ZURICH MEDICAL LABS, LLC