

**SANAFITIL- undecylenic acid ointment**  
**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.*

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**Sanafitil® Ungüento**

**Drug Facts**

**Active Ingredients**

Undecylenic Acid 10%

**Purpose**

Antifungal

**Uses**

- For the treatment of most athlete's foot, jock itch & ringworm
- Relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.

**Warning**

- **For external use only.**
- 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.
- Not for diaper rash

**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 and 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 (15° - 30°C)

**Other ingredients**

petrolatum white, benzocaine, paraffin wax, salicylic acid, benzoic acid, boric acid, methyl salicylate, methyl paraben, propyl paraben, menthol crystals

**PRINCIPAL DISPLAY PANEL - 28.35 g Tube Carton*****SANAFITIL*<sup>®</sup>****(Undecylenic Acid 10%)****ANTIFUNGAL****OINTMENT****1 OZ. (28.35g)**

# SANAFITIL<sup>®</sup>

(Undecylenic Acid 10% \ Ácido Undecilénico 10 %)

## ANTIFUNGAL

- Relieves itching, burning, cracking, scaling
- Cures most athlete's foot, jock itch & ringworm

## ANTIHONGOS

- Alivia la picazón, ardor, grietas, descamación
- Cura la mayoría de los casos de pie de atleta, tiña inguinal y tiña corporis

# SANAFITIL<sup>®</sup>

## ANTIFUNGAL ANTIHONGOS

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(Undecylenic Acid 10% \ Ácido Undecilénico 10 %)

## ANTIFUNGAL

## ANTIHONGOS

ointment | unguento

1 OZ. (28.35g)

Honduras: No. M.06031

Panamá: No.55512

El Salvador: No.

Costa Rica: No.

Guatemala: No.

Nicaragua: No.

Rep Dominicana: No



UPC  
85499400519

**Advertencia:**  
• Para el tratamiento de la mayoría de los casos de pie de atleta, tiña inguinal y tiña corporis.  
• Alivia la picazón, ardor, grietas, descamación y molestias que acompañan a estas condiciones.

**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 recomendación y la supervisión de un médico.  
• No use para dermatitis del pañal.  
• No utilizar si estas molestias menores de 2 años de edad, excepto bajo la recomendación y la supervisión de un médico.  
• Para 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.  
• Aplique una capa delgada sobre el área afectada dos veces al día (mañana y noche) o como lo indique su médico.  
• Para el pie de atleta preste atención especial al espacio entre los dedos de los pies. Use zapatos bien ajustados y bien ventilados. Cambie sus zapatos y medias por lo menos una vez al día.  
• Para la tiña inguinal use el producto diariamente durante 4 semanas.  
• Para el pie de atleta y la tiña, use el producto diariamente durante 2 semanas.  
• Supervisar a los niños en el uso de este producto.  
• Producto no es efectivo en el cuero cabelludo o las uñas.

**Otras informaciones:** Almacenar a 59° - 86° F (15° - 30° C)

**Otros ingredientes:** petrolatum blanco, benzocaina, cera de parafina, ácido salicílico, ácido bórico, ácido bórico, sulfato de metilo, metil paraben, propil paraben, mentol, oxalato

**Warnings:**  
• For the treatment of most athlete's foot, jock itch & ringworm.  
• Relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.

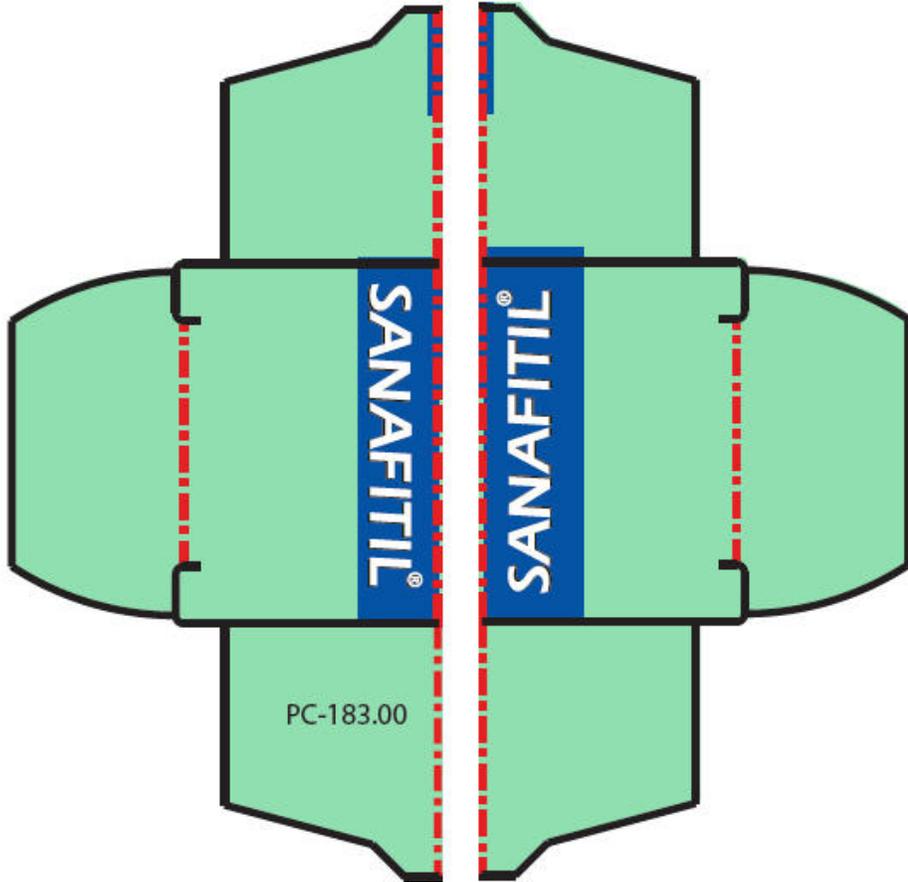
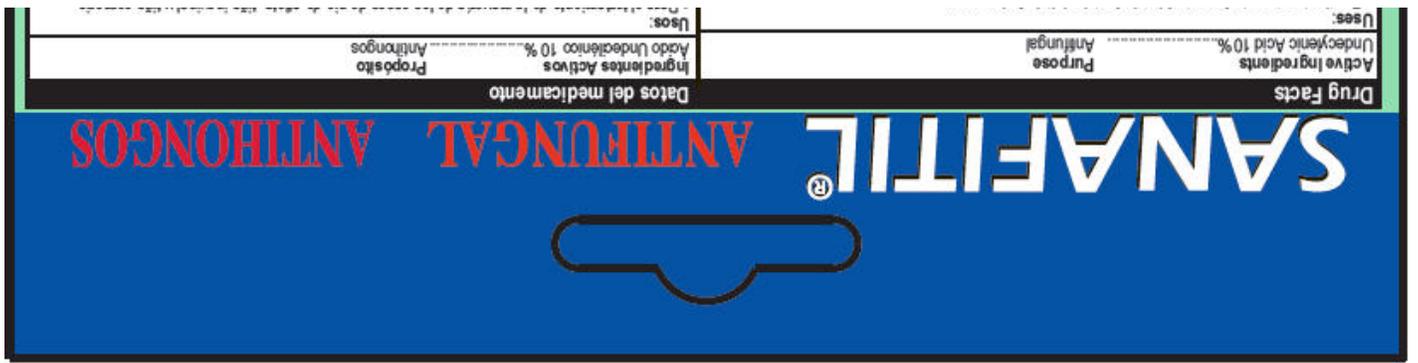
**For external use only.**  
• Do not use on children under 2 years of age except under the advice and supervision of a doctor.  
• Do not use for diaper rash.  
• Stop use and ask a doctor if:  
• Irritation occurs. • There is no improvement within 4 weeks of treatment for athlete's foot and ringworm and 2 weeks of treatment for jock itch discontinuance use and consult a doctor.  
• For use and consult a professional assistant or contact a poison control center right away.

**KEEP OUT OF REACH OF CHILDREN.** In case of accidental ingestion seek professional assistance.

**Directions:**  
• Apply a thin layer over affected area twice daily (morning and night) or as directed by a doctor.  
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**Other ingredients:** petrolatum white, benzocaine, paraffin wax, salicylic acid, boric acid, methyl salicylate, methyl paraben, propyl paraben, menthol, oxalate



**SANAFITIL**  
undecylenic acid ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6 1357-149
<b>Route of Administration</b>	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 g

**Inactive Ingredients**

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
BENZOCAINE (UNII: U3RSY48JW5)	
PARAFFIN (UNII: I9O0E3H2ZE)	
HEXYL SALICYLATE (UNII: 8F78EY72YL)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BORIC ACID (UNII: R57ZHV85D4)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
MENTHOL (UNII: L7T10EIP3A)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61357-149-01	1 in 1 CARTON		
1		28.35 g in 1 TUBE		

### 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(61357-149)

Revised: 3/2014

ZURICH MEDICAL LABS, LLC