

SANAFITIL TALCO- undecylenic acid and zinc undecylenate powder
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® Talco

Drug Facts

Active Ingredients	Purpose
Undecylenic Acid 2%	Antifungal
Zinc Undecylenate 20%	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

talc

PRINCIPAL DISPLAY PANEL - 57 g Bottle Label

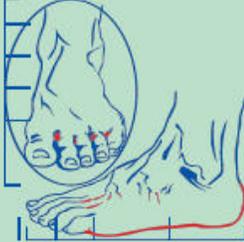
SANAFITIL®

ANTIFUNGAL
POWDER

- Treats most *Athlete's foot, Jock itch & Ringworm*

NET WEIGHT / PESO

NETO : 2 OZ (57 g)

 <p>ANTIFUNGAL POWDER</p>  <p>ANTIIONGOS TALCO / POLVO</p> <ul style="list-style-type: none"> • Treats most <i>Athlete's foot, Jock itch & Ringworm</i> • Tratamiento para la mayoría de los casos de <i>Pie de atleta, Tiña inguinal y Tiña corporis</i> 	<p>Datos del medicamento</p> <table border="1"> <tr> <th>Ingredientes Activos</th> <th>Propósito</th> </tr> <tr> <td>Ácido Undecilénico 2%.....</td> <td>Antihongos</td> </tr> <tr> <td>Zinc Undecylenate 20%.....</td> <td>Antihongos</td> </tr> </table> <p>Usos:</p> <ul style="list-style-type: none"> • 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 <p>Advertencia:</p> <ul style="list-style-type: none"> • 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 para dermatitis del pañal <p>Pare el uso y consulte a un médico si</p> <ul style="list-style-type: none"> • 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. 	Ingredientes Activos	Propósito	Ácido Undecilénico 2%.....	Antihongos	Zinc Undecylenate 20%.....	Antihongos	<p>Datos del medicamento (continuado)</p> <p>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.</p> <p>Instrucciones:</p> <ul style="list-style-type: none"> • Limpie la zona afectada y seque bien. • Aplique una capa delgada sobre el área afectada dos veces al día (mañana y noche) o como indique su médico • Para el pie de atleta preste atención 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 el pie de atleta y la tiña, use el producto diariamente durante 4 semanas • Para la tiña inguinal use el producto diariamente durante 2 semanas. • Supervisar a los niños en el uso de este producto • Producto no es efectivo en cuero cabelludo o las uñas <p>Otras información: Almacenar a 59° - 86° F</p> <p>Otros ingredientes: Talco</p>
	Ingredientes Activos	Propósito						
Ácido Undecilénico 2%.....	Antihongos							
Zinc Undecylenate 20%.....	Antihongos							
<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Undecylenic Acid 2%.....</td> <td>Antifungal</td> </tr> <tr> <td>Zinc Undecylenate 20%.....</td> <td>Antifungal</td> </tr> </table> <p>Uses:</p> <ul style="list-style-type: none"> • Cures most athlete's foot, jock itch & ringworm • Relieves itching, burning, cracking, and discomfort which accompany these conditions <p>Warning:</p> <ul style="list-style-type: none"> • 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. <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> • 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 	Active Ingredients	Purpose	Undecylenic Acid 2%.....	Antifungal	Zinc Undecylenate 20%.....	Antifungal	<p>Drug Facts (continued)</p> <p>KEEP OUT OF REACH OF CHILDREN. In case of accidental ingestion seek professional assistance or contact a poison control center right away.</p> <p>Directions:</p> <ul style="list-style-type: none"> • 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. <p>Other Information: Store at 59° - 86° F</p> <p>Other ingredients: talc</p>	
Active Ingredients	Purpose							
Undecylenic Acid 2%.....	Antifungal							
Zinc Undecylenate 20%.....	Antifungal							

85499400521



**zürich
medical
labs**

502 NE 190th St. • Miami, FL 33179

SANAFITIL TALCO

undecylenic acid and zinc undecylenate powder

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:61357-152

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UNDECYLENIC ACID (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	20 mg in 1 g
ZINC UNDECYLENATE (UNII: 388VZ25DUR) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	ZINC UNDECYLENATE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61357-152-01	1 in 1 CARTON		
1		57 g 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(61357-152)

Revised: 3/2014

ZURICH MEDICAL LABS, LLC