

SILKA ANTIFUNGAL- tolnaftate liquid

Genomma Lab USA

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.

Silka® Antifungal Liquid

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- For effective treatment of most athlete's foot and ringworm
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation and discomfort. Helps prevent most athlete's foot (dermatophytosis) with daily use.

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.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm).

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

Directions

- This product is not effective on the scalp or nails. For athlete's foot and ringworm: use daily for 4 weeks. 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

- To prevent athlete's foot, apply once or twice daily (morning and/or night)
- Apply to skin around the nail and cuticle.

Other information

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

Inactive ingredients

Aloe Barbadensis Leaf Extract, BHT, Carthamus Tinctorius (Safflower) Seed Oil, Hydrogenated Polyisobutene, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Oryza Sativa (Rice) Bran Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopheryl Acetate.

Questions or comments?

Call toll free 1-877-994-3666

Monday to Friday, 8 am to 6 pm Central time.

Distributed by:

Genomma Lab., Houston, TX 77027

PRINCIPAL DISPLAY PANEL - 13 ML Bottle Carton

SILKA®

MAX STRENGTH

ANTIFUNGAL
LIQUID

- » KILLS
FUNGUS
- » STOPS ITCHING
AND BURNING
- » HELPS RESTORE
SKIN HEALTH

BEFORE
AFTER
DRAMATIZATION

WITH BRUSH
APPLICATOR

CLINICALLY PROVEN
AGAINST ATHLETE'S
FOOT FUNGUS

0.45 FL OZ / 13 ML

SILKA[®]
ANTIFUNGAL LIQUID
 LÍQUIDO ANTIFÚNGICO

SILKA[®]
MAX STRENGTH
ANTIFUNGAL LIQUID



- » KILLS FUNGUS
- » STOPS ITCHING AND BURNING
- » HELPS RESTORE SKIN HEALTH

CLINICALLY PROVEN AGAINST ATHLETE'S FOOT FUNGUS

0.45 FL. OZ. / 13 ML

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 Monday to Friday, 8 am to 6 pm Central time.
 Lunes a viernes de 8 a. m. a 6 p. m., hora del Centro.

SILKA[®]
MÁXIMA POTENCIA
LÍQUIDO ANTIFÚNGICO



- » MATA HONGOS
- » ALIVIA LA PICAZÓN Y ARDOR
- » AYUDA A RESTAURAR LA SALUD DE PIEL

CLÍNICAMENTE PRUBADO CONTRA EL HONGO DEL PIE DE ATLETA

0.45 FL. OZ. / 13 ML

Información del Medicamento
Ingrediente Activo Tolnaftate 1% **Propósito** Anti-Hongos

Usos
 ■ Para el tratamiento eficaz de la mayoría de pies de atleta y tiña ■ Alivia picazón, descamación, agrietamiento, ardor, enrojecimiento, dolor, irritación y malestar. Ayuda a prevenir la mayoría del pie de atleta (dermatofitosis) con el uso diario.

Precauciones
 Sólo para uso externo
 ■ No lo use en niños menores de 2 años a menos que lo indique un médico.

Al utilizar este producto evite el contacto con los ojos.

Deje de usarlo y consulte a un médico si ■ se produce irritación
 ■ no hay mejoría en 4 semanas (para pie de atleta y tiña).

Mantener fuera del alcance de los niños. En caso de ingestión, busque ayuda médica o comuníquese con un centro de control de intoxicaciones de inmediato.

Instrucciones ■ Este producto no es efectivo en el cuero cabelludo ni en las uñas. Para el pie de atleta y la tiña: usar a diario durante 4 semanas. Limpiar la zona afectada y secar bien. ■ Aplicar una fina capa del producto sobre la zona afectada dos veces al día (mañana y noche) o según las indicaciones de un médico. ■ Supervise a los niños en el uso de este producto. ■ Para el pie de atleta: preste especial atención a los espacios entre los dedos de los pies; Use zapatos que le queden bien ventilados y cámbiense los zapatos y las medias al menos una vez al día. ■ Para prevenir el pie de atleta, aplicar una o dos veces al día (mañana y / o noche) ■ Aplique en la piel alrededor de la uña y cutícula.

Otra información
 ■ Almacenar a temperatura ambiente de 15° - 30° C (59° - 86° F)

Ingredientes Inactivos
 Extracto de hoja de aloe barbadensis, BHT, Aceite de semilla de Carthamus Tinctorius (cártamo), Polisisobuteno hidrogenado, Aceite de Lavandula Angustifolia (Lavanda), Aceite de hoja de Melaleuca Alternifolia (árbol de té), Aceite de salvado de oryza sativa (arroz), Aceite de Prunus Amygdalus Dulcis (Almendras dulces), Aceite de semilla de sesamum indicum (sésamo).

Distributed by / Distribuido por:
 Genomma Lab., Houston, TX 77027
 www.genommelab.us



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Lot. No. / LOTE:
 Exp. date. / Exp.:

SILKA ANTIFUNGAL

tolnaftate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Tolnaftate (UNII: 06KB629TKV) (Tolnaftate - UNII:06KB629TKV)	Tolnaftate	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
RICE BRAN OIL (UNII: LZ06K1506A)	
SESAME OIL (UNII: QX10HYY4QV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-083-01	1 in 1 CARTON	03/22/2022	
1		13 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/22/2022	

Labeler - Genomma Lab USA (832323534)

Revised: 3/2022

Genomma Lab USA