

LUXURY- athlete foot powder aerosol, spray
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI

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.

LUXURY Athlete's Foot Powder Spray

Active Ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevents most athlete's foot with daily use
- for effective relief of itching, cracking and burning

Warnings

For external use only.

Extremely flammable:

Do not use while smoking or near heat or flame

When using this product

- avoid contact with the eyes
- use only as directed. intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal
- contents under pressure. Do not puncture or incinerate. Do not store temperature above 120 F (49 C)

Stop use and ask a doctor if

- irritation occurs
- There is no improvement within 4 weeks

Do not use

on children under 2 years of age unless directed by a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake can well and spray a thin layer over affected area twice daily (morning and night)
- wash affected area and dry thoroughly
- hold can 4-6 inches away from affected area
- 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 daily for 4 weeks; if condition persists longer, ask a doctor
- if condition persists longer, consult a doctor
- this product is not effective on the scalp or nails
- in case of clogging , clean nozzle with a pin

Other information

- store between 20° and 25°C (68° and 77°F)

Inactive ingredients

Alcohol denat, Butane , Isobutene , Triethanolamine , zea mays (corn) starch.

Principal Display Panel

LUXURY[®]

Athlete's Foot Powder Spray

Tolnaftate 1%
Antifungal

- Goes on dry
- Cures and prevents most athlete's foot
- Relieves itching and burning

NET WT. 2 OZ. (57 g)

Drug Facts

Active ingredient

Tolnaftate 1%.....Antifungal

Purpose

Uses ■ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ■ helps prevent most athlete's foot with daily use ■ for effective relief of itching, burning and cracking

Warnings

For external use only

Flammable: Do not use while smoking or near heat or flame

Do not use on children under 2 years of age unless directed by a doctor

When using this product ■ avoid contact with the eyes ■ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal ■ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F (49°C.)

Stop use and ask a doctor if ■ irritation occurs ■ There is no improvement within 4 weeks

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions ■ wash affected area and dry thoroughly ■ shake can well and spray a thin layer over affected area twice daily (morning and night) ■ 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 daily for 4 weeks; if condition persists longer, ask a doctor ■ to prevent athlete's foot, apply once or twice daily (morning and/or night) ■ this product is not effective on the scalp or nails ■ in case of clogging, clean nozzle with pin.

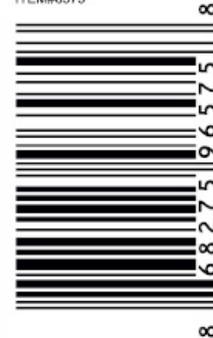
Other information

store at 20-25°C (68-77°F)

Inactive ingredients

Alcohol denat, butane, isobutene, triethanolamine, zeamays (corn) starch

ITEM#6575



LUXURY

athlete foot powder aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76772-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1.3 g in 57 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

BUTANE (UNII: 6LV4FOR43R)	
ISOBUTYLENE (UNII: QA2LMR467H)	
TROLAMINE (UNII: 9O3K93S3TK)	
STARCH, CORN (UNII: O8232NY3SJ)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-022-57	57 g in 1 CANISTER; Type 0: Not a Combination Product	03/10/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/10/2021	

Labeler - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Registrant - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Establishment			
Name	Address	ID/FEI	Business Operations
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI		533120570	manufacture(76772-022)

Revised: 3/2021

TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI