

**TOLNAFTATE ANTIFUNGAL- tolnaftate powder**  
**Ger-Care Pharmaceuticals, Corp**

*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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**GC TOLNAFTATE**

**ACTIVE INGREDIENT**

DRUG FACTS

TOLNAFTATE 1 PERCENT

**PURPOSE SECTION**

ANTIFUNGAL

**KEEP OUT OF REACH OF CHILDREN**

KEEP OUT OF REACH OF CHILDREN

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

**INDICATIONS AND USES SECTION**

USES

FOR EFFECTIVE TREATMENT OF MOST ATHLETE'S FOOT(LINEA PEDIS) AND RING WORM (THEA CORPORIS)

FOR EFFECTIVE RELIEF OF ITCHY, SCALY SKIN BETWEEN THE TOES

CLEAR UP MOST ATHLETE'S FOOT INFECTION AND WITH DAILY USE HELPS KEEP IT FROM COMING BACK

**WARNINGS SECTION**

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE ON CHILDREN UNDER 2 YEARS OF AGE EXCEPT UNDER THE ADVICE AND SUPERVISION OF A DOCTOR.

WHEN USING THIS PRODUCT AVOID CONTACT WITH THE EYES

STOP USE AND CONSULT A DOCTOR IF IRRITATION OCCURS THERE IS NO IMPROVEMENT WITHIN 4 WEEKS

OTHER INFORMATION

STORE AT ROOM TEMPERATURE

**DOSAGE AND ADMINISTRATION SECTION**

DRUG FACTS

## **DIRECTIONS**

SHAKE WELL BEFORE USE 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 USE DAILY FOR 4 WEEKS. IF CONDITION PERSISTS LONGER,  
CONSULT A DOCTOR

### **FOR ATHLETE'S FOOT**

PAY SPECIAL ATTENTION TO THE SPACES BETWEEN THE TOES WEAR WELL  
VENTILATED SHOES CHANGE SHOES AND SOCKS AT LEAST ONCE A DAY TO PREVENT  
ATHLETE'S FOOT, CLEAN AND DRY FEET THOROUGHLY. APPLY AS ABOVE ONCE OR  
TWICE DAILY.

THIS PRODUCT IS NOT EFFECTIVE ON THE SCALP OR NAILS.

## **INACTIVE INGREDIENTS SECTION**

CORN STARCH AND TALC

## **PACKAGE LABEL**

NDC 57896-199-45 GERICARE TOLNAFTATE ANTIFUNGAL POWDER 1 PERCENT  
CURES AND PREVENTS MOST ATHLETE'S FOOT

COMPARE TO THE ACTIVE INGREDIENT OF TINACTIN THIS PRODUCT IS NOT  
MANUFACTURED OR DISTRIBUTED BY THE OWNER OF THE REGISTERED TRADEMARK  
TINACTIN DISTRIBUTED BY GERI-CARE PHARMACEUTICALS 1650 63RD STREET  
BROOKLYN NY 11204 REV. 11/10 310-29009-0

NET WT. 45G (1 1/2 OZ.)

NDC 57896-199-45

**Drug Facts**

**Active Ingredient** Tolnaftate 1%.....**Purpose** Antifungal

**Uses**

- for effective treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- for effective relief of itchy, scaly skin between the toes
- clears up most athlete's foot infection and with daily use helps keep it from coming back

**Warnings**

For external use only

Do not use on children under 2 years of age except under the advice and supervision of a doctor.

When using this product avoid contact with the eyes

Stop use and consult 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.



**TOLNAFTATE  
ANTIFUNGAL  
POWDER 1%**

**Cures and Prevents Most  
Athlete's Foot**

Compare to the Active Ingredient of Tinactin®\*

**Drug Facts (continued)**

**Directions**

- shake well before use
- 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
- use daily for 4 weeks. If condition persists longer, consult a doctor.

**For athlete's foot**

- pay special attention to the spaces between the toes
- wear well-fitting ventilated shoes
- change shoes and socks at least once daily
- to prevent athlete's foot, clean and dry feet thoroughly. Apply as above once or twice daily.

This product is not effective on the scalp or nails.

**Other information**

- store at room temperature

**Inactive Ingredients** corn starch and talc

\*This product is not manufactured or distributed by the owner of the registered trademark Tinactin®.

Distributed by  
Geri-Care Pharmaceuticals  
1650 63rd Street  
Brooklyn, NY 11204

Rev. 11/10  
310-29009-0



**Net Wt. 45g (1 1/2 oz.)**

TOLNAFTATE ANTIFUNGAL				
tolnaftate powder				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-199(NDC:75841-199)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	STARCH, CORN (UNII: O8232NY3SJ)			
	TALC (UNII: 7SEV7J4R1U)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-199-45	45 g in 1 BOTTLE, DISPENSING; Type 7: Separate Products Requiring Cross Labeling	08/01/2011	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/01/2011	

**Labeler** - Geri-Care Pharmaceuticals, Corp (611196254)

**Registrant** - GCP Laboratories (965480861)

## Establishment

Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(57896-199) , relabel(57896-199)

Revised: 12/2019

Geri-Care Pharmaceuticals, Corp