

**LEADER MEDICATED- tolnaftate aerosol, powder**  
**Cardinal Health Inc.**

*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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**Drug Facts**

***Active ingredient***

Tolnaftate 1%

***Purpose***

Antifungal

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away. **Do not use** on children under 2 years of age unless directed by a doctor

***Uses***

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- cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris)
- if used daily, can prevent recurrence of athlete's foot
- relieves symptoms of athlete's foot, including itching, burning and cracking

***Warnings***

**For external use only.**

**Flammable:**

Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120° F

**When using this product**

- do not get into eyes or mouth
- use only as directed; intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal

**☐ Stop use and ask a doctor if**

- irritation occurs
- no improvement after four weeks for athlete's foot,

***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 toes, wear well-fitting, ventilated shoes and change shoes and socks at least once daily

- use daily for 4 weeks for athlete's foot and ringworm; use daily for 2 weeks for jock itch, if condition persists, consult a doctor
- to prevent athlete's foot, apply daily (morning and night)
- this product is not effective on scalp or nails
- in case of clogging, clear nozzle under running water

### Other information

Store between 20° and 30° C (68° and 86° F)

### Inactive ingredients

SD alcohol 40-B (14% w/w), BHT, Isobutane (propellant), PPG-12-buteth-16, talc

### Questions

Call 1-866-964-0939

### Box Label

**LEADER**  
Compare to Tioactive active ingredients\*

**Antifungal Powder Spray**

**Medicated**  
TOLNAFTATE 1%

- Cures Most Symptoms of Jock Itch
- Relieves Itching, Chafing and Burning

NET WT 4.6 OZ (130g)

Drug Facts	Purpose
<b>Active ingredient</b> Tolnaftate 1%	Antifungal
<b>Uses</b> • Cures most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris) • If used daily, can prevent recurrence of athlete's foot • Relieves symptoms of athlete's foot, including itching, burning and cracking	
<b>Warnings</b> For external use only <b>Flammable:</b> Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°F. <b>When using this product do not get into eyes or mouth</b> • Use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal <b>Stop use and ask a doctor if irritation occurs</b> • No improvement within 4 weeks for athlete's foot and ringworm; 2 weeks for jock itch <b>Keep out of reach of children. If removed, get medical help or contact a Poison Control Center right away.</b> Do not use on children under 2 years of age unless directed by a doctor.	
<b>Directions:</b> • Wash affected area and dry thoroughly • Shake can well and spray a thin layer over affected area twice daily (morning and night) • In supervised children in the use of this product • For athlete's foot, pay special attention to spaces between toes, wear well-fitting, ventilated shoes and change shoes and socks at least once daily • Use daily for 4 weeks for athlete's foot and ringworm; use daily for 2 weeks for jock itch. If condition persists, consult a doctor • To prevent athlete's foot, apply daily (morning and night) • This product is not effective on scalp or nails • In case of clogging, clear nozzle under running water	
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<b>Questions? 1-866-964-0939</b>	

**UPC PRINTS IN**  
PMS 282  
F.P.O.  
0-96295 11192

\*This product is not manufactured or distributed by Schering-Plough Healthcare Products Inc., owner of the registered trademark Tioactive.  
Distributed by Cardinal Health  
Dublin, Ohio 43017  
CIN 3469832  
www.myleader.com  
1400-004013  
Made in U.S.A.  
All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

APTELL-2

Leader Medicated Tolnaftate 1% Powder Spray

## LEADER MEDICATED

tolnaftate aerosol, powder

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-344
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M)	0.14 g in 1 g
ISOBUTANE (UNII: BXR49TP611)	
PPG-12-BUTETH-16 (UNII: 58CG7042J1)	
TALC (UNII: 7SEV7J4RIU)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:37205-344-66	130 g in 1 CAN		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part333C	03/15/2008	

**Labeler** - Cardinal Health Inc. (097537435)**Registrant** - Premier Brands of America (063849780)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Premier Brands of America		063849780	repack(37205-344) , relabel(37205-344)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
American Spray Tech LLC		137135237	manufacture(37205-344)