

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-124**

**APPROVED LABELING**

**APPROVED**

**A. CARTON LABEL:  
athlete's foot, jock itch, and ringworm  
30 ml spray pump**

MAR 17 2000

**1. FRONT (principal display) PANEL (PDP)**

**NEW**

**LAMISIL®AT™ (LOGO)**

**SOLUTION**

**Terbinafine Hydrochloride Solution 1%**

**Antifungal**

**NOW AVAILABLE WITHOUT A PRESCRIPTION**

**CURES ATHLETE'S FOOT BETWEEN THE TOES\***

**FULL PRESCRIPTION STRENGTH**

**\*See back panel for Uses information**

**For Effective Relief of:**

- Itching
- Burning

**Provides Targeted Delivery**

**NET CONTENTS 30 ml (1 fl oz)**

**2. SIDE PANEL**

**LAMISIL®AT™ (LOGO) SPRAY PUMP**

**3. TOP FRONT PANEL**

**LAMISIL®AT™ (LOGO) SPRAY PUMP**

**4. SIDE PANEL**

**LAMISIL®AT™ (LOGO) SPRAY PUMP**

**Lamisil®AT™ Spray Pump Cures Athlete's Foot Between the Toes, Jock Itch, and Ringworm**

**Non-aerosol Lamisil®AT™ Spray Pump:**

- Dries fast
- Not greasy

**Each 1 oz bottle contains approximately 300 sprays.**

**1 oz**

**5. BACK PANEL**

**LAMISIL®AT™ (LOGO)**

**SOLUTION**

**Terbinafine Hydrochloride Solution 1%**

**Antifungal**

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## ***Drug Facts***

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### ***Active ingredient***

Terbinafine hydrochloride 1%.....

### ***Purpose***

Antifungal

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### ***Uses***

- cures athlete's foot (tinea pedis) between the toes. Effectiveness on the bottom or sides of foot is unknown
  - cures jock itch (tinea cruris), and ringworm (tinea corporis)
  - relieves itching, burning, cracking, and scaling which accompany these conditions
- 

### ***Warnings***

**For external use only**

#### **Do not use**

- on nails or scalp
  - in or near the mouth or the eyes
  - for vaginal yeast infections
- 

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

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Stop use and ask a doctor if too much irritation occurs or gets worse

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

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### ***Directions***

- adults and children 12 years and older
    - wash the affected skin with soap and water and dry completely before applying
    - for athlete's foot between the toes spray twice a day (morning and night) for 1 week or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily. (Foot Diagram) 1 week between the toes
    - for jock itch and ringworm spray affected area once a day (morning or night) for 1 week or as directed by a doctor
  - wash hands after each use
  - children under 12 years: ask a doctor
- 

### ***Other information***

- store at 8°–25°C (46°–77°F)
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### ***Inactive ingredients***

cetomacrogol, ethanol, propylene glycol, purified water, USP

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**Questions?** call 1-800-570-9611 24 hours a day 7 days a week

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Lot Number and Expiration Date

**B. CARTON LABEL:  
jock itch  
30 ml spray pump**

**1. FRONT (principal display) PANEL (PDP)**

**NEW  
LAMISIL®AT™ (LOGO)  
SOLUTION  
Terbinafine Hydrochloride Solution 1%  
Antifungal  
NOW AVAILABLE WITHOUT A PRESCRIPTION  
CURES JOCK ITCH  
FULL PRESCRIPTION STRENGTH  
For Effective Relief of:**

- Itching
- Burning

**Provides Targeted Delivery  
NET CONTENTS 30 ml (1 fl oz)**

**2. SIDE PANEL**

**LAMISIL®AT™ (LOGO) SPRAY PUMP**

**3. TOP FRONT PANEL**

**LAMISIL®AT™ (LOGO) SPRAY PUMP**

**4. SIDE PANEL**

**LAMISIL®AT™ (LOGO) SPRAY PUMP  
Lamisil®AT™ Spray Pump Cures Jock Itch  
Non-aerosol Lamisil®AT™ Spray Pump:**

- Dries fast
- Not greasy

**Each 1 oz bottle contains approximately 300 sprays.  
1 oz**

**5. BACK PANEL**

**LAMISIL®AT™ (LOGO)  
SOLUTION  
Terbinafine Hydrochloride Solution 1%  
Antifungal**

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## ***Drug Facts***

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### ***Active ingredient***

Terbinafine hydrochloride 1%.....Antifungal

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### ***Purpose***

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### ***Uses***

- cures jock itch (tinea cruris)
  - relieves itching, burning, cracking, and scaling which accompany this condition
- 

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### ***Warnings***

#### **For external use only**

#### **Do not use**

- on nails or scalp
  - in or near the mouth or the eyes
  - for vaginal yeast infections
- 

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

---

Stop use and ask a doctor if too much irritation occurs or gets worse

---

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

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### ***Directions***

- adults and children 12 years and older
    - wash the affected skin with soap and water and dry completely before applying
    - spray affected area once a day (morning or night) for 1 week or as directed by a doctor
  - wash hands after each use
  - children under 12 years: ask a doctor
- 

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### ***Other information***

- store at 8°–25°C (46°–77°F)
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### ***Inactive ingredients***

cetomacrogol, ethanol, propylene glycol, purified water, USP

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**Questions? call 1-800-570-9611 call 24 hours a day 7 days a week**

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**C. CARTON LABEL**  
**athlete's foot, jock itch, and ringworm**  
**30 ml dropper**

**1. FRONT (principal display) PANEL (PDP)**

**NEW**  
**LAMISIL®AT™ (LOGO)**  
**SOLUTION**  
**Terbinafine Hydrochloride Solution 1%**  
**Antifungal**  
**CURES ATHLETE'S FOOT BETWEEN THE TOES\***  
**\*See back panel for Uses information**  
**For Effective Relief of:**  

- Itching
- Burning

**NET CONTENTS 30 ml (1 fl oz)**

**2. SIDE PANEL**

**LAMISIL®AT™ (LOGO) SOLUTION DROPPER**

**3. TOP FRONT PANEL**

**LAMISIL®AT™ (LOGO) SOLUTION DROPPER**

**4. SIDE PANEL**

**LAMISIL®AT™ (LOGO) SOLUTION DROPPER**  
**Lamisil®AT™ Solution Dropper Cures Athlete's Foot Between the Toes, Jock Itch,**  
**and Ringworm**  
**Non-aerosol Lamisil®AT™ Solution Dropper:**  

- Dries fast
- Not greasy

**5. BACK PANEL**

**LAMISIL®AT™ (LOGO)**  
**SOLUTION**  
**Terbinafine Hydrochloride Solution 1%**  
**Antifungal**

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## **Drug Facts**

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### **Active ingredient**

Terbinafine hydrochloride 1%.....

### **Purpose**

Antifungal

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### **Uses**

- cures athlete's foot (tinea pedis) between the toes. Effectiveness on the bottom or sides of foot is unknown
  - cures jock itch (tinea cruris), and ringworm (tinea corporis)
  - relieves itching, burning, cracking, and scaling which accompany these conditions
- 

### **Warnings**

#### **For external use only**

#### **Do not use**

- on nails or scalp
  - in or near the mouth or the eyes
  - for vaginal yeast infections
- 

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

---

Stop use and ask a doctor if too much irritation occurs or gets worse

---

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

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### **Directions**

- adults and children 12 years and older
    - wash the affected skin with soap and water and dry completely before applying
    - for athlete's foot between the toes apply twice a day (morning and night) for 1 week or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily. (Foot Diagram) 1 week between the toes
    - for jock itch and ringworm apply to affected area once a day (morning or night) for 1 week or as directed by a doctor
  - wash hands after each use
  - children under 12 years: ask a doctor
- 

### **Other information**

- store at 8°–25°C (46°–77°F)
- 

### **Inactive ingredients**

cetomacrogol, ethanol, propylene glycol, purified water, USP

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**Questions? call 1-800-570-9611 24 hours a day 7 days a week**

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Lot Number and Expiration Date

## G. CONSUMER EDUCATIONAL BROCHURE

athlete's foot, jock itch, and ringworm; 30 ml spray

Consumer Educational Brochure  
LAMISIL<sup>®</sup>AT<sup>™</sup> (LOGO) SPRAY PUMP

Terbinafine hydrochloride solution 1%  
Antifungal

### What is Lamisil<sup>AT</sup>™ Spray Pump solution?

Lamisil<sup>AT</sup>™ Spray Pump solution is a non-prescription treatment for athlete's foot (tinea pedis) between the toes, jock itch, (tinea cruris) and body ringworm (tinea corporis).

Lamisil<sup>AT</sup>™ Spray Pump solution contains terbinafine, which belongs to a class of antifungals once available only by prescription. It is now available to you without a prescription at full prescription strength.

Lamisil<sup>AT</sup>™ Spray Pump solution is a non-aerosol spray. The non-aerosol pump works upside down, so it is easy to spray those hard to reach places, in particular, between the toes.

Lamisil<sup>AT</sup>™ Spray Pump solution dries fast and is not greasy.

### What are athlete's foot, jock itch, and ringworm?

Each of these conditions is an infection of the outer layer of skin caused by fungus.

Athlete's foot can occur between the toes or on the bottom or sides of the foot. The symptoms of athlete's foot may include redness, painful cracking of the skin, an annoying itching, and/or a burning sensation. You may also see blisters. (This product has not been studied in patients with athlete's foot on the bottom or sides of the foot. This product is for athlete's foot between the toes.)

Jock itch occurs in the genital area and can spread to the top of your legs. The symptoms of jock itch may include chafing, itching, burning, and scaling and reddish, ring-shaped patches, which tends to form complete rings with raised borders.

Ringworm occurs on the skin of your face, body, arms, and/or legs. The symptoms of ringworm may include itching, scaling, and a red spreading rash which tends to form complete rings with raised borders and a clear center.

### Who can use Lamisil<sup>AT</sup>™ Spray Pump solution?

Adults and children ages 12 and over can use Lamisil<sup>AT</sup>™ Spray Pump solution. For children under 12 years of age, ask a doctor.



**Will I experience side effects while using Lamisil<sup>AT</sup>™ Spray Pump solution?**

Side effects are rare and are like the symptoms of the skin disease you are treating. If you experience an increase in the redness, itching, burning, blistering, swelling, or oozing of the skin, stop applying this product and see a doctor.

**How should I apply Lamisil<sup>AT</sup>™ Spray Pump solution?**

First, wash the infected area with soap and water and dry completely. Do not cover the treated skin with any bandages. Wash your hands with soap and water after touching the infected skin so that you do not spread the infection on yourself or to others.

For athlete's foot between the toes spray twice a day (morning and night) for 1 week or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.

(Foot Diagram) 1 week between the toes

For jock itch and ringworm spray the infected skin and surrounding area once a day (morning or night) for 1 week or as directed by a doctor.

**When will the symptoms disappear?**

Many get relief from their symptoms after the completion of 1 week of treatment. Spray as directed. Your skin may continue to show some of the signs of infection described above until the outer layer of the treated skin naturally replaces itself. Skin replacement takes longer on some parts of the body than others. If you do not see any improvement within 4 weeks for athlete's foot and within 2 weeks for jock itch and ringworm, you should see a doctor. (note: this statement should also be modified by the sponsor because it implies that this drug product could be used up to 4 weeks)

**Can I use Lamisil<sup>AT</sup>™ Spray Pump solution on any part of my body?**

Lamisil<sup>AT</sup>™ Spray Pump solution should not be used:

- on nails or scalp
- in or near the mouth or the eyes
- for vaginal yeast infections

**Can I give this skin infection to others?**

Yes. Fungal infections can be spread by the bathtub, shower, clothing, or towels. Regularly use a disinfecting cleaner for the tub or shower. Wash clothing and towels with detergent, bleach, and hot water to help reduce the spread of infection.

**Can I do anything to avoid getting another fungal skin infection?**

Yes. Athlete's foot, jock itch, and ringworm can be spread by direct contact with infected skin or objects such as towels, floors, or showers. Bathe or shower daily with warm water and soap. Be sure to dry completely, especially your feet, the areas between your toes, and your genital area. Do not use the same towel to dry infected and noninfected areas, and wash towels with detergent, bleach, and hot water. Wear clean cotton socks and clean underwear every day. If possible, do not wear the same pair of shoes every day.

If you have questions about Lamisil<sup>AT</sup>™ Spray Pump solution please call toll-free, 1-800-570-9611 weekdays 9 am - 5 pm eastern time

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## H. CONSUMER EDUCATIONAL BROCHURE

### jock itch

Consumer Educational Brochure  
LAMISIL<sup>AT</sup>™ (LOGO) SPRAY PUMP  
Terbinafine hydrochloride solution 1%  
Antifungal

#### What is Lamisil<sup>AT</sup>™ Spray Pump solution?

Lamisil<sup>AT</sup>™ Spray Pump solution is a non-prescription treatment for jock itch (tinea cruris)

Lamisil<sup>AT</sup>™ Spray Pump solution contains terbinafine, which belongs to a class of antifungals once available only by prescription. It is now available to you without a prescription at full prescription strength.

Lamisil<sup>AT</sup>™ Spray Pump solution is a non-aerosol spray. The non-aerosol pump works upside down, so it is easy to spray the affected area. Lamisil<sup>AT</sup>™ Spray Pump solution dries fast and is not greasy.

#### What is jock itch?

This condition is an infection of the outer layer of skin caused by fungus.

Jock itch occurs in the genital area and can spread to the top of your legs. The symptoms of jock itch may include chafing, itching, burning, and scaling and reddish, ring-shaped patches, which tends to form complete rings with raised borders.

#### Who can use Lamisil<sup>AT</sup>™ Spray Pump solution?

Adults and children ages 12 and over can use Lamisil<sup>AT</sup>™ Spray Pump solution. For children under 12 years of age, ask a doctor.

#### Will I experience side effects while using Lamisil<sup>AT</sup>™ Spray Pump solution?

Side effects are rare and are like the symptoms of the skin disease you are treating. If you experience an increase in the redness, itching, burning, blistering, swelling, or oozing of the skin, stop applying this product and see a doctor.

#### How should I apply Lamisil<sup>AT</sup>™ Spray Pump solution?

First, wash the infected area with soap and water and dry completely. Do not cover the treated skin with any bandages. Wash your hands with soap and water after touching the infected skin so that you do not spread the infection on yourself or to others.

**For jock itch** spray the infected skin and surrounding area once a day (morning or night) for 1 week or as directed by a doctor.

**When will the symptoms disappear?**

Many get relief from their symptoms after the completion of 1 week of treatment. Spray as directed. Your skin may continue to show some of the signs of infection described above until the outer layer of the treated skin naturally replaces itself. Skin replacement takes longer on some parts of the body than others. If you do not see any improvement within 2 weeks, you should see a doctor.

**Can I use Lamisil<sup>AT</sup> Spray Pump solution on any part of my body?**

Lamisil<sup>AT</sup> Spray Pump solution should not be used:

- on nails or scalp
- in or near the mouth or the eyes
- for vaginal yeast infections

**Can I give this skin infection to others?**

Yes. Fungal infections can be spread by the bathtub, shower, clothing, or towels. Regularly use a disinfecting cleaner for the tub or shower. Wash clothing and towels with detergent, bleach, and hot water to help reduce the spread of infection.

**Can I do anything to avoid getting another fungal skin infection?**

Yes. Jock itch can be spread by direct contact with infected skin or objects such as towels, floors, or showers. Bathe or shower daily with warm water and soap. Be sure to completely dry your genital area. Do not use the same towel to dry infected and noninfected areas, and wash towels with detergent, bleach, and hot water. Wear clean underwear every day.

If you have questions about Lamisil<sup>AT</sup> Spray Pump solution please call toll-free, 1-800-570-9611 weekdays 9 am - 5 pm eastern time

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