

Novartis Consumer Health, Inc.
 NDA 21-958

Confidential
 Jock Itch
 Product
 6g Tube

Lamisil® (terbinafine) DermGel™, 1% Gel

NDC XXXXX-XXXX-XX



LAMISIL^{AT} Gel
 TERBINAFINE GEL 1% - ANTIFUNGAL

CURES MOST JOCK ITCH

Relieves Itching & Burning

NET WT.
 6 g (.21 oz)

Drug Facts

Active ingredient	Purpose
Terbinafine 1%	Antifungal

Uses

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

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 the eyes. If eye contact occurs, rinse 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.

Directions

- adults and children 12 years and over
 - use the tip of the cap to break the seal and open the tube
 - wash the affected skin with soap and water and dry completely before applying
 - apply 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

- do not use if seal on tube is broken or is not visible
- store at or below 30°C (86°F)

Inactive ingredients: benzyl alcohol, butylated hydroxytoluene, carbomer 974 P, ethanol, isopropyl myristate, polysorbate 20, purified water, sodium hydroxide, sorbitan monolaurate

Questions? call 1-800-452-0051 24 hours a day, 7 days a week.

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Distributed by:
Novartis Consumer Health, Inc.
 Parsippany, NJ 07054-0622 ©2006 0000000
 Made in Germany

Lot No.
 Exp. Date



6g Tube - Enlarged 300%



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LAMISIL^{AT} Gel

TERBINAFINE GEL 1% - ANTIFUNGAL

NET WT. 6g (0.21 oz)

Store at or below 30°C (86°F)
See crimp for lot number and expiration date

Active Ingredient

Terbinafine 1%.....Antifungal

Uses

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Warnings

For external use only

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 - for vaginal yeast infections

When using this product do not get into eyes. If eye contact occurs, rinse 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.

Directions

- adults and children 12 years and older
- use the tip of the cap to break the seal and open the tube
- wash the affected skin with soap and water and dry completely before applying
- apply 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

Novartis Consumer Health, Inc.
NDA 21-958

Confidential
Athlete's Foot
Product
6g Pillow Pack

Lamisil® (terbinafine) DermGel™, 1% Gel 2

NDC XXXXX-XXXX-XX



LAMISIL^{AT} Gel
TERBINAFINE GEL 1% - ANTIFUNGAL

Advanced
THE ONLY 7 DOSE (ONCE A DAY)
TREATMENT FOR ATHLETE'S FOOT

CURES MOST ATHLETE'S FOOT BETWEEN THE TOES
Relieves Itching & Burning

NET WT.
6g (.21 oz)

Drug Facts

Active ingredient	Purpose
Terbinafine 1%	Antifungal

Uses

- cures most athlete's foot (tinea pedis) between the toes.
- Effectiveness on the bottom or sides of foot is unknown.
- cures most 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 the eyes. If eye contact occurs, rinse 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.

Directions

- adults and children 12 years and over
- use the tip of the cap to break the seal and open the tube
- wash the affected skin with soap and water and dry completely before applying
- **for athlete's foot between the toes:** apply once a day at bedtime for 1 week or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
- **for jock itch and ringworm:** apply 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



1 week between the toes

Other information

- do not use if seal on tube is broken or is not visible
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Made in Germany

Lot No.
Exp. Date

F.P.O.



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6g Tube - Enlarged 300%



<p>0000000</p> <p>Store at or below 30°C (86°F) See crimp for lot number and expiration date</p>	<p>Distributed by: Novartis Consumer Health, Inc. Parsippany, NJ 07054-0622 ©2006 Made in Germany</p>	<p style="text-align: center;">LAMISIL^{AT} Gel</p> <p style="text-align: center;">TERBINAFINE GEL 1% - ANTIFUNGAL</p> <p style="text-align: right;">NET WT. 6g (21.0g)</p> <p style="text-align: center; font-size: small;">THE ONLY 1 DOSE (ONCE A DAY) TREATMENT FOR ATHLETE'S FOOT</p>
<p>Active Ingredient Terbinafine 1%</p> <p>Uses</p> <ul style="list-style-type: none"> • cures most athlete's foot (tinea pedis) between the toes. Effectiveness on the bottom or sides of foot is unknown. • cures most jock itch (tinea cruris) and ringworm (tinea corporis) • relieves itching, burning, cracking, and scaling which accompany these conditions <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> • on nails or scalp • in or near the mouth or the eyes • for vaginal yeast infections <p>When using this product do not get into the eyes. If eye contact occurs, rinse thoroughly with water.</p>	<p>Purpose Antifungal</p> <p>Stop use and ask a doctor if too much irritation occurs or gets worse.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • adults and children 12 years and over • use the tip of the cap to break the seal and open the tube • wash the affected skin with soap and water and dry completely before applying • for athlete's foot between the toes: apply once a day at bedtime for 1 week or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily. • for jock itch and ringworm: apply 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 	

Novartis Consumer Health, Inc.
 NDA 21-958

Confidential
 Jock Itch
 Product
 12g Pillow Pack

Lamisil® (terbinafine) DermGel™, 1% Gel 11

XX-XXXX-XXXX-00N



**CURES MOST
 JOCK ITCH**



Relieves Itching & Burning

NET WT.
 12g (.42oz)

Drug Facts

Active ingredient	Purpose
Terbinafine 1%.....	Antifungal

Uses

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

Warnings

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Other information

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LAMISIL^{AT}® Gel

TERBINAFINE GEL 1% - ANTIFUNGAL

NET WT. 12g (42oz)

Active Ingredient

Terbinafine 1%.....Antifungal

Uses

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

Warnings

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Directions

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NDA 21-958

Confidential
Athlete's Foot
Product
12g Pillow Pack

Lamisil® (terbinafine) DermGel™, 1% Gel

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XX-XXXX-XXXX-00N

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TERBINAFINE GEL 1% - ANTIFUNGAL

Advanced

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Uses

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 Athlete's Foot
 Product

Lamisil® (terbinafine) Derm Gel™, 1% Gel

12g Tube - Enlarged 300%

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