CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

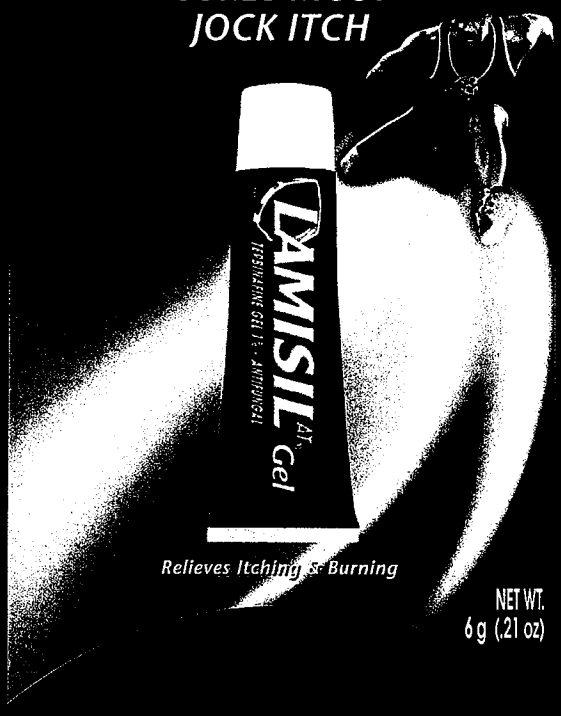
21-958

LABELING

NDC XXXX-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.

NOVARTIS

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Novartis Consumer Health, Inc.
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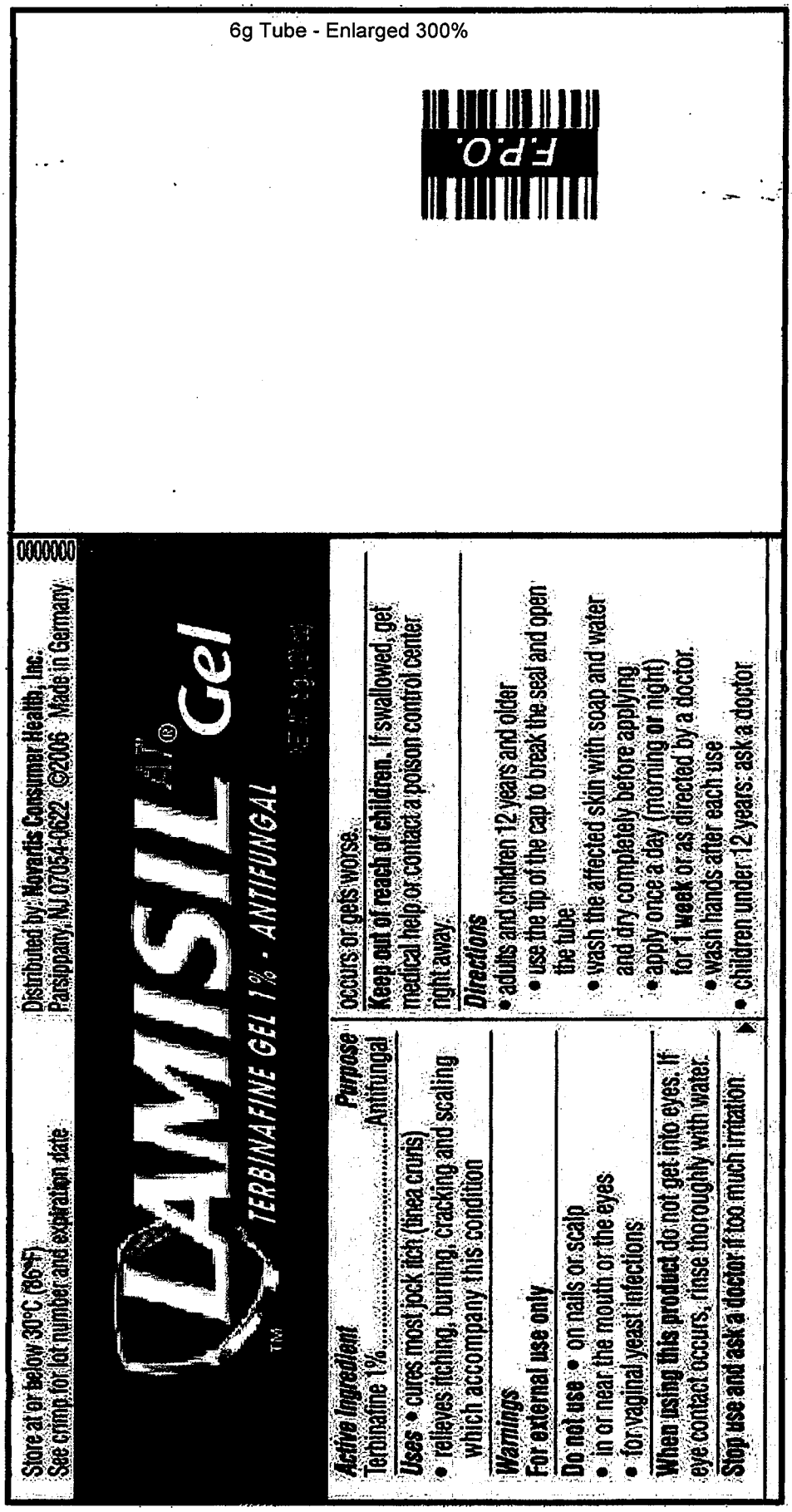
Made in Germany

Lot No.
Exp. Date

F.P.O.
0 0000-0000-00 0

6g Tube - Enlarged 300%

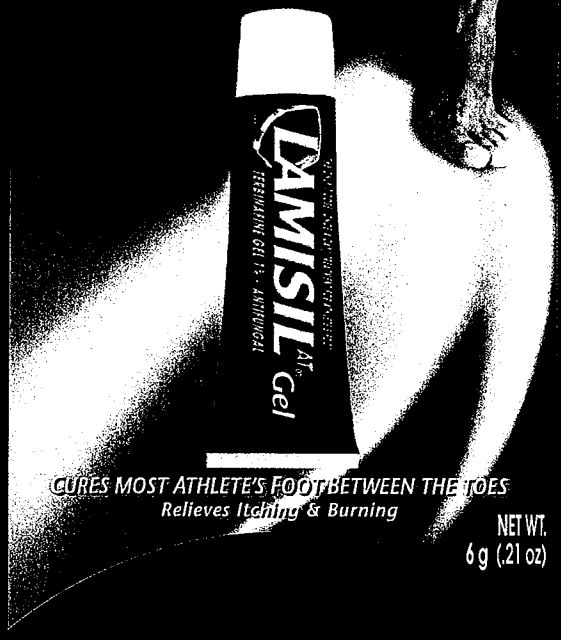


NDC XXXX-XXXX-XX

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.
6 g (.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
- store at or below 30°C (86°F)

Inactive ingredients: benzyl alcohol, butylated hydroxytoluene, carbomer 974 P, ethanol, isopropryl 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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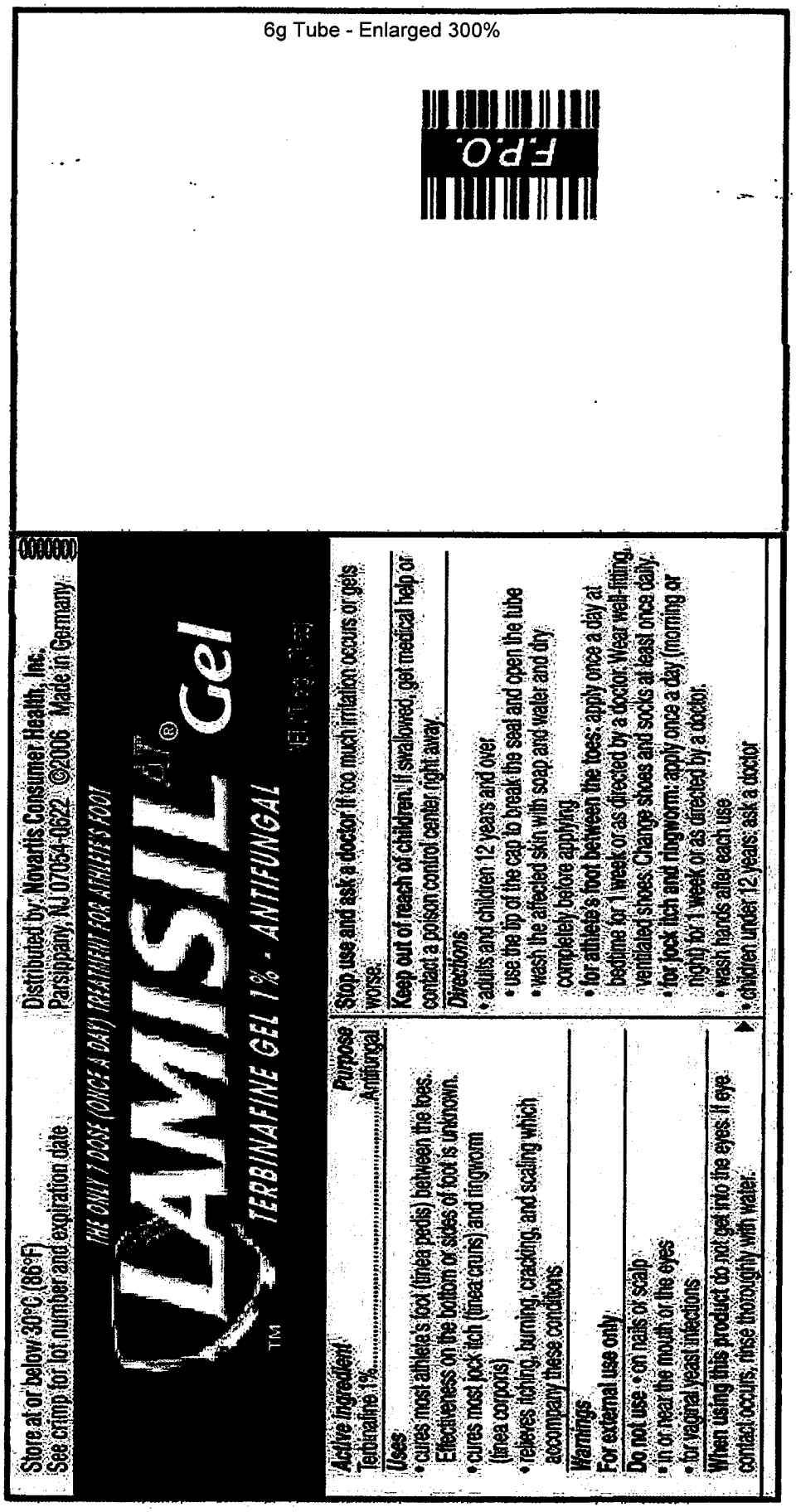
Exp. Date

F.P.O.
0 0000-0000-00 0

6g Tube - Enlarged 300%

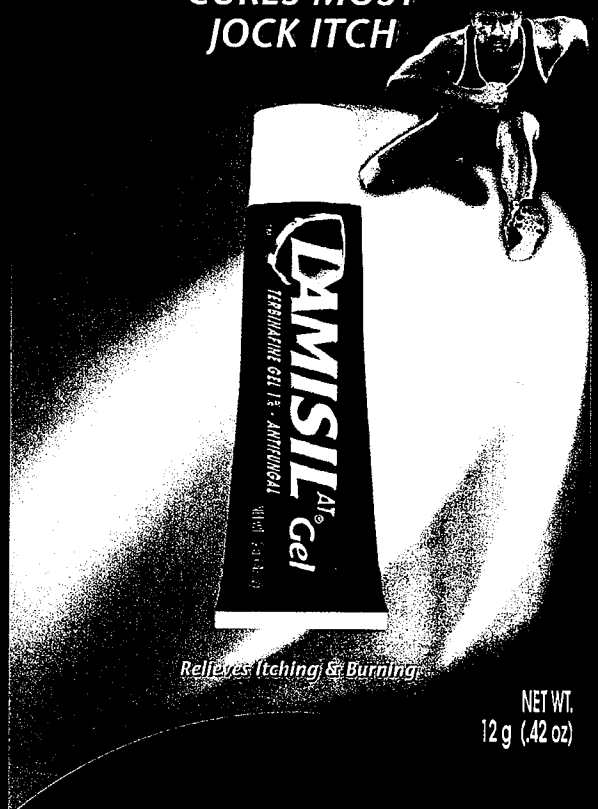


NDC XXXX-XXXX-XX

LAMISIL AT® Gel

TERBINAFINE GEL 1% • ANTIFUNGAL

CURES MOST JOCK ITCH



Relieves Itching & Burning

NET WT.
12 g (.42 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

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

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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 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
Jock Itch
Product
12g Tube - Enlarged 300%

Lamisil® (terbinafine) DermGel™ 1% Gel 13

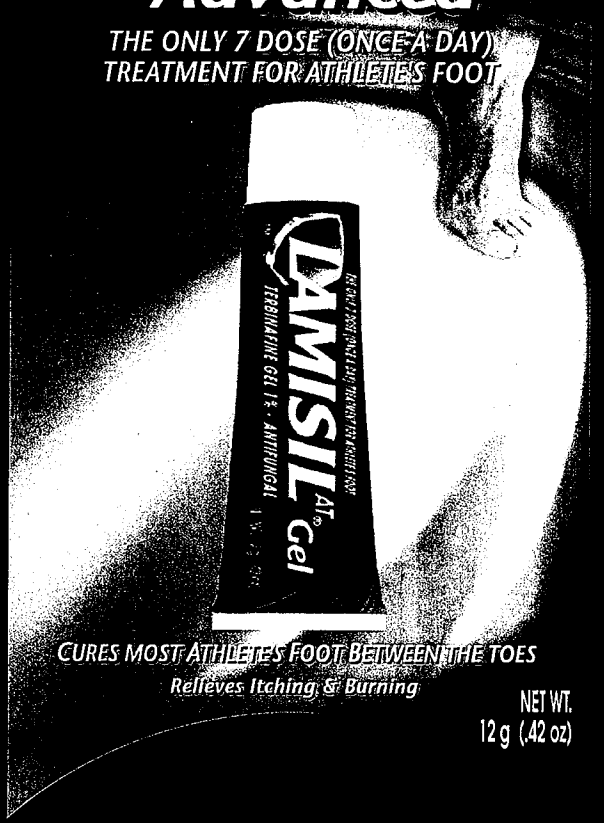
XX-XXXX-XXXX-XX

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.
12 g (.42 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
- store at or below 30°C (86°F)

Inactive ingredients: benzyl alcohol, butylated hydroxytoluene, carbomer 974 P, ethanol, isopropryl 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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THE ONLY 7 DOSE (ONCE A DAY) TREATMENT FOR ATHLETE'S FOOT

LAMISIL AT® Gel

TERBINAFINE GEL 1% - ANTIFUNGAL

TM

NET WT. 12 g (.42 oz)

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

Novartis Consumer Health, Inc.
NDA 21-958

Confidential
Athlete's Foot
Product
12g Tube - Enlarged 300%

Lamisil® (terbinafine) Dermgel™, 1% Gel 7