

LAMISIL AT CREAM- terbinafine hydrochloride cream
Voyant Beauty Inc.

Formula# 39900

Terbinafine hydrochloride 1%

Antifungal

Uses

- cure most jock itch (tinea cruris) and ringworm (tinea corporis)
- 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 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 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 wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
 - between the toes only: apply twice a day (morning and night) for 1 week or as directed by a doctor
 - on the bottom or sides of the foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor
 - 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

Other Information

- do not use if seal on tube is broken or is not visible
- store at controlled room temperature 20-25C (68-77F)

Inactive Ingredients

benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearly alcohol

Questions or comments?

call 1-800-330-9876

12 g Tube with Carton - For Jock Itch

Lamisil AT

Cream Terbinafine Hydrochloride Cream 1% - Antifungal

For JOCK ITCH

- cures most jock itch

- for effective relief of itching and burning

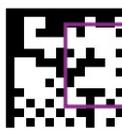
NET WT

12 g (0.42 oz)

Store at controlled room temperature 20-25°C (68-77°F)
See crimp for lot number and expiration date
Do not use if seal on tube is broken or is not visible

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 <p>LAMISIL^{AT} CREAM TERBINAFINE HYDROCHLORIDE CREAM 1% - ANTIFUNGAL FOR JOCK ITCH</p>	<p>NDC 0067-3999-42</p> <p>NET WT 12 g (0.42 oz)</p>
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<p>Active ingredient Terbinafine hydrochloride 1%.....</p>	<p>Purpose Antifungal</p>	<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
<p>Uses</p> <ul style="list-style-type: none"> • cures most jock itch (tinea cruris) • relieves itching, burning, cracking and scaling which accompany this condition 		<p>Directions</p> <ul style="list-style-type: none"> • adults and children 12 years and over: <ul style="list-style-type: none"> • 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
<p>Warnings For external use only</p> <p>Do not use • on nails or scalp • in or near the mouth or eyes • for vaginal yeast infections</p> <p>When using this product do not get into eyes. If eye contact occurs, rinse thoroughly with water.</p> <p>Stop use and ask a doctor if too much irritation occurs or gets worse ▶</p>		



12 g Tube with Carton - For Athlete's Foot
 Lamisil AT Cream
 Terbinafine Hydrochloride Cream 1% - Antifungal
 For Athlete's Foot
 Net Wt
 12 g (0.42 oz)

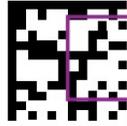
Store at controlled room temperature 20-25°C (68-77°F)
 See crimp for lot number and expiration date
 Do not use if seal on tube is broken or is not visible

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LAMISIL^{AT} CREAM

TERBINAFINE HYDROCHLORIDE CREAM 1% - ANTIFUNGAL
 FOR **ATHLETE'S FOOT**

NDC 0067-3998-42
NET WT 12 g (0.42 oz)

<p>Active ingredient Terbinafine hydrochloride 1%</p> <p>Purpose Antifungal</p> <p>Uses</p> <ul style="list-style-type: none"> • cures most athlete's foot (tinea pedis) • cures most jock itch (tinea cruris) and ringworm (tinea corporis) • relieves itching, burning, cracking and scaling which accompany these conditions <p>Warnings</p> <p>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 eyes • for vaginal yeast infections <p>When using this product do not get into eyes. If eye contact occurs, rinse thoroughly with water.</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: <ul style="list-style-type: none"> • 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 wear well-fitting, ventilated shoes. Change shoes and socks at least once daily. • between the toes only: apply twice a day (morning and night) for 1 week or as directed by a doctor • on the bottom or sides of the foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor • 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   
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Drug Facts

Active ingredient
Terbinafine hydrochloride 1%

Uses

- cures most athlete's foot (tinea pedis)
- 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 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 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 wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.

Apply the cream only:

- **between the toes only:** apply twice a day (morning and night) for **1 week** or as directed by a doctor
- **on the bottom or sides of the foot:** apply twice a day (morning and night) for **2 weeks** or as directed by a doctor
- **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

Other information

- do not use if seal on tube is broken or is not visible
- store at controlled room temperature 20-25°C (68-77°F)





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Drug Facts (continued)

Inactive ingredients
benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 80, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol

Questions or comments? call 1-800-330-9876

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LAMISIL^{AT} CREAM

TERBINAFINE HYDROCHLORIDE CREAM 1% - ANTIFUNGAL
 FOR **ATHLETE'S FOOT**

NET WT 12 g (0.42 oz)



LAMISIL^{AT} CREAM

TERBINAFINE HYDROCHLORIDE CREAM 1% - ANTIFUNGAL
 FOR **ATHLETE'S FOOT**

RELIEVES ITCHING
 CLINICALLY PROVEN TO CURE
 BETWEEN THE TOES
 FULL PRESCRIPTION STRENGTH



30 g Tube with Carton - For Athlete's Foot

Lamisil AT Cream

Terbinafine Hydrochloride Cream 1% - Antifungal

For Athlete's Foot

NET WT

30 g (1 oz)

Store at controlled room temperature 20-25°C (68-77°F)
See crimp for lot number and expiration date
Do not use if seal on tube is broken or is not visible

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NDC 0067-3998-30

LAMISIL^{AT} CREAM

TERBINAFINE HYDROCHLORIDE CREAM 1% - ANTIFUNGAL
FOR ATHLETE'S FOOT

NET WT
30 g (1 oz)

<p>Active ingredient Terbinafine hydrochloride 1%</p> <p>Uses</p> <ul style="list-style-type: none"> • cures most athlete's foot (tinea pedis) • cures most jock itch (tinea cruris) and ringworm (tinea corporis) • relieves itching, burning, cracking and scaling which accompany these conditions 	<p>Purpose Antifungal</p>	<p>Directions</p> <ul style="list-style-type: none"> • adults and children 12 years and over: <ul style="list-style-type: none"> • 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 wear well-fitting, ventilated shoes. Change shoes and socks at least once daily. • between the toes only: apply twice a day (morning and night) for 1 week or as directed by a doctor • on the bottom or sides of the foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor • 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
<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 eyes • for vaginal yeast infections <p>When using this product do not get into eyes. If eye contact occurs, rinse thoroughly with water.</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>1 week between the toes</p>  <p>2 weeks on the bottom or sides of the foot</p> 

LAMISIL AT CREAM
TERBINAFINE HYDROCHLORIDE CREAM 1% - ANTIFUNGAL
FOR ATHLETE'S FOOT

RELIEVES ITCHING
RELIEVES BURNING
RELIEVES PAIN TO
MOST ATHLETE'S FOOT
BETWEEN THE TOES
FULL PRESCRIPTION STRENGTH

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1-800-330-9876

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Drug Facts (continued)

- wash the affected skin with soap and water and dry completely before applying.
- Change shoes and socks at least once daily.
- between the toes only:** apply twice a day (morning and night) for 1 week or as directed by a doctor.
- on the bottom or sides of the foot:** apply twice a day (morning and night) for 2 weeks or as directed by a doctor.
- for jock itch and ringworm:** apply once daily 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 controlled room temperature 20-25 °C (68-77°F).

Inactive ingredients: benzyl alcohol, cetyl alcohol, cetyl palmitate, isopropyl myristate, polysorbate 60, purified water, sodium hydroxide, sorbitan monostearate, stearyl alcohol.

Questions or comments? call 1-800-330-9876

Drug Facts

Active ingredient
terbinafine hydrochloride 1%
Antifungal

Uses

- cures most athlete's foot (tinea pedis)
- 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 warts or scabs
- in or near the mouth or 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 over:
open the seal and use the cap to break the seal and open the tube.

1-800-330-9876

NET WT 30 g (1 oz)

LAMISIL AT CREAM

terbinafine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61047-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TERBINAFINE HYDRO CHLORIDE (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP)	TERBINAFINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61047-120-01	1 in 1 CARTON	02/24/2020	
1		12 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:61047-120-02	1 in 1 CARTON	03/02/2020	
2		12 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:61047-120-03	1 in 1 CARTON	02/20/2020	
3		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020980	02/20/2020	

Labeler - Voyant Beauty Inc. (243547333)

Establishment

Name	Address	ID/FEI	Business Operations
Voyant Beauty Inc.		243547333	manufacture(61047-120)

Revised: 12/2020

Voyant Beauty Inc.