

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**21-307**

**Final Printed Labeling**

# LOTRIMIN<sup>®</sup> Ultra<sup>™</sup>

23562-00

butenafine hydrochloride cream 1%

ANTIFUNGAL

**Active Ingredient**  
Butenafine hydrochloride 1%

**Purpose**  
Antifungal

**Net Wt** 12g (0.42 oz)

**Uses** • cures most athlete's foot between the toes, jock itch and ringworm  
• 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 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

• for athlete's foot between the toes: apply to affected skin between and around the toes twice a day for 1 week (morning and night), or once a day for 4 weeks, or as directed by a doctor.

• for jock itch and ringworm: apply once a day to affected skin for 2 weeks or as directed by a doctor.

• wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.

• wash hands after each use

• children under 12 years: ask a doctor

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**LOTRIMIN<sup>®</sup>ultra<sup>™</sup>** ANTIFUNGAL Net Wt 24g (0.85 oz)  
butenafine hydrochloride cream 1%

23564-00

**Active ingredient**  
Butenafine hydrochloride 1%.....**Purpose**  
Antifungal

**Uses**

- cures most athlete's foot between the toes, jock itch and ringworm
- 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 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
  - for athlete's foot between the toes: apply to affected skin between and around the toes twice a day for 1 week (morning and night), or once a day for 4 weeks, 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 to affected skin for 2 weeks or as directed by a doctor
- wash hands after each use
- children under 12 years: ask a doctor

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**LOTRIMIN<sup>®</sup> Ultra<sup>™</sup>** ANTIFUNGAL 23565-00

butenafine hydrochloride cream 1%

<b>Active ingredient</b>	<b>Purpose</b>	<b>Net Wt 12g (0.42 oz)</b>
Butenafine hydrochloride 1%	Antifungal	

**Uses**  
• cures most jock itch  
• relieves itching, burning, cracking, and scaling which accompany this condition

**Warnings**  
For external use only

**Do not use**  
• on sores 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 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 to affected skin for 2 weeks or as directed by a doctor  
• wash hands after each use  
• children under 12 years: ask a doctor

Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date.  
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**LOTRIMIN<sup>®</sup> Ultra<sup>™</sup>**  
butenafine hydrochloride cream 1% ANTIFUNGAL

29562-00

Net Wt 15g (0.53 oz)

**Active Ingredient** Butenafine hydrochloride 1% **Purpose** Antifungal

**Uses** • cures most athlete's foot between the toes, jock itch and ringworm  
• 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 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

• for athlete's foot between the toes: apply to affected skin between and around the toes twice a day for 1 week (morning and night), or once a day for 4 weeks, 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 to affected skin for 2 weeks or as directed by a doctor

• wash hands after each use

• children under 12 years: ask a doctor

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**NEW!**  
**DIFFERENT INGREDIENT**

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

- Relieves Itching and Burning
- Full Prescription Strength

**LOTRIMIN**<sup>ultra</sup>

butenafine hydrochloride cream 1%  
ANTIFUNGAL

**LOTRIMIN**<sup>ultra</sup>

butenafine hydrochloride cream 1%  
ANTIFUNGAL

Net Wt 15g (0.53 oz)



3 11017-239-43 8



visit us at www.lotrimin.com

butenafine hydrochloride cream 1%  
ANTIFUNGAL

**LOTRIMIN**<sup>ultra</sup>

LOTRIMIN

**Drug Facts**

**Active ingredient**  
butenafine hydrochloride cream 1%

**Purpose**  
Antifungal

**Uses**  
• To relieve itching and burning between the toes.  
• To treat athlete's foot between the toes.

**Warnings**  
• For external use only.  
• Do not use if you are allergic to butenafine hydrochloride or any of the other ingredients.  
• Stop use and ask a doctor if you experience a severe allergic reaction, such as hives, itching, difficulty breathing, or swelling of the face, lips, or tongue.

**Directions**  
• Apply between the toes.  
• Rub gently.  
• Use twice a day, once in the morning and once in the evening.  
• For best results, use Lotrimin Ultra for 2 weeks.

**Other information**  
• Lotrimin Ultra is a prescription strength antifungal cream.  
• Lotrimin Ultra is not for use on the face or scalp.

**Inactive ingredients**  
• Polyethylene glycol 400, polyethylene glycol 100, polyethylene glycol 150, polyethylene glycol 200, polyethylene glycol 300, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 3000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000.



**NEW!**  
**DIFFERENT INGREDIENT**

**CURES MOST  
JOCK ITCH**

- **Relieves Itching,  
Burning and  
Chafing**
- **Full Prescription  
Strength**

**LOTRIMIN**

butenafine hydrochloride cream 1%  
ANTIFUNGAL

**LOTRIMIN**

butenafine hydrochloride cream 1%  
ANTIFUNGAL

Net Wt 15g (0.53 oz)



3 11017-242-41 4



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butenafine hydrochloride cream 1%  
ANTIFUNGAL  
**LOTRIMIN**

LOTRIMIN

<b>Drug Facts</b>
<b>Active ingredient</b>
<b>Purpose</b>
<b>Uses</b>
<b>Warnings</b>
<b>Directions</b>
<b>Other information</b>
<b>Inactive ingredients</b>

**LOTRIMIN**  
butenafine hydrochloride cream 1%

# LOTRIMIN<sup>®</sup> Ultra<sup>™</sup>

33269-00

butenafine hydrochloride cream 1% ANTIFUNGAL

Net Wt 15g (0.53 oz)

<i>Active ingredient</i> Butenafine hydrochloride 1%.....	<i>Purpose</i> Antifungal
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**Uses**

- cures most jock itch
- 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 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 to affected skin for 2 weeks or as directed by a doctor
- wash hands after each use
- children under 12 years: ask a doctor

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# LOTRIMIN Ultra

butenafine hydrochloride cream 1%

## Drug Facts

### Active ingredient

Butenafine hydrochloride 1%

### Purpose

Antifungal

### Uses

- cures most athlete's foot between the toes. It has been used on the bottom or sides of feet if that is unknown.
- cures most jock itch and ringworm.
- relieves itching, burning, stinging, and soiling 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 it to the eyes. If you get it to your eyes, wash thoroughly with water.

Stop use and ask a doctor if the itching and burning does not go away.

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

### Directions

- adults and children 12 years and older
- use the tip of the tip 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 to the top of the foot and around the heel to extend for 1 week. For itching and redness on the body for 4 weeks or as directed by a doctor. For ringworm, apply to the patches. Change shoes and socks at least once daily.
- for jock itch and ringworm: apply once a day to the affected area for 2 weeks or as directed by a doctor.
- wash hands after each use.
- children under 12 years: ask a doctor.

Apply between and around the toes



1 week twice a day or 4 weeks once a day

### Other information

- contains alcohol, parabens, and other chemicals.
- store at 59° - 82°F (15° - 28°F).

### Inactive ingredients

benzyl alcohol, carbomer, cetanol, dibutyltin dilaurate, glycerol monostearate SE, polyoxyethylene 25 castor oil prepolymer, polyoxyethylene 40 stearate, polyoxyethylene 6 stearate, polyoxyethylene 12 stearate.

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# LOTRIMIN Ultra

butenafine hydrochloride cream 1%

ANTIFUNGAL

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3 11017-236-66 6

Net Wt 3.0g (1.1 oz)

ANTIFUNGAL

butenafine hydrochloride cream 1%

# LOTRIMIN Ultra

ANTIFUNGAL

butenafine hydrochloride cream 1%

# LOTRIMIN Ultra



CURES MOST  
ATHLETE'S FOOT  
BETWEEN  
THE TOES  
Relieves itching  
and burning  
- Full Prescription  
Strength

NEW!  
DIFFERENT INGREDIENT

**LOTRIMIN<sup>®</sup> Ultra<sup>™</sup>** ANTIFUNGAL  
butenafine hydrochloride cream 1%

29560-00

Net Wt 30g (1.1 oz)

<i>Active ingredient</i>	<i>Purpose</i>
Butenafine hydrochloride 1%	Antifungal

**Uses**

- cures most athlete's foot between the toes, jock itch and ringworm
- 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.

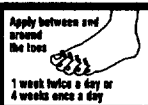
**Directions**

- adults and children 12 years and 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
- for athlete's foot between the toes: apply to affected skin between and around the toes twice a day for 1 week (morning and night), or once a day for 4 weeks, 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 to affected skin for 2 weeks or as directed by a doctor
- wash hands after each use
- children under 12 years: ask a doctor

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**LOTRIMIN Ultra**  
butenafine hydrochloride cream 1%

<b>Drug Facts</b>	
<b>Active ingredient</b> Butenafine hydrochloride 1%	<b>Purpose</b> Antifungal
<b>Uses</b>	
● cures most athlete's foot between the toes. Effectiveness on the bottom or sides of the feet is less sure.	
● cures most jock itch and ringworm	
● relieves itching, burning, cracking, and peeling of the secondary effects of conditions.	
<b>Warnings</b>	
For external use only	
Do not use ● on balls or scalp ● in or near the eyes or the eyes ● on cuts, abrasions, or blisters	
When using this product do not get into the eyes. If you do enter your eyes, rinse thoroughly with water.	
Stop use and ask a doctor if the rash that it treats becomes worse or spreads.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
● adults and children 12 years and older	 Apply between and around the toes 1 week twice a day or 4 weeks once a day
● 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 to all affected areas between and around the toes twice a day for 1 week (morning and night) or once a day for 4 weeks (once created by a doctor). Wear all fitting, breathable shoes. Do any shoes and socks that have holes.	
● for jock itch and ringworm: apply once a day to affected skin for 2 weeks or once a day for 4 weeks.	
● wash hands after each use	
● If rash does not clear, ask a doctor	
<b>Other information</b>	
● do not use if any of the following apply: ● if you are pregnant ● if you are breastfeeding ● if you are taking any other medicine	
<b>Inactive ingredients</b>	
Benzyl alcohol, cetyl alcohol, dimethyl sulfoxide, glycerin, hydroxyacetone, polyethylene glycol, polyethylene glycol 400, polyethylene glycol 600, propylene glycol, sorbitol, purified water, sodium lauryl sulfate, sodium hydroxide, and titanium dioxide.	

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**LOTRIMIN Ultra**  
butenafine hydrochloride cream 1%  
ANTIFUNGAL

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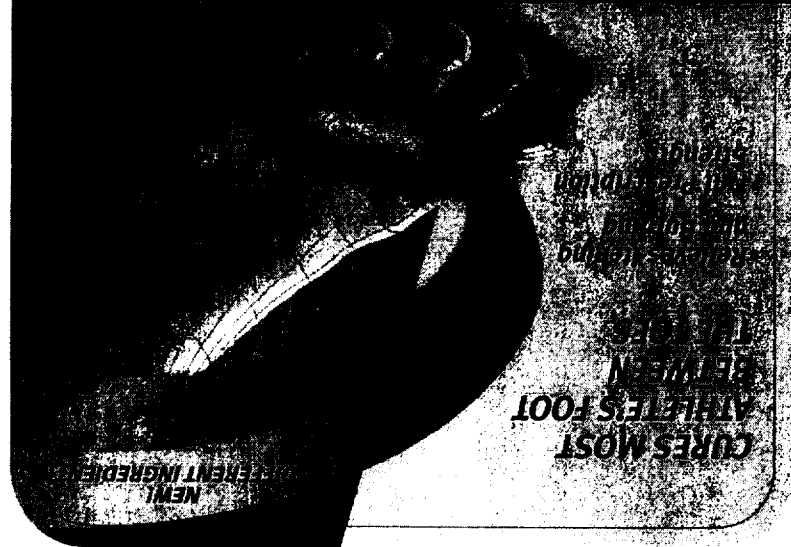


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Net Wt 1.2g (0.42 oz)

**LOTRIMIN Ultra**  
butenafine hydrochloride cream 1%  
ANTIFUNGAL

**LOTRIMIN Ultra**  
butenafine hydrochloride cream 1%  
ANTIFUNGAL



**CURES MOST  
ATHLETE'S FOOT**



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