LOTRIMIN® *ultra*™

23562-00

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 12g (0.42 oz)

Active ingredient ***Purpose***
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

Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date
Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. Made in U.S.A.

LOTRIMIN® *ultra*™

butenafine hydrochloride cream 1%

23564-00

ANTIFUNGAL Net Wt 24g (0.85 oz)

Active ingredient	***Purpose***
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.

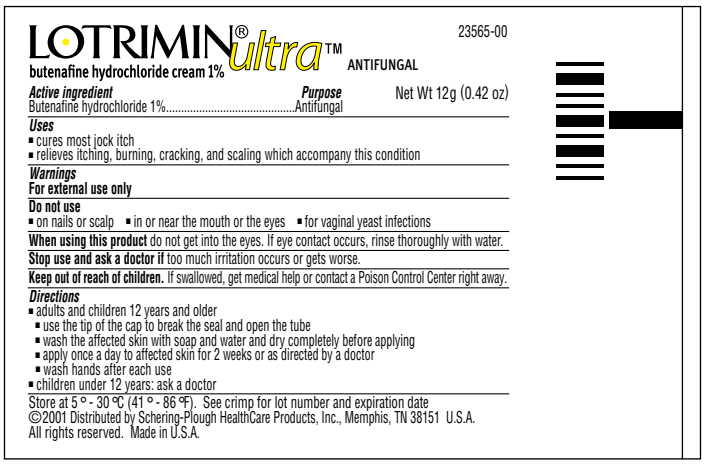
Stop use and ask a doctor if too much irritation occurs or gets worse.

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

Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date


LOTRIMIN® ultra™
23565-00
butenafine hydrochloride cream 1%
ANTIFUNGAL
Active ingredient
Purpose
Butenafine hydrochloride 1%
Antifungal
Net Wt 12g (0.42 oz)
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.
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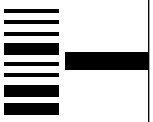
▪ wash hands after each use
▪ children under 12 years: ask a doctor
Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date
©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A.
All rights reserved. Made in U.S.A.

LOTRIMIN® *ultra*™ ANTIFUNGAL

butenafine hydrochloride cream 1%

29562-00

Net Wt 15g (0.53 oz)



Active ingredient ***Purpose***
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

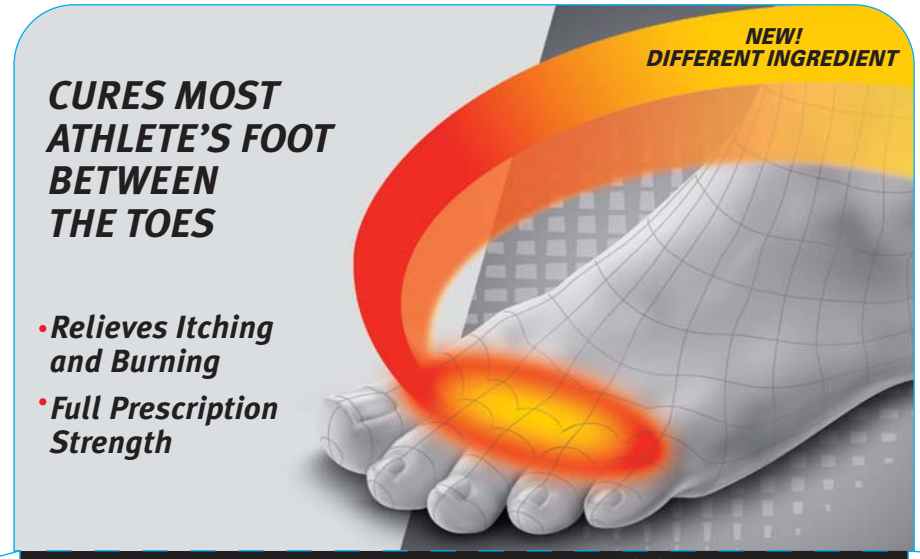
When using this product do not get into the eyes. If eye contact occurs, rinse thoroughly with water.

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

Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date



LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 15g (0.53 oz)

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Visit us at www.lotrimin.com

recyclable carton

3 11017-239-43 8

Drug Facts

Active ingredient — **Purpose**

Butenafine hydrochloride 1% ..... Antifungal

Uses

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
- cures most 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

Other information

- store at 5° - 30°C (41° - 86°F)
- do not use if seal on tube is broken or is not visible

Inactive ingredients

benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

 29559-00

LOTRIMIN® ultra™

www.lotrimin.com

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%

Drug Facts

Active ingredient	**Purpose**
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 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 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.

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 to affected skin for 2 weeks 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 5° - 30°C (41° - 86°F)

Inactive ingredients
benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

Visit us at www.lotrimin.com

 33267-00

www.lotrimin.com

LOTRIMIN® ultra™

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL

visit us at www.lotrimin.com

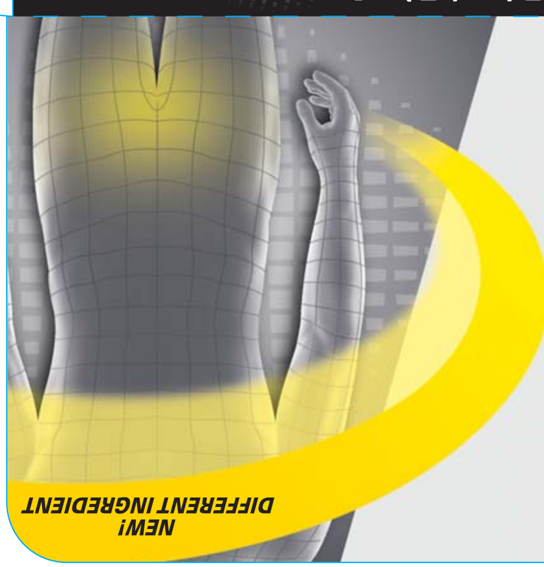
recyclable carton

3 11017-242-41 4

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL

Net Wt 15g (0.53 oz)

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL



NEW!
DIFFERENT INGREDIENT

CURES MOST JOCK ITCH

- Relieves Itching, Burning and Chafing
- Full Prescription Strength

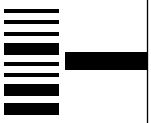
LOTRIMIN® *ultra*™

butenafine hydrochloride cream 1%

ANTIFUNGAL

33269-00

Net Wt 15g (0.53 oz)



Active ingredient ***Purpose***
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 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

Store at 5°- 30°C (41°- 86°F). See crimp for lot number and expiration date

NEW!
DIFFERENT INGREDIENT

CURES MOST ATHLETE'S FOOT BETWEEN THE TOES

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

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 30g (1.1 oz)

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Visit us at www.lotrimin.com

recyclable carton

3 11017-236-66 6

Drug Facts

Active ingredient — **Purpose**

Butenafine hydrochloride 1% ..... Antifungal

Uses

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
- cures most 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
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- **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

Other information

- do not use if seal on tube is broken or is not visible
- store at 5° - 30°C (41° - 86°F)

Inactive ingredients

benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

 29561-00

LOTRIMIN® ultra™

www.lotrimin.com

29560-00

LOTRIMIN® *ultra*™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 30g (1.1 oz)

Active ingredient ***Purpose***
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
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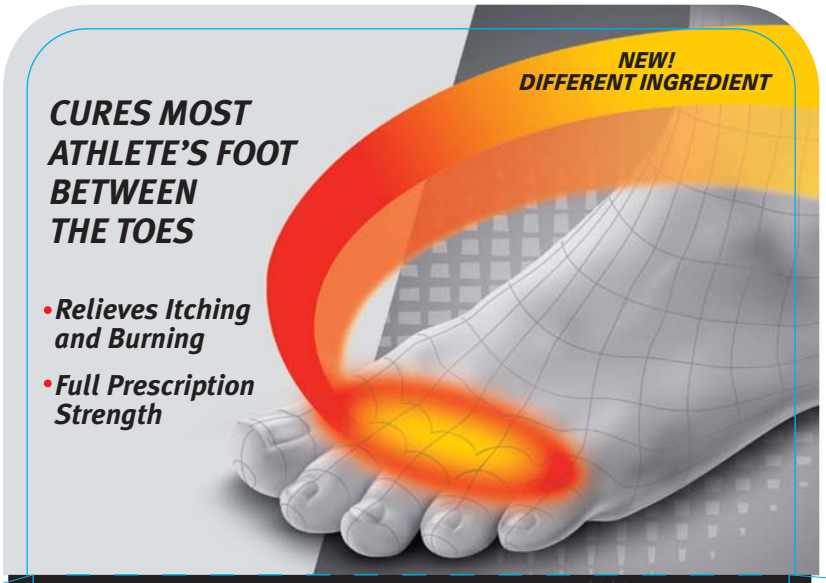
  - wash hands after each use
- children under 12 years: ask a doctor

Store at 5°- 30°C (41°- 86°F). See crimp for lot number and expiration date Made in U.S.A.



LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 12g (0.42 oz)

Visit us at www.lotrimin.com

recyclable carton

3 11017-235-23 2

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

Drug Facts

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

Uses

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

Warnings

For external use only

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- wash hands after each use
- children under 12 years: ask a doctor

Other information

- store at 5° - 30°C (41° - 86°F)
- do not use if seal on tube is broken or is not visible

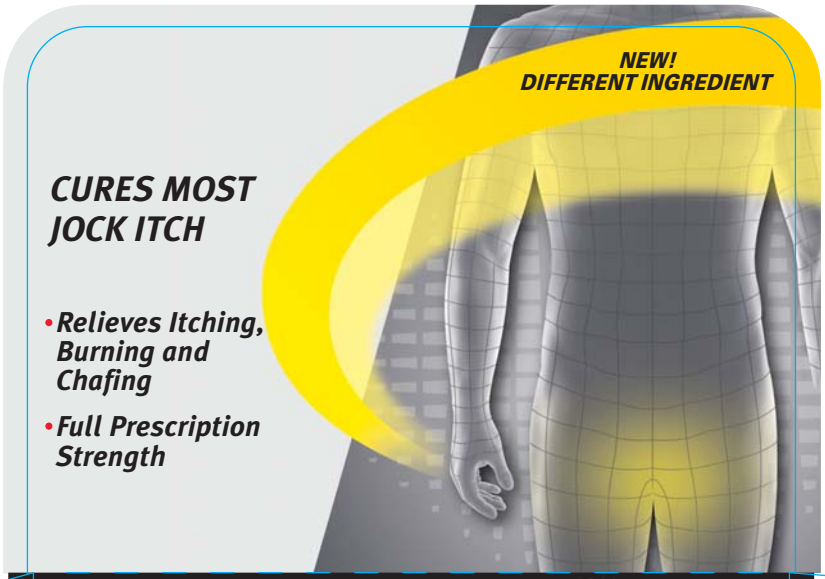
Inactive ingredients

benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

Visit us at www.lotrimin.com 23773-00

LOTRIMIN® ultra™

www.lotrimin.com



LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

ID BAR CODE

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 12g (0.42 oz)

Visit us at www.lotrimin.com

recyclable carton

3 11017-235-32 4

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Visit us at www.lotrimin.com

23778-00

LOTRIMIN® ultra™

www.lotrimin.com

Drug Facts

Active ingredient — **Purpose**

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 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 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.

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 to affected skin for 2 weeks 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 5° - 30°C (41° - 86°F)

Inactive ingredients

benzyl alcohol, cetyl alcohol, diethanolamine, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%

Drug Facts

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

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- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
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  - 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 5° - 30°C (41° - 86°F)

Inactive ingredients
benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

Visit us at www.lotrimin.com

23775-00

www.lotrimin.com

LOTRIMIN® ultra™

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL
visit us at www.lotrimin.com

recyclable carton

3 11017-235-25 6

Net Wt 24g (0.85 oz)

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL

CURES MOST ATHLETE'S FOOT BETWEEN THE TOES

- Relieves Itching and Burning
- Full Prescription Strength

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Division of Dermatologic and Dental Drug Products

Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: December 7, 2001 Number of Pages (including cover sheet) – 18

TO: Mary E. Williams, Associate Director, Regulatory Affairs
COMPANY: Schering-Plough HealthCare Products
FAX #: 908-679-1741

MESSAGE: Attached to this facsimile transmission, please find a copy of our Action Letter for your NDA 21-307, Lotrimin Ultra butenafine HCl cream, 1%.

Thank you.

FROM: Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer
PHONE #: 301-827-2063
FAX #: 301-827-2075/2091

and

FROM: Daniel P. Keravich, R.Ph., M.B.A., Regulatory Project Manager
PHONE #: 301-827-2248
FAX #: 301-827-2316

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-307

Schering-Plough HealthCare Products
Attention: Mary E. Williams,
Associate Director, Regulatory Affairs
Three Connell Drive
P.O. Box 603
Berkeley Heights, New Jersey 07922-0603

Dear Ms. Williams:

Please refer to your new drug application (NDA) dated September 28, 2000, received September 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for butenafine hydrochloride cream, 1%.

Please also refer to our Approvable Letter for Lotrimin Ultra butenafine hydrochloride cream 1% dated July 27, 2001.

We acknowledge receipt of your submissions dated October 5, November 5, and December 3 and 7 (facsimile), 2001.

This new drug application provides for the use without prescription of Lotrimin Ultra butenafine hydrochloride cream 1%, for the topical treatment of the following superficial dermatophytoses: interdigital tinea pedis (athlete's foot), tinea corporis (ringworm) and tinea cruris (jock itch) due to *E. floccosum, T. mentagrophytes, T. rubrum,* and *T. tonsurans*.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels) and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

We note that copies of final printed labeling (FPL) have been submitted on October 5, 2001.

We remind you of your postmarketing study commitments in your submissions dated July 25, December 3 and 7 (facsimile), 2001. These commitments are listed below.

1. Conduct a study to test consumers= ability to differentiate the Lotrimin AF labeling from the Lotrimin Ultra labeling in terms of distinguishing the different active ingredients

   Protocol Submission: Within 1 month of the date of this letter submit the protocol for Agency review and approval.

   Study Start: Within 3 months of the date of this letter initiate the study.

   Final Report Submission: Within 6 months of the date of this letter submit the final report.

2. Conduct a study to evaluate the safety of this drug for tinea corporis in the 2 - 12 year old pediatric population. This study should include pharmacokinetic sampling (systemic absorption data under maximal use conditions) and a comprehensive evaluation of local intolerance. Any additional information regarding local effects in children may be submitted, if available.

   Protocol Submission: Within 3 months of the date of this letter submit the protocol for Agency review and approval and any additional information regarding local effects in children.

   Study Start: Within 6 months of the date of this letter initiate the study.

   Final Report Submission: Within 16 months of the date of this letter submit the final report.

3. Conduct a study to evaluate the efficacy of this drug for tinea corporis in the 2 - 12 year old pediatric population, especially since the dermatophyte species responsible may vary from adults. Alternatively, information may be submitted that demonstrates that the dermatophyte species responsible for tinea corporis in the 2 - 12 year old pediatric population does not vary from adults. If this information is demonstrated, the need for an efficacy study could be waived.

   Protocol Submission: Within 3 months of the date of this letter submit the protocol and alternative information for Agency review and approval.

   Study Start: Within 9 months of the date of this letter initiate the study, if the FDA concludes that the alternative information is not convincing.

   Final Report Submission: Within 19 months of the date of this letter submit the final report.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study.

All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled '**Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). Because of the low prevalence of tinea cruris and tinea pedis in the 12 year old and under pediatric population these indications would be difficult to study and are waived. Additionally, because of the low prevalence of tinea corporis in the 2 year old and under pediatric population this indication would be difficult to study and is waived. We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27) for pediatric studies in pediatric patients aged 2 – 12 years old for tinea corporis. We are deferring submission of these pediatric studies until April 7, 2003, for the pediatric safety study and July 7, 2003, for the pediatric efficacy study. We note your submission of a protocol to study tinea corporis in the 2 – 12 year old pediatric population.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

In addition, please submit two copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Dermatologic & Dental Drug Products, one to the Division of Over-the-Counter Drug Products. For administrative purposes, this submission should be sent to the NDA and should be identified as a correspondence to approved NDA 21-307.
Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, please contact Daniel Keravich, Regulatory Health Project Manager, at (301) 827-2222.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Charles Ganley
12/7/01 03:53:09 PM

Jonathan Wilkin
12/7/01 04:04:16 PM

LOTRIMIN® *ultra*™

23562-00

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 12g (0.42 oz)

Active ingredient ***Purpose***
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

Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date
Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. Made in U.S.A.

LOTRIMIN® *ultra*™

butenafine hydrochloride cream 1%

23564-00

ANTIFUNGAL Net Wt 24g (0.85 oz)

Active ingredient	***Purpose***
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.

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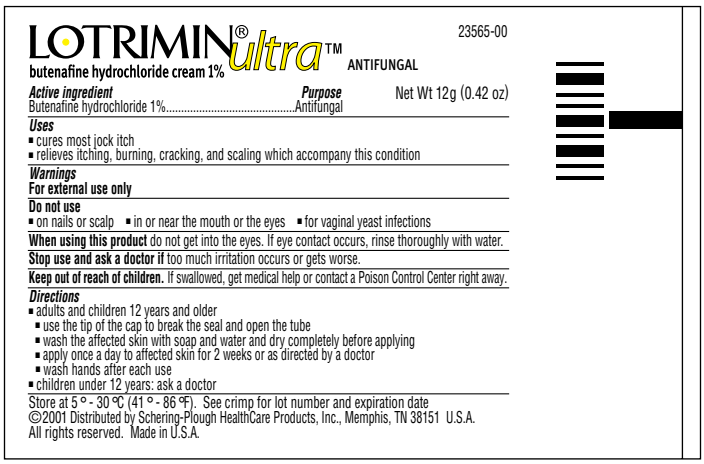
  - wash hands after each use
- children under 12 years: ask a doctor

Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date


LOTRIMIN® ultra™
23565-00
butenafine hydrochloride cream 1%
ANTIFUNGAL
Active ingredient
Purpose
Butenafine hydrochloride 1%
Antifungal
Net Wt 12g (0.42 oz)
Uses
▪ cures most jock itch
▪ relieves itching, burning, cracking, and scaling which accompany this condition
Warnings
For external use only
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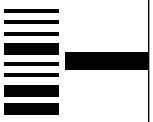
Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date
©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A.
All rights reserved. Made in U.S.A.

LOTRIMIN® *ultra*™ ANTIFUNGAL

butenafine hydrochloride cream 1%

29562-00

Net Wt 15g (0.53 oz)



Active ingredient ***Purpose***
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
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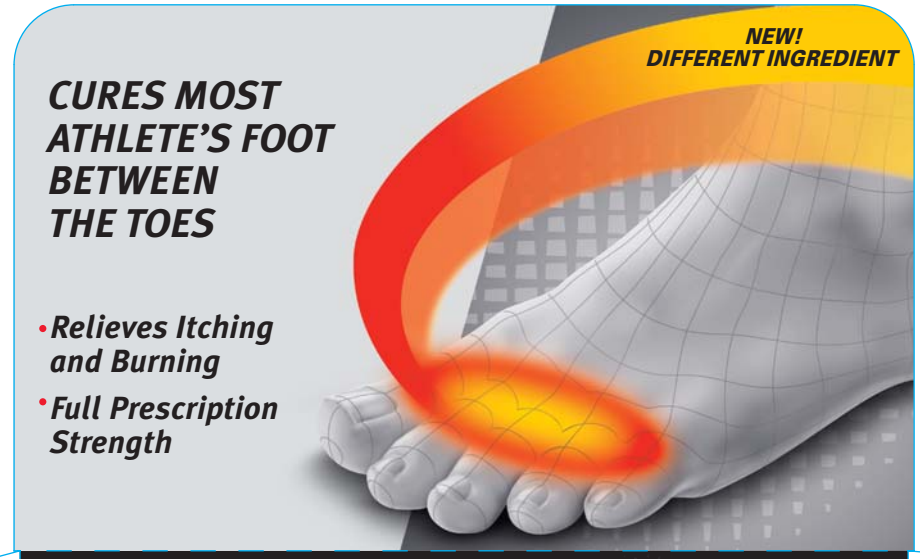
  - wash hands after each use
- children under 12 years: ask a doctor

Store at 5° - 30°C (41° - 86°F). See crimp for lot number and expiration date



LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 15g (0.53 oz)

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Visit us at www.lotrimin.com

recyclable carton

3 11017-239-43 8

Drug Facts

Active ingredient — **Purpose**

Butenafine hydrochloride 1% ..... Antifungal

Uses

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
- cures most 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

Other information

- store at 5° - 30°C (41° - 86°F)
- do not use if seal on tube is broken or is not visible

Inactive ingredients

benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

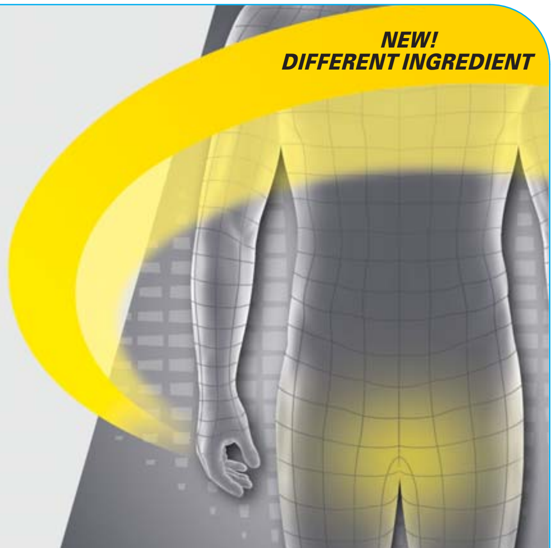
 29559-00

LOTRIMIN® ultra™

www.lotrimin.com

CURES MOST JOCK ITCH

- Relieves Itching, Burning and Chafing
- Full Prescription Strength



LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL
Net Wt 15g (0.53 oz)

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL
visit us at www.lotrimin.com
recyclable carton
3 11017-242-41 4

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%

Drug Facts

Active ingredient	Purpose
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 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 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.

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 to affected skin for 2 weeks 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 5° - 30°C (41° - 86°F)

Inactive ingredients
benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

Visit us at www.lotrimin.com

 33267-00

www.lotrimin.com

LOTRIMIN® ultra™

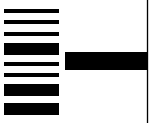
LOTRIMIN® *ultra*™

butenafine hydrochloride cream 1%

ANTIFUNGAL

33269-00

Net Wt 15g (0.53 oz)



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

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

Warnings
For external use only

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  - 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

NEW!
DIFFERENT INGREDIENT

CURES MOST ATHLETE'S FOOT BETWEEN THE TOES

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

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 30g (1.1 oz)

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Visit us at www.lotrimin.com

recyclable carton

3 11017-236-66 6

Drug Facts

Active ingredient — **Purpose**

Butenafine hydrochloride 1% ..... Antifungal

Uses

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
- cures most 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

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Directions

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- **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

Other information

- do not use if seal on tube is broken or is not visible
- store at 5° - 30°C (41° - 86°F)

Inactive ingredients

benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

 29561-00

LOTRIMIN® ultra™

www.lotrimin.com

29560-00

LOTRIMIN® *ultra*™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 30g (1.1 oz)

Active ingredient ***Purpose***
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.

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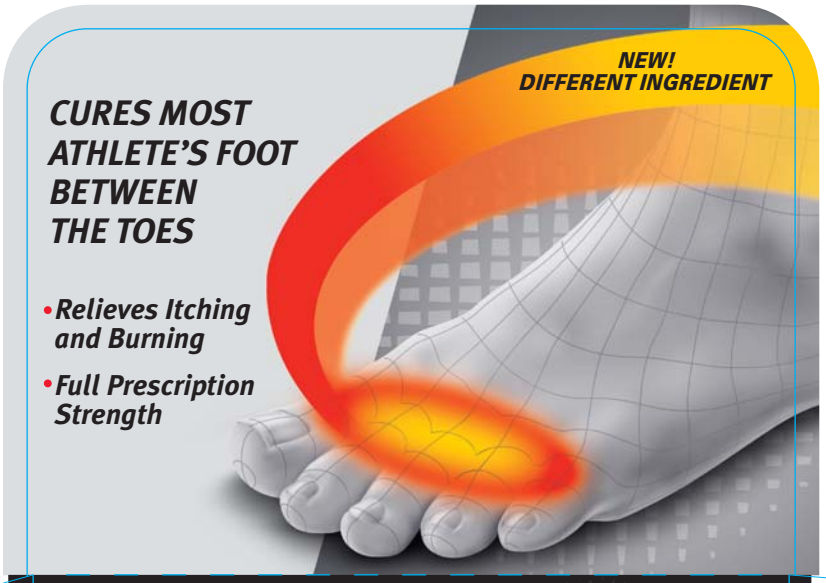
Store at 5°- 30°C (41°- 86°F). See crimp for lot number and expiration date Made in U.S.A.



LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 12g (0.42 oz)

Visit us at www.lotrimin.com

recyclable carton

3 11017-235-23 2

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

Drug Facts

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

Uses

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
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Inactive ingredients

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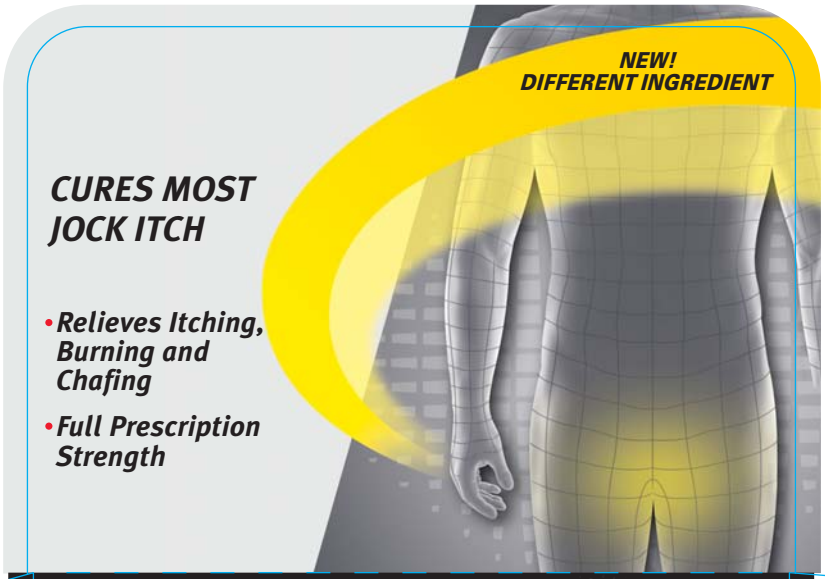
Visit us at www.lotrimin.com 23773-00

LOTRIMIN® ultra™

www.lotrimin.com



LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

ID BAR CODE

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Net Wt 12g (0.42 oz)

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recyclable carton

3 11017-235-32 4

LOTRIMIN® ultra™

butenafine hydrochloride cream 1%

ANTIFUNGAL

Visit us at www.lotrimin.com

23778-00

LOTRIMIN® ultra™

www.lotrimin.com

Drug Facts

Active ingredient — **Purpose**

Butenafine hydrochloride 1% ..... Antifungal

Uses

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

Warnings

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LOTRIMIN® ultra™
butenafine hydrochloride cream 1%

Drug Facts

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Visit us at www.lotrimin.com

23775-00

www.lotrimin.com

LOTRIMIN® ultra™

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL
visit us at www.lotrimin.com

recyclable carton

3 11017-235-25 6

Net Wt 24g (0.85 oz)

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL

LOTRIMIN® ultra™
butenafine hydrochloride cream 1%
ANTIFUNGAL

CURES MOST ATHLETE'S FOOT BETWEEN THE TOES

- Relieves Itching and Burning
- Full Prescription Strength

********** -COMM. JOURNAL- ********** DATE DEC-07-2001 ***** TIME 16:46 ********

MODE = MEMORY TRANSMISSION START=DEC-07 16:38 END=DEC-07 16:46

FILE NO.=413

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********** -301 827 2091 - ***** - 301 827 2091- **********

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: December 7, 2001 Number of Pages (including cover sheet) – 18

TO: Mary E. Williams, Associate Director, Regulatory Affairs
COMPANY: Schering-Plough HealthCare Products
FAX #: 908-679-1741

MESSAGE: Attached to this facsimile transmission, please find a copy of our Action Letter for your NDA 21-307, Lotrimin Ultra butenafine HCl cream, 1%.

Thank you.

FROM: Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer
PHONE #: 301-827-2063
FAX #: 301-827-2075/2091

and

FROM: Daniel P. Keravich, R.Ph., M.B.A., Regulatory Project Manager
PHONE #: 301-827-2248
FAX #: 301-827-2316