

LOTRIMIN[®]ultra[™]		23562-00
butenafine hydrochloride cream 1%		ANTIFUNGAL
Active ingredient	Purpose	Net Wt 12g (0.42 oz)
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 ©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. Made in U.S.A.		



23564-00

LOTRIMIN[®]ultra[™] ANTIFUNGAL Net Wt 24g (0.85 oz)
butenafine hydrochloride cream 1%

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.

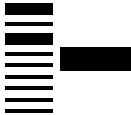
Stop use and ask a doctor if too much irritation occurs or gets worse.

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 ©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. All rights reserved. Made in U.S.A.

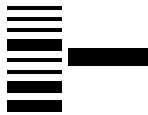




LOTTRIMIN[®]ultra[™] ANTIFUNGAL		23565-00
butenafine hydrochloride cream 1%		
Active ingredient	Purpose	Net Wt 12g (0.42 oz)
Butenafine hydrochloride 1%.....	Antifungal	
Uses		
▪ cures most jock itch		
▪ relieves itching, burning, cracking, and scaling which accompany this condition		
Warnings		
For 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.		
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LOTTRIMIN[®] Ultra[™]		29562-00
butenafine hydrochloride cream 1%		ANTIFUNGAL 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 ©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. All rights reserved. Made in U.S.A.		



**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 15g (0.53 oz)



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

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LOTRIMIN[®] ultra[™]

www.lotrimin.com

Drug Facts
butenafine hydrochloride cream 1%
Active ingredient
Antifungal
Purpose

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
■ do not use if seal on tube is broken or is not visible
■ store at 3° - 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

Apply between and around the toes
1 week twice a day or 4 weeks once a day

NEW!
DIFFERENT INGREDIENT

**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)



3 11017-242-41 4

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

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LOTRIMIN[®] ultra[™]

www.lotrimin.com

Drug Facts
Active ingredient
 Butenafine hydrochloride 1%
Purpose
 Antifungal

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

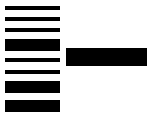
Warnings
For external use only
 Do not use ■ on nails or scalp ■ in or near the mouth or the eyes ■ for vaginal yeast infections
 When using this product do not get into the eyes. If eye contact occurs, rinse eyes thoroughly with water.
 Stop use and ask a doctor if too much irritation occurs or gets 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

LOTTRIMIN[®]ultra[™] ANTIFUNGAL		33269-00
butenafine hydrochloride cream 1%		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. ©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. All rights reserved. Made in U.S.A.		



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

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



LOTTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

LOTTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%
 ANTIFUNGAL
 Net Wt 30g (1.1 oz)



LOTTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

visit us at www.lotrimin.com

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LOTTRIMIN[®] ultra[™]

www.lotrimin.com

Drug Facts
Active ingredient 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 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
 ■ do not use if seal on tube is broken or is not visible
 ■ store at 9° - 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



LOTRIMIN[®]ultra[™] ANTIFUNGAL 29560-00
butenafine hydrochloride cream 1% Net Wt 30g (1.1 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

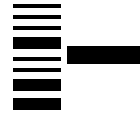
When using this product do not get into the eyes. If eye contact occurs, rinse thoroughly with water.

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

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.



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

- Relieves Itching and Burning
- Full Prescription Strength



LOTRIMIN[®] ultra™
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

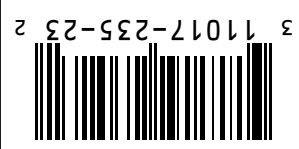
LOTRIMIN[®] ultra™
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

Net Wt 12g (0.42 oz)



LOTRIMIN[®] ultra™
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

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 23773-00

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
 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
 ■ 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 (20) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

visit us at www.lotrimin.com
 23773-00

LOTRIMIN[®] ultra™

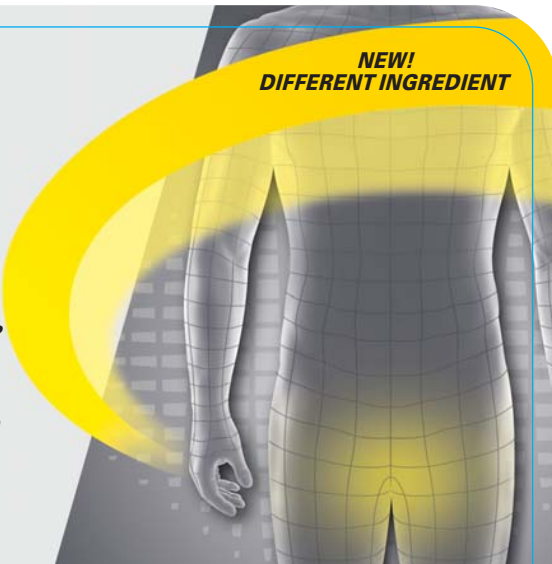
www.lotrimin.com



**CURES MOST
 JOCK ITCH**

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

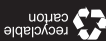
**NEW!
 DIFFERENT INGREDIENT**



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

LOTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

23778-00

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visit us at www.lotrimin.com

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

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

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

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

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

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

Do not use ■ on nails or scalp ■ in or near the mouth or the eyes ■ for vaginal yeast infections

For external use only

Warnings

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

Uses

Active Ingredient
 Butenafine hydrochloride 1%
 Antifungal

Drug Facts

LOTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%

LOTRIMIN[®] ultra[™]

www.lotrimin.com

**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 24g (0.85 oz)



LOTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

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LOTRIMIN[®] ultra[™]

www.lotrimin.com

Drug Facts
 Butenafine hydrochloride 1%
Active ingredient
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
 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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 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
 ■ 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





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.

NDA 21-307

Page 2

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.

NDA 21-307

Page 3

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.

NDA 21-307

Page 4

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
Active ingredient	Purpose	Net Wt 12g (0.42 oz)
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 ©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. Made in U.S.A.		



23564-00

LOTRIMIN[®]ultra[™] ANTIFUNGAL Net Wt 24g (0.85 oz)
butenafine hydrochloride cream 1%

<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

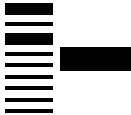
When using this product do not get into the eyes. If eye contact occurs, rinse thoroughly with water.

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

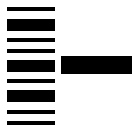
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

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.



LOTTRIMIN[®]ultra[™] ANTIFUNGAL		23565-00
butenafine hydrochloride cream 1%		
Active ingredient	Purpose	Net Wt 12g (0.42 oz)
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.		
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LOTTRIMIN[®] Ultra[™]		29562-00
butenafine hydrochloride cream 1%		ANTIFUNGAL 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 ©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. All rights reserved. Made in U.S.A.		



**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 15g (0.53 oz)



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

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LOTRIMIN[®] ultra[™]

www.lotrimin.com

Drug Facts
butenafine hydrochloride cream 1%
Active ingredient
Antifungal
Purpose

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
■ do not use if seal on tube is broken or is not visible
■ store at 3° - 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

Apply between and around the toes
1 week twice a day or 4 weeks once a day

NEW!
DIFFERENT INGREDIENT

**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)



3 11017-242-41 4

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

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LOTRIMIN[®] ultra[™]

www.lotrimin.com

Drug Facts
Active ingredient Butenafine hydrochloride 1%
Purpose Antifungal

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

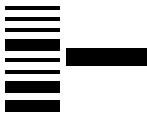
Warnings
For external use only
 Do not use ■ on nails or scalp ■ in or near the mouth or the eyes ■ for vaginal yeast infections
 When using this product do not get into the eyes. If eye contact occurs, rinse eyes thoroughly with water.
 Stop use and ask a doctor if too much irritation occurs or gets 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)

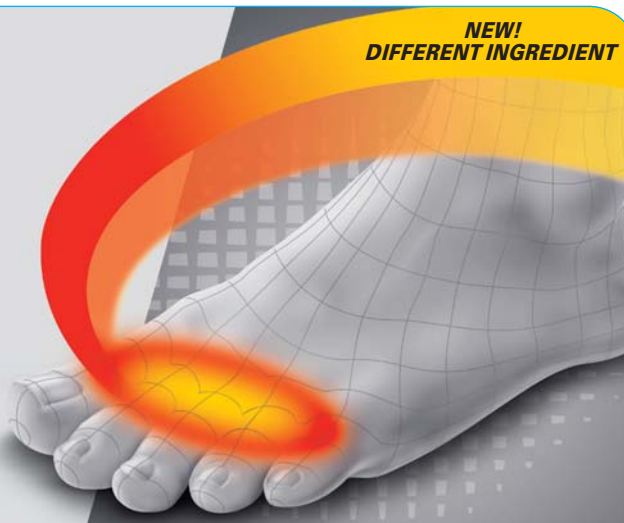
Inactive ingredients
 benzyl alcohol, cetyl alcohol, diethanolamine, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum

LOTTRIMIN[®]ultra[™]	33269-00
butenafine hydrochloride cream 1% ANTIFUNGAL	Net Wt 15g (0.53 oz)
Active ingredient Butenafine hydrochloride 1%.....	Purpose 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. ©2001 Distributed by Schering-Plough HealthCare Products, Inc., Memphis, TN 38151 U.S.A. All rights reserved. Made in U.S.A.	



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

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



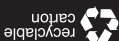
LOTTRIMIN[®] ultra[™]
butenafine hydrochloride cream 1%
ANTIFUNGAL

LOTTRIMIN[®] ultra[™]
butenafine hydrochloride cream 1%
ANTIFUNGAL

Net Wt 30g (1.1 oz)



3 11017-236-66 6



recyclable carton

visit us at www.lotrimin.com

LOTTRIMIN[®] ultra[™]
butenafine hydrochloride cream 1%
ANTIFUNGAL

LOTTRIMIN[®] ultra[™]

www.lotrimin.com

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visit us at www.lotrimin.com

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

Other information

- do not use if seal on tube is broken or is not visible
- store at 9° - 30° C (41° - 86° F)

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 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



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.

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

Drug Facts
Active ingredient
 Butenafine hydrochloride 1%
Purpose
 Antifungal

LOTTRIMIN[®] ultra[™]
butenafine hydrochloride cream 1%

LOTRIMIN[®]ultra[™] ANTIFUNGAL 29560-00
butenafine hydrochloride cream 1% Net Wt 30g (1.1 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

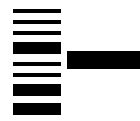
When using this product do not get into the eyes. If eye contact occurs, rinse thoroughly with water.

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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**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 12g (0.42 oz)



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

3 11017-235-23 2

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 Visit us at www.lotrimin.com 23773-00

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
 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
 ■ 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 (20) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, white petrolatum



LOTRIMIN[®] ultra[™]

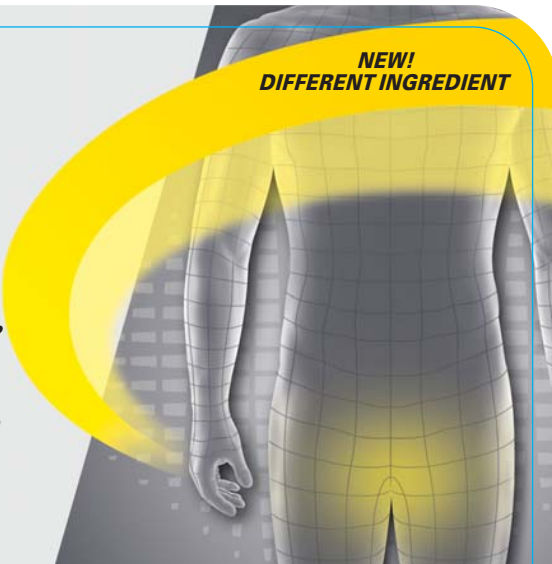
www.lotrimin.com

LOTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%

**CURES MOST
 JOCK ITCH**

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

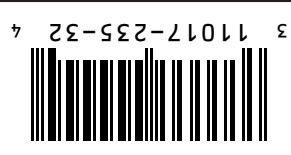
**NEW!
 DIFFERENT INGREDIENT**



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

LOTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%
 ANTIFUNGAL

23778-00

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

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

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

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

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

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

Do not use ■ on nails or scalp ■ in or near the mouth or the eyes ■ for vaginal yeast infections

For external use only

Warnings

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

Uses

Active Ingredient
 Butenafine hydrochloride 1%
 Antifungal

Drug Facts

LOTRIMIN[®] ultra[™]
 butenafine hydrochloride cream 1%

LOTRIMIN[®] ultra[™]

www.lotrimin.com

**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 24g (0.85 oz)



LOTRIMIN[®] ultra[™]
butenafine hydrochloride cream 1%
ANTIFUNGAL

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LOTRIMIN[®] ultra[™]

www.lotrimin.com

Drug Facts
Butenafine hydrochloride 1%
Active ingredient
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
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
■ 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



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

MODE = MEMORY TRANSMISSION START=DEC-07 16:39 END=DEC-07 16:46

FILE NO.=413

STN NO.	COMM.	ONE-TOUCH/ ABBR NO.	STATION NAME/EMAIL ADDRESS/TELEPHONE NO.	PAGES	DURATION
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-FDA/CDER/DDDDP/HFD540 -

***** -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

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