



Actual Size 100%

FDA00439-3

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	9 pt
Drug Facts Continued	8 pt	-
Headings [†]	8 pt bold italic [†]	8 pt
Subheadings	>6 pt	6 pt
Body Text	>6 pt	6 pt
Bullets	5 pt	5 pt
Leading	>0.5 pt	0.5 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barlines [†]	>0.5 pt rule	1 pt
Characters Per Inch	No more than 38	≤38

[†] Headings are to be at least 20% larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP.
^{††} FDA recommends 2.5pt rule.

LOTRIMIN[®] ULTRA

butenafine hydrochloride cream 1% ANTIFUNGAL Net Wt 20g (0.70 oz)

Active ingredient
Butenafine hydrochloride 1% Antifungal

Uses ■ cures most athlete's foot between the toes ■ 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 irritation 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: ■ wash the affected skin with soap and water and dry completely before applying ■ to open the applicator, twist the base to the ON position. Squeeze tube to dispense cream. ■ 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. ■ wipe applicator tip with a tissue and close the applicator by twisting the base to the OFF position. ■ wash hands after each use ■ children under 12 years: ask a doctor

See crimp for lot number and expiration date. Store between 20° to 25°C (68° to 77°F). Questions? 1-866-360-3266. Bayer and Lotrimin Ultra are registered trademarks of Bayer. © 2020 Bayer. Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 Product of Japan

Bayer

Actual Size 100%

FDA00440-2

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	N/A
Drug Facts Continued	7 pt*	N/A
Headings	7 pt-bold italic*	7 pt
Subheadings	6 pt*	6 pt
Body Text	6 pt*	6 pt
Bullets	5 pt	5 pt
Hairlines	0.5 pt rule	0.5 pt
Barlines†	> 0.5 pt rule	N/A
Characters per inch rule is not applicable to ICL. *ICL minimum font size is 4.5 pt. < 0.5 pt leading may be used as long as ascenders and descenders do not touch. † FDA recommends size 2.5 pt type		