

# Luzu (luliconzole)

STRENGTH	DOSAGE FORM	ROUTE	GPID
1%	Cream	Topical	35638

## MANUFACTURER

Valeant Pharmaceuticals

## INDICATION

For the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*, in patients 18 years of age and older.

## DRUG CLASS

DERMATOLOGY – ANTIINFECTIVE; TOPICAL ANTIFUNGALS

## PLACE IN THERAPY

Luzu is an azole antifungal that joins several other topical creams, over-the-counter and prescription, that are available to treat tinea infections. The two types of topical antifungals primarily used are azoles (clotrimazole, ketoconazole and miconazole) and allylamines (naftifine and terbinafine). Other agents that can be utilized but do not fall within either of these classes include: tolnaftate, haloprogin, ciclopirox and butenafine.

Tinea infections are superficial fungal infections caused by dermatophytes commonly: *Trichophyton*, *Microsporum* and *Epidermophyton*. Tinea infections are often named for the location involved, for example, tinea pedis (feet), tinea cruris (groin) and tinea corporis (general skin). These tinea infections are commonly referred to as athlete's foot (pedis), jock itch (cruris) and ringworm (corporis) and are typically superficial in nature.

It is unlikely that the physician will know the infecting species of the dermatophyte infection but will decide on treatment based on clinical symptoms for example: acute tinea pedis is more often associated with *Trichophyton mentagrophytes* and the chronic form with *Trichophyton rubrum*. The dosing for the different agents used to treat tinea infections can range from once to twice daily application and duration can be anywhere from 2 to 4 weeks.

Luzu is most likely to be utilized in patients with more difficult to treat dermatophyte infections. Newer agents like Luzu provide once daily application, shorter course of therapy and high efficacy rates.

## EFFICACY

The efficacy of Luzu was examined in three clinical trials. Two trials in patients with interdigital tinea pedis and one in patients diagnosed with tinea cruris.

A total of 423 patients with clinical and culture-confirmed diagnosis of interdigital tinea pedis were evaluated in two randomized, double-blind, vehicle-controlled, multicenter studies. Patients applied

# Luzu (luliconzole)

Luzu or vehicle cream to the entire area of the forefeet and interdigital web and approximately 1 inch of the surrounding area of the foot daily for 14 days. Treatment success was defined as complete clearance (clinical cure and mycological cure) 4 weeks post treatment. A higher percentage of treatment success was seen in Luzu treated patients in both studies as compared to the vehicle controlled patients.

Table 1: Response to Luzu- Efficacy at 4 Weeks Post Treatment (from Luzu prescribing information):

**Table 1: Efficacy Results at 4 Weeks Post-treatment – Interdigital Tinea Pedis**

	Study 1		Study 2	
	LUZU Cream, 1% N= 106 n (%)	Vehicle Cream N= 103 n (%)	LUZU Cream, 1% N= 107 n (%)	Vehicle Cream N= 107 n (%)
Complete Clearance <sup>1</sup>	28 (26%)	2 (2%)	15 (14 %)	3 (3%)
Effective Treatment <sup>2</sup>	51 (48%)	10 (10%)	35 (33%)	16 (15%)
Clinical Cure <sup>3</sup>	31 (29%)	8 (8%)	16 (15%)	4 (4%)
Mycological Cure <sup>4</sup>	66 (62%)	18 (18%)	60 (56%)	29 (27%)

<sup>1</sup> Proportion of subjects who achieved both clinical cure and mycological cure

<sup>2</sup> Negative KOH and culture and at most mild erythema and/or scaling and no pruritus

<sup>3</sup> Absence of erythema, scaling and pruritus

<sup>4</sup> Negative KOH and negative fungal culture

A total of 256 patients with a clinical and culture confirmed diagnosis of tinea cruris were evaluated in a randomized, double-blind, vehicle-controlled, multicenter study. Patients applied Luzu or vehicle cream to the approximately 1 inch of the surrounding area once daily for 7 days. Treatment success was defined as complete clearance (clinical cure and mycological cure) 3 weeks post treatment. A higher percentage of treatment success was seen in patients on Luzu as compared to the vehicle controlled patients.

Table 2: Response to Luzu- Efficacy at 3 Weeks Post Treatment (from Luzu prescribing information):

**Table 2. Efficacy Results at 3 Weeks Post-treatment - Tinea Cruris**

	LUZU Cream, 1% N= 165 n (%)	Vehicle Cream N= 91 n (%)
Complete Clearance <sup>1</sup>	35 (21%)	4 (4%)
Effective Treatment <sup>2</sup>	71 (43%)	17 (19%)
Clinical Cure <sup>3</sup>	40 (24%)	6 (7%)
Mycological Cure <sup>4</sup>	129 (78%)	41 (45%)

<sup>1</sup> Proportion of subjects who achieved both clinical cure and mycological cure

<sup>2</sup> Negative KOH and culture and at most mild erythema and/or scaling and no pruritus

<sup>3</sup> Absence of erythema, scaling and pruritus

<sup>4</sup> Negative KOH and negative fungal culture

## SAFETY

The most common adverse reactions observed in clinical trials were application site reactions, which occurred in less than 1% of subjects. Luzu is pregnancy category C.

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## DOSAGE

Luzu is for topical use only and is not for ophthalmic, oral or vaginal use.

- For Interdigital Tinea Pedis: Luzu should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for two (2) weeks.
- Tinea Cruris and Tinea Corporis: Luzu should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once a day for one week.

## COST

Drug	Cost/unit	Cost per tube*
Luzu (Iuliconazole 1% cream) 30 gram tube- <b>Rx</b>	AWP=pending	pending
Tolnaftate 1% cream (Tinactin) 28 gram tube- <b>OTC</b>	MAC= \$0.15	\$4.20
Miconazole 2% cream (Micatin) 28 gram tube- <b>OTC</b>	MAC= \$0.11	\$3.08
Clotrimazole 1% cream (Lotrimin AF) 24 gram tube- <b>OTC</b>	MAC=\$0.79	\$18.96
Clotrimazole 1% cream (Lotrimin) 30 gram tube- <b>Rx</b>	MAC= \$0.79	\$23.70
Butenafine 1% cream (Lotrimin Ultra) 30 gram tube - <b>OTC</b>	AWP=\$0.43	\$12.90
Butenafine 1% cream (Mentax) 30 gram tube- <b>Rx</b>	AWP=\$6.71	\$201.30
Naftifine 1% cream (Naftin) 60 gram tube- <b>Rx</b>	AWP= \$6.04	\$362.40
Terbinafine 1% cream (Lamisil AT) 30 gram tube- <b>Rx</b>	AWP= \$0.43	\$12.90

\* Cost based on one tube- patient may require more drug depending on treatment area size and duration of therapy

## FORMULARY PLACEMENT RECOMMENDATIONS

Based on this initial assessment of available clinical and financial information, consider NOT ADDING Luzu to the formulary pending complete review by the appropriate oversight committee for the plan.

## REFERENCES

- Luzu [Prescribing Information]. Bridgewater, NJ: Medicis; November 2013.
- Goldstein [Feb 2014] Dermatophyte (tinea) infections. Retrieved from: <http://www.uptodate.com> [Accessed on February 19, 2014].
- Weinstein, A, Berman, B. Topical Treatment of Common Superficial Tinea Infections. Am Fam Physician. 2002 May 15;65(10):2095-102.