INDICATIONS AND USAGE
LUZU® (luliconazole 1%) is indicated 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. (1)

DOSAGE FORMS AND STRENGTHS
- Cream, 1%.

ADVERSE REACTIONS
- Clinical Trials Experience
- The most commonly reported adverse reactions observed in clinical studies of LUZU Cream, 1% were dermatitis, erythema, pruritus, and treatment-related adverse events.

CONTRAINDICATIONS
- None.

DRUG INTERACTIONS
- Drug-drug interactions were not studied in clinical studies of LUZU Cream, 1%.

FULL PRESCRIBING INFORMATION: CONTENTS*
- HIGHLIGHTS OF PRESCRIBING INFORMATION: THE FOLLOWING ARE Important Information about LUZU Cream, 1%
- FULL PRESCRIBING INFORMATION:
- PATIENT COUNSELING INFORMATION

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 ADVERSE REACTIONS
6 POSTMARKETING EXPERIENCE
7 DRUG INTERACTIONS
8 CLINICAL PHARMACOLOGY
9 NONCLINICAL TOXICOLOGY
10 PATIENT COUNSELING INFORMATION
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
14 CLINICAL STUDIES
14.1 Phase 2 Studies
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14.3 Phase 3 Studies
15 PATIENT COUNSELING INFORMATION
16 HOW SUPPLIED/STORAGE AND HANDLING
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11 DESCRIPTION
LUZU® (luliconazole 1%) is a weak inhibitor of CYP2C19 and CYP2C9, and 121.74 ± 53.36 ng*hr/mL after the final dose. In subjects with tinea cruris, the mean ± SD Cmax was 21.0 ± 5.55 hours after the first dose and 6.5 ± 8.25 hours after the final dose.

Plasma concentrations of luliconazole on Day 15 were 21.0 ± 5.55 and 6.5 ± 8.25 ng/mL after the first and final doses, respectively. The mean terminal half-life in adults was 5.8 ± 7.61 hours after the final dose.

The mean time to the maximum concentration (Tmax) was 5.7 ± 2.56 hours after the first dose and 18.74 ± 27.05 ng*hr/mL after the final dose.

The mean area under the concentration-time curve (AUC0-24), was 6.88 ± 14.50 ng*hr/mL after a single dose and 21.77 ± 50.37 ng*hr/mL after a 14-day dosing regimen.

Lucas Emotive
Lucas is a selective antagonist of the VLA-4 receptor (CD49d/α4/integrin α4β1), which is highly expressed on leukocytes, including T cells, monocytes, and neutrophils. Lucas Emotive is designed to inhibit the adhesion of leukocytes to leukocyte selectins and the vascular endothelium, thereby reducing the infiltration of leukocytes into inflamed tissue. In clinical trials, Lucas Emotive has been shown to reduce the number of leukocytes in the peripheral blood and to improve symptoms in patients with inflammatory diseases, such as rheumatoid arthritis and Crohn's disease.

The pharmacokinetic profile of Lucas Emotive, as evaluated in healthy volunteers, shows a rapid absorption with a Tmax of approximately 1.5 hours and a terminal half-life of approximately 8 hours. The drug is eliminated primarily through the liver, with minimal renal excretion. Lucas Emotive is well tolerated, with the most common adverse events being mild to moderate gastrointestinal symptoms.

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LUZU Cream (luliconazole) is a prescription medicine used for the treatment of:

- Tinea Cruris (jock itch).
- Interdigital Tinea Pedis (between the toes).

LUZU Cream is for use on skin only. Do not get LUZU Cream in or near your eyes, mouth, or vagina.

What is LUZU Cream? LUZU Cream is a prescription medicine used on the skin (topical) to treat adult or teen (12 years and older) that is caused by the non-inflamed (non-dermatophyte) fungi, and is usually a skin infection in people 10 years of age and older. It is not known if LUZU Cream is safe and effective in children.

Table 1: Efficacy Results at 4 Weeks Post-treatment – Tinea Cruris

<table>
<thead>
<tr>
<th>Treatment N=106</th>
<th>Complete Clearance</th>
<th>Clinical Cure</th>
<th>Mycological Cure</th>
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<tbody>
<tr>
<td>LUZU Cream</td>
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Table 2: Clinical, Mycological, and Dermatophyte Cure Rates for Interdigital Tinea Pedis

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What is LUZU Cream? LUZU Cream is a prescription medicine used on the skin (topical) to treat adult or teen (12 years and older) that is caused by the non-inflamed (non-dermatophyte) fungi, and is usually a skin infection in people 10 years of age and older. It is not known if LUZU Cream is safe and effective in children.

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