Luzu® (luliconazole) – Expanded indication

- On February 20, 2018, the FDA approved Valeant's Luzu (luliconazole) cream, for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*.
    - Previously, Luzu was approved only for patients 18 years of age or older for the same indication.
- Data to support the expanded indication for Luzu was based on a vehicle-controlled study of 75 patients aged 2 to < 18 years old with a diagnosis of tinea corporis. Patients were treated for 7 days.
    - Complete clearance (clinical cure and mycological cure) three weeks after treatment was achieved in 71% of the Luzu-treated patients vs. 36% of the vehicle-treated patients.
    - In addition, the safety and effectiveness of Luzu in pediatric patients 12 to < 18 years of age with tinea pedis and tinea cruris have been established by evidence from well-controlled trials in adult and pediatric patients and a pharmacokinetic study in pediatric patients.
- The recommended dosage of Luzu is to apply the cream to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily.
    - Interdigital tinea pedis should be treated for two weeks.
    - Tinea cruris or tinea corporis should be treated for one week.
    - Luzu is for topical use only. Luzu is not for ophthalmic, oral, or intravaginal use.