

Naftin[®] (naftifine) 2% cream – Expanded Indication

- On November 10, 2016, the [FDA approved](#) Merz's [Naftin \(naftifine\)](#) 2% cream, to include additional data in pediatric subjects aged 2 years to 17 years 11 months with tinea corporis.
 - The additional data expands Naftin cream for use in children aged 2 and above with tinea corporis.
 - Previously, the safety and effectiveness of Naftin cream in children 12 years of age and older was only established with interdigital tinea pedis and tinea cruris. The safety and effectiveness in pediatric patients less than 12 years of age had not been established.
- Naftin 2% cream is indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum*.
- Naftin is also available as [1%](#) and [2%](#) gels and generically as a [1% cream](#).
 - Naftin 1% gel is indicated for the topical treatment of tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Trichophyton tonsurans*, and *Epidermophyton floccosum*.
 - Naftin 2% gel is indicated for the topical treatment of interdigital tinea pedis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*.
 - Naftin 1% cream is indicated for the topical treatment of tinea pedis, tinea cruris and tinea corporis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*.
- The expanded indication for Naftin 2% cream was based on a safety and efficacy study conducted in 184 pediatric patients (≥ 2 to < 18 years) with tinea corporis. Patients received Naftin cream or vehicle. The primary efficacy endpoint was the proportions of patients with a complete cure at day 21.
 - Complete cure was achieved in 46% of Naftin-treated patients vs. 28% of vehicle-treated patients.
- The recommended dosing regimen of Naftin 2% cream: apply a thin layer once daily to the affected areas plus a ½ inch margin of healthy surrounding skin for 2 weeks.
 - Naftin 2% cream is not for ophthalmic, oral, or intravaginal use.
 - Refer to package labels for the dosing of the other forms of Naftin.